ASTRO
American Society for Therapeutic Radiology and Oncology

(17)

October 11, 2005

Secretary, U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001
Via electronic submission

Re: RIN 3150-AH48

The American Society for Therapeutic Radiology and Oncology (ASTRO)[1] appreciates the opportunity to provide written comments on the proposed rule, "National Source Tracking of Sealed Sources" published in the *Federal Register* on July 28, 2005. ASTRO strongly supports the Commission's diligent efforts to create regulations that promote the health, safety and welfare of Americans. We encourage the current rulemaking and the intent of such regulations. We would like to provide comments on a number of issues for the Commission to consider as it finalizes the rule. Our comments will primarily address the inclusion of Category 3 sources in the "National Source Tracking System" and cost impact of regulations on the practice of radiation oncology.

The Inclusion of Category 3 Sources in the National Source Tracking System

As stated in the text of the proposed rule, "Category 3 sources are typically used in high dose remote afterloaders for medical therapy." These sources are lower activity sources and do not pose a significant terrorist threat in comparison to Category 1 and 2 sources. In the medical community, Category 3 sources are well protected and documented. The inclusion of these sources would significantly increase the number of impacted licensees. Essentially, all medical facilities that perform radiation therapy procedures would be affected.

We respectfully request that the following be taken into consideration as the Commission contemplates the inclusion of these sources in the "National Source Tracking System":

- Before including Category 3 sources into the "National Source Tracking System", it would be beneficial for the Commission to conduct roundtable discussions with stakeholders, such as ASTRO, and appropriate advisory panels, such as the Advisory Committee for the Medical Use of Isotopes, to fully understand the impact of rulemaking on the medical community and to ensure that final regulations do not cause unintended problems in the practice of medicine.

[1] ASTRO has more than 8,000 members, including physicians (radiation oncologists), radiation scientists (radiobiologists, radiological physicists), radiation therapy technologists, and radiation oncology nurses. These specialists make up the expert medical team that uses radiation to treat patients with cancer. Radiation therapy is recognized as one of the most effective methods of treating cancer and other diseases. Between 50 and 60 percent of cancer patients are treated with radiation at some time during the course of their disease. ASTRO's membership represents community cancer centers and hospitals as well as major education and research centers from the U.S. and around the world. ASTRO publishes the leading scientific journal in radiation oncology in the world.

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- Medical institutions are presently required to audit and inventory all radioactive sources, therefore, any additional requirements should be reviewed and analyzed to ensure compatibility with existing requirements and to minimize overlapping or conflicting requirements.

- The greatest impact of these regulations will be felt in facilities that have teletherapy or gamma stereotactic radiosurgery units as codified in 10 CFR § 35.600. Once the radioactive sources are placed in these machines, tampering with or stealing the sources becomes very difficult. We believe that regulations that focus on the transportation of these sources would be more appropriate to accomplish the goals of the Commission.

- Due to the major increase in licensees impacted, if lower activity sources are included, the Commission should make sure that the web-based recording system for Category 1 and 2 sources is well tested and fully operational before adding Category 3 sources.

- Because Category 3 sources must be present in large quantities in order to pose a radiation threat, the Commission should state specific threshold amounts that must be exceeded in order to trigger the "National Source Tracking System" requirements, so as not to cause an undue burden on community medical facilities that only possess very small quantities of these lower activity radiation sources.

Cost Impact on the Practice of Radiation Oncology

When mandating new regulations such as the "National Source Tracking System", the Commission should consider the time and resources that will be needed for compliance. If implemented, the "National Source Tracking System" would require additional manpower and office equipment and place a significant financial burden on a healthcare delivery system already under stress. Therefore, we ask that the Commission support efforts to Congress, CMS, and private payors to increase funding for the delineated radionuclide procedures to alleviate the financial burden placed on medical institutions and postpone the tracking of these sources until such funding is secured.

Conclusion

Thank you for this opportunity to comment on the proposed rule. We look forward to continued dialogue with NRC officials and would be happy to bring in experts to discuss the impact of these regulations on the healthcare system, and in particular, radiation oncology. Should you have any questions on the items addressed in this comment letter, please contact Roshunda Drummond-Dye, Esq., ASTRO Senior Policy Analyst at (703) 502-1550 or roshundad@astro.org.

Respectfully,

Laura Thevenot

Laura Thevenot
ASTRO, Chief Executive Officer

From: "Roshunda Drummond" <roshundad@astro.org>
To: <SECY@nrc.gov>
Date: Fri, Oct 7, 2005 3:10 PM
Subject: RE- RIN: 3150-AH48 Proposed Rule; National Source Tracking of Sealed Sources

Dear Secretary of the U.S. Nuclear Regulatory Commission:

On behalf of the American Society for Therapeutic Radiology and Oncology (ASTRO), I would like to thank you for the opportunity to submit comments to the Nuclear Regulatory Commission (NRC) in regard to the Proposed Rule: National Source Tracking of Sealed Sources. I have attached for your review an electronic copy of our comment letter, and we will also submit them via the NRC's rulemaking website.
Upon your review of our comment letter, please feel free to contact me, Roshunda Drummond-Dye via e-mail at roshundad@astro.org, or by telephone at 1-800-962-7876, at any time and I will be happy to assist you with any questions, concerns, or further discussion that you may require.
Once again we thank you for this opportunity.
<<NRC Source Tracking Rule Comment letter.pdf>>
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