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September 11, 2006 (2:54pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

September 11, 2006

Dale E. Klein, Ph.D.
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Proposed Rule on the Requirements for Expanded Definition of Byproduct Material (RIN 3150-AH84)

Dear Dr. Klein,

The American Society for Therapeutic Radiology and Oncology (ASTRO) appreciates the opportunity to provide comments on the proposed rule issued July 28, 2006, regarding the expanded definition of byproduct materials at 71 Fed.Reg. 42952 (July 28, 2006). ASTRO is the largest radiation oncology society in the world, with more than 8,500 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research, disseminating research results and representing radiation oncology in a rapidly changing healthcare environment. We applaud the Nuclear Regulatory Commission (NRC) for its diligent and thoughtful work in developing this proposed rule.

Linear Accelerators Used for Medical Treatment

We agree with the NRC's delineation of particle accelerators into three varieties, one category being those accelerators that are operated to produce only particle beams and not radioactive materials. As the agency indicated in the proposed rule, an example of such an accelerator would be a linear accelerator used in radiation therapy. ASTRO supports the proposed rule's approach to not expand the regulation to include incidental radioactive material produced by these linear accelerators used for medical treatment of cancer. We concur that this approach reflects the Congressional intent of the expanded definition in the Energy Policy Act of 2005, and we request that this exclusion be amplified in the final rule to include an exemption for commercial linear accelerators used to treat patients.

Decommissioning Issues

The agency has requested comments on the decommissioning of accelerator facilities and accelerator components. As the NRC is proposing to exempt linear accelerators used for medical treatment from this regulation, we request that NRC likewise clarify in Part 35 that the term decommissioning does not apply to the removal or replacement of a linear accelerator used for medical treatment.

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NRC appropriately focuses on patient safety and the safety of the general public in its regulations. We are concerned, however, that the term "sufficient quantities" is too vague in determining which radionuclides with a half-life of more than 120 days may cause a public health and safety concern that could lead to license termination and decommissioning. We request that the NRC refine this policy in the final rule to include specifications of which radionuclides and the threshold amounts the agency views to be sufficient to lead to license termination.

ASTRO also believes that the NRC may want to consider creating an exemption from the financial assurance for decommissioning requirements for facilities with PET cyclotrons at or below 18 MeV. The costs associated with these requirements may be greater than the potential risk and could possibly deter prospective hospitals and educational institutions from obtaining onsite cyclotrons, which could impact patient access to services.

Implementation and Transition Plan

As stated in the proposed rule, the NRC issued a waiver on August 31, 2005 for persons who would be covered by this byproduct rule. This waiver extends through August 7, 2009, unless NRC determines that earlier termination is warranted. The transition time created by the waiver is critical for non-Agreement States that have little regulation of these materials so that patient care and research activities can continue without interruption. ASTRO requests that the NRC maintain the waiver until the local medical and scientific communities are fully prepared for the new licensing costs and requirements.

Grandfathering of Personnel

We support the "grandfathering" of nuclear pharmacists and other individuals responsible for the production of PET radionuclides, and we would encourage NRC to consider using this rulemaking to resolve issues related to the grandfathering of authorized medical physicists and radiation safety officers.

ASTRO looks forward to a continued close collaboration with the NRC on these issues, and we appreciate the opportunity to comment upon this proposed rule.

Sincerely,

Laura Thevenot

Laura Thevenot

From: "Jamie Gale" <jamieg@astro.org>
To: <SECY@nrc.gov>
Date: Mon, Sep 11, 2006 2:07 PM
Subject: ASTRO's Comments- Byproduct Definition Expansion RIN 3150-AH84

Dear Madam or Sir,

Please find the attached comment letter from ASTRO on the proposed rule for the expanded definition of byproduct material.

Best regards,

Jamie Gale

Government Relations and Research

Administrative Assistant

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CC: "Emily Wilson" <emilyw@astro.org>

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Subject:	ASTRO's Comments- Byproduct Definition Expansion RIN 3150-AH84
Creation Date	Mon, Sep 11, 2006 2:07 PM
From:	"Jamie Gale" <jamieg@astro.org>
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MESSAGE	511	Monday, September 11, 2006 2:07 PM
TEXT.htm	5121	
Final_Byproduct Comments-9-11-06.pdf	70972	
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Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
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Security:	Standard

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Message is eligible for Junk Mail handling
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