PR 20 and 32
(73FR19749)

Rulemaking Comments

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From: Helen Johansson [helenj@astro.org]
Sent: Wednesday, June 25, 2008 2:44 PM
To: Rulemaking Comments
Cc: Richard Martin
Subject: Comments_Expansions of the National Source Tracking System
Attachments: Letter_NRC_Vietti-Cook_June 25 2008.pdf

Attached is a letter from Laura I. Thevenot, CEO, American Society for Therapeutic Radiology and Oncology on the above subject.

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ASTRO
AMERICAN SOCIETY FOR THERAPEUTIC RADIOLOGY AND ONCOLOGY

June 25, 2008

VIA E-Mail to: Rulemaking.Comments@nrc.gov
Ms. Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

Re: Comments on Nuclear Regulatory Commission's Proposed Rule Regarding Expansion of the National Source Tracking System (73 FR 19749), April 11, 2008, RIN-3150-AI29

Dear Ms. Vietti-Cook:

The American Society for Therapeutic Radiology and Oncology (ASTRO) understands the need for adequate security to prevent those with malevolent intent from purposefully using medical or industrial radioactive materials to cause harm, and it applauds the efforts of the U.S. Nuclear Regulatory Commission (NRC) to develop the National Source Tracking System (NSTS) to provide for better radioactive source accountability. ASTRO believes, however, that the proposed extension of NSTS to include Category 3 and 1/10 of Category 3 sources is flawed, and welcomes the opportunity to participate in this rulemaking process by offering the following comments.

ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As a 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 and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

ASTRO maintains that this rulemaking to expand NSTS is premature because there is currently no functioning NSTS for the priority Category 1 and 2 sources. Moreover, NSTS development and deployment have experienced significant technological delays and increased costs, and there is no assurance that the system will be implemented as now projected on January 31st, 2009. Without a history of use, it is impossible to estimate how

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an expansion of NSTS will impact medical licensees and health care services provided to patients. ASTRO recommends a pilot program to test NSTS's effectiveness in tracking Category 1 and 2 sources as well as a delay in this rulemaking until after a thorough assessment of the pilot program can be made. A studied, pragmatic approach of gaining experience in implementation of NSTS for Category 1 and 2 sources before determining the viability of expanding NSTS to include Category 3 sources would afford stakeholders an opportunity to provide informed comments as to the system's capabilities and projected burden.

Further, ASTRO believes that the proposed rules are unnecessary because existing licensing and inspection requirements allow adequate safeguarding of sources. Recent enhancements to security requirements have increased the regulator's ability to ensure the legitimacy of source recipients. Licensing guidance has been revised in response to the General Accountability Office's (GAO) audit of NRC's licensing process in the spring of 2007 (GAO-07-1038T, dated July 12, 2007), and there is enhanced tracking, control and monitoring of sources of concern below the Category 2 level. In addition, byproduct materials licensees are subject to 10 CFR § 30.41 "Transfer for byproduct material," which requires the licensee to verify, prior to transfer of generally or specifically licensed material, that the recipient is authorized to receive the type, form, and quantity of byproduct material to be transferred. Medical facilities are required to audit and inventory all radioactive sources, including Category 3 sources used for brachytherapy in high dose rate remote afterloaders. Accordingly, ASTRO submits that the goals of the proposed rule could be more effectively achieved by implementing the most recent prelicensing guidance and providing sufficient resources for existing licensing, inspection, and enforcement programs to achieve their mission, without increasing regulatory burden on licensees.

ASTRO recognizes that there are limited resources to dedicate for security measures and believes that the funds that would be spent on NSTS expansion might be better directed toward existing NRC and Agreement State licensing, inspection, and enforcement programs. The increased control of sources and fingerprinting requirements imposed by NRC in 2005 and 2007, have strained some Agreement States' resources and the need to dedicate resources to implement an expanded NSTS would exacerbate funding woes.

Finally, ASTRO is concerned about the effect that the proposed rule may have on brachytherapy procedures for cancer patients. The proposed rule does not address how sealed sources used in permanent implant brachytherapy procedures would be handled under the NSTS. ASTRO believes that seeds permanently implanted in patients should be excluded from tracking or removed from the licensee's inventory in the NSTS when implanted.

Thank you for affording us this opportunity to provide comments on the NRC's proposed rule regarding expansion of the National Source Tracking System. Please contact Emily Wilson at 703-839-7364 or emilyw@astro.org or Richard Martin at 703-839-7366 or richardm@astro.org if you have any questions.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

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