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ACR AMERICAN COLLEGE OF RADIOLOGY

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

(20)

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

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Via Electronic Mail
September 11, 2006

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Subject: 10 CFR Part 20, 30, 31 et al. Requirements for Expanded Definition of Byproduct Material; Proposed Rule (RIN 3150–AH84)

Dear Rulemakings and Adjudications Staff:

The undersigned organizations are pleased to submit the following comments in response to the Proposed Rule: Requirements for Expanded Definition of Byproduct Material (RIN 3150-AH84).[1]

We appreciate the exceptional effort expended by NRC staff in devising the proposed rule and their receptiveness to hearing the medical community's needs and concerns related to this rulemaking. As organizations whose members utilize radioactive materials for research and medical purposes, our comments reflect our commitment to preserving patient access to this material, particularly short-lived accelerator products. We believe that with the modifications suggested herein, including category exemptions from decommissioning assurance requirements, further clarification of the applicability of fee category 3.S, an enhanced transition plan, and specific Derived Air Concentrations (DACs) for N-13 and O-15, the NRC will come closer to achieving a regulatory balance that preserves patient access to life-enhancing and life-preserving radioactive material.

Financial Assurance for Decommissioning

Our organizations strongly support adding a category exemption from financial assurance for decommissioning for facilities with cyclotrons 18 MeV and less, as the existing requirements within 10 CFR Part 30.35 are not adequately suited to the realities of lower energy accelerator facilities. We do not believe PET cyclotrons with energies at or below 18 MeV are capable of producing activation products in the quantity sufficient to trigger the financial assurance requirements of Part 30.35. Many burdensome expenditures are associated with calculating and securing financial assurance for decommissioning, including expensive concrete bunker boring and analysis. These costs would inevitably put some existing medical and scientific accelerator facilities out of business, and would also deter prospective hospitals and educational institutions from obtaining onsite cyclotrons, potentially depriving the patients of lifesaving diagnostic tests. Thus, a category exemption is required to make operations of lower energy cyclotrons feasible.

[1] The Society of Nuclear Medicine (SNM) is an international scientific and professional organization of over 16,000 members dedicated to promoting the science, technology, and practical applications of molecular imaging and therapy.

The American College of Radiology (ACR) is a professional organization serving more than 32,000 radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists who use radiation and radioactive material in the diagnosis and treatment of patients.

The American Society of Nuclear Cardiology (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.

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SECY-02

License Application and Annual Fees

The proposed rule states that the majority of NRC licensees affected by the NARM rulemaking will be using radioactive material in a manner similar to their existing authorizations, and thus their fee categories should not change as a result of the rule. It also states that Agreement State licensees are adequately regulated and should not be financially affected. We expect that these statements are correct, as additional fees could adversely affect cost and access issues for patients.

While our organizations do not endorse the proposed creation of the fee category 3.S for production of accelerator radionuclides in 10 CFR Part 170 and 171, we understand that additional resources are needed by the NRC to account for their expansion of regulatory authority, and that these resources must recover ninety percent of NRC's budget authority each year under the Omnibus Budget Reconciliation Act of 1990. However, we request that the language of the final rule explicitly state that fee category 3.S is applied per facility, not per accelerator, and that the NRC be mindful that additional costs will inevitably be passed to the health care system and patients in need of radiopharmaceuticals.

Implementation and Transition Plan

As indicated by the proposed NARM rulemaking and related documents, the waiver (70 FR 51581: August 31, 2005) is effective through August 7, 2009, unless the NRC deems early termination necessary for specific entities or states. Although most existing Agreement States regulate NARM currently and will not need extensive time to adjust to the new regulatory scheme, the transition time provided by the waiver is essential in non-Agreement States with previously low regulation of these materials so that patient care and research activities can continue without interruption. The waiver must remain in effect for these locations until the local medical and scientific communities are fully prepared for the new licensing costs and requirements.

Education of the entire user community is crucial to ensuring a smooth transition to NRC regulatory authority over NARM. Therefore, we support the development of a comprehensive guidance document to be released upon implementation of the rule. Furthermore, we invite the NRC to utilize our organizations' publications, websites, and meetings to educate the medical user community about the NARM rule costs and requirements.

Grandfathering of Personnel

We support the "grandfathering" of nuclear pharmacists and other individuals responsible for the production of PET radionuclides, as well as individuals using NARM for medical applications. We agree that individuals authorized to use byproduct material in 10 CFR Part 35 should automatically be authorized to use the newly covered accelerator-produced material. We are mindful of Commissioner Jaczko's comments related to the grandfathering of Authorized Medical Physicists and Radiation Safety Officers, and we would encourage the use of this current rulemaking to resolve those issues.

Derived Air Concentration Values for Oxygen-15 and Nitrogen-13

We concur with others in the medical community that specific derived air concentration (DAC) values for oxygen-15 and nitrogen-13 should be added to 10 CFR Part 20, Appendix B. The SNM and ACR have reviewed the specific DAC calculations prepared by Dr. Mike Stabin at

Vanderbilt University and concur with CORAR and the HPS that these values should be used in the final rulemaking. These values are as follow:

Radionuclide	Class	Table 1, Column 3	Table 2, Column 1
		Inhalation DAC	Effluent Concentration – Air
Nitrogen-13	Submersion	1.4×10^5 Bq/m^3 (3.8×10^{-6} μCi/mL)	6.5×10^2 Bq/m^3 (1.8×10^{-8} μCi/mL)
Oxygen-15	Submersion	1.4×10^5 Bq/m^3 (3.8×10^{-6} μCi/mL)	6.5×10^2 Bq/m^3 (1.8×10^{-8} μCi/mL)

In conclusion, we appreciate the conscious efforts of the NRC rulemaking staff to avoid disruption to accelerator product accessibility for medical and research use by incorporating NARM into the existing NRC regulatory framework for byproduct material. To further minimize the impact on patient care and innovation, we request category exemptions from financial assurance for decommissioning for cyclotrons 18 MeV and less, explicit language limiting fee category 3.S to a per facility basis, specific DACs for O-15 and N-13, comprehensive companion guidance documentation, and further efforts to inform and educate the regulated community during the transition period

Please contact any of the following individuals if you have any questions or concerns:

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Thank you for your consideration of these comments.

Sincerely,

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From: "Peters Michael" <MPeters@snm.org>
To: <SECY@nrc.gov>
Date: Mon, Sep 11, 2006 4:32 PM
Subject: (RIN 3150-AH84) Public Comments from SNM, ACR, and ASNC

Attached for submission are public comments jointly signed by the Society of Nuclear Medicine (SNM), American College of Radiology (ACR), and American Society of Nuclear Cardiology (ASNC) regarding "10 CFR Part 20, 30, 31 et al. Requirements for Expanded Definition of Byproduct Material; Proposed Rule (RIN 3150-AH84)".

Thank you,

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