**PR 20 and 32**
**(73FR19749)**

**Rulemaking Comments**

(15)

**From:** Michael Peters [mpeters@acr.org]
**Sent:** Wednesday, June 25, 2008 4:42 PM
**To:** Rulemaking Comments
**Cc:** Gloria Romanelli; Michael Peters
**Subject:** RIN 3150-AI29 / ACR comments
**Attachments:** nrc_nsts_expansion_acr_comments_06-25-2008.pdf

Please see the attached comments from the American College of Radiology (ACR) regarding *[RIN 3150-AI29] Expansion of the National Source Tracking System, Proposed Rule* (http://edocket.access.gpo.gov/2008/E8-7756.htm).

Thank you,

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Secy-02


June 25, 2008

U.S. Nuclear Regulatory Commission
ATTN: Rulemaking and Adjudications Staff
Washington, DC 20555-0001

Re: RIN 3150-AI29, Expansion of the National Source Tracking System, Proposed Rule

As a professional organization serving more than 32,000 radiologists, radiation oncologists, interventional radiologists, and medical physicists, the American College of Radiology (ACR) appreciates the opportunity to comment on the proposed rule to expand the National Source Tracking System (NSTS) to include Category 3 and 1/10 of Category 3 sealed sources. Members of the ACR—in particular, radiation oncologists and medical physicists—make up a significant component of the stakeholder population affected by this proposed rule. Because the sources discussed in this rulemaking are commonly used in medical procedures to treat patients with cancer and other life-threatening diseases, it is essential that the NRC exercise caution in expanding the NSTS to ensure that patients' access to life-saving procedures is not impeded.

**Comment 1: Delay the Rulemaking Until After the NSTS is Operational**

The ACR commented in 2005, and continues to maintain, that the NSTS should be fully operational and successfully tracking Category 1 and 2 sources before Category 3 sources are added. This is critical, both in terms of ensuring that resources are not diverted from higher-risk Category 1 and 2 sources, and also to allow the NRC to make the determination that the system is ready and able to successfully incorporate Category 3 sources. According to the proposed rule, the expansion of the NSTS to include Category 3 and 1/10 of Category 3 sealed sources is scheduled to occur six months after the January 31, 2009 implementation date for Category 1 and 2 licensees. However, because the public comment period on this proposed rule will close June 25, 2008—seven months before the NSTS is operational—it is impossible to estimate how the expansion will impact medical licensees, and by extension, the health care services provided to patients. Also, without a history of use we are unable to assess how administering the NSTS will stress the internal operations, staff workload, and resources of the NRC and Agreement States. The preferred course of action would be to delay this rulemaking until a year or so after the implementation date for Category 1 and 2 sources; this would provide an opportunity for the public to assess the workability of the system and provide informed comments as to its capabilities and the projected burden to licensees and regulatory bodies if the NSTS is expanded to include sources below Category 2.

**Comment 2: Continue to Limit the Sources Tracked by the NSTS**

Although we believe Category 3 sources should not be included in the system until after a review of Category 1 and 2 licensees' experiences using NSTS, the ACR agrees with the NRC's proposed approach to limit the sources tracked to only those sealed sources listed in Appendix E. Tracking other materials, including Category 3 unsealed sources, would be unnecessary and extremely arduous for medical licensees. To avoid any potential for misinterpretation, the text of the final rule should consistently and explicitly state "sealed source(s)" wherever the word "source(s)" appears.

**Comment 3: Address Permanent Brachytherapy Seeds Implanted in Patients**

The ACR is concerned that the proposed rule does not specifically address how sealed sources used in permanent brachytherapy procedures would be handled under the NSTS. We believe that seeds permanently implanted in patients should be deemed to be "removed" from the licensees' inventory in the NSTS. Furthermore, any seeds remaining after implantation should continue to be considered part of the

licensee's inventory. This circumstance should be explicitly addressed in the summaries and guidance documentation accompanying the final rule.

**Comment 4: Ensure User Friendliness and Flexibility to Resolve Problems**

The keys to the success of the NSTS in the medical community will be user-friendliness and efficiency. An inventory reporting system that is too resource intensive could cause hospital administrators to determine it is nonviable to use these sources in their institutions. Such a determination could in turn lead to impaired patient access to health care services. To ensure the system and related processes are user-friendly, the NSTS must be compatible with medical licensees' existing technological capabilities, the NRC and/or Agreement States must offer free and accessible training, and there must be flexibility for the NRC staff to quickly suspend and improve the NSTS system and related processes should they prove to be problematic for medical licensees and/or regulatory bodies.

**Comment 5: Consolidate the NSTS with the Future WBL**

The NRC Independent External Review Panel to Identify Vulnerabilities in the Materials Licensing Program recommended the development of a single Web-Based Licensing (WBL) and NSTS system, as opposed to two separate systems. A single system would encourage enhanced real-time tracking and license verification services, improving security, reliability, and user-friendliness. Although WBL is many years away from realization, having two separate systems in the future would be arduous—particularly for manufacturers/distributors who must account for many transactions per day. The ACR supports the recommendation of the panel and encourages the NRC to explore methods to streamline the process as WBL is developed.

As always, the ACR welcomes the opportunity for continued dialogue with the NRC on this proposed rule and other areas of mutual interest. Please contact Gloria Romanelli, ACR Senior Director, Legislative and Regulatory Relations, or Michael Peters, ACR Regulatory Affairs Specialist, if our organization can be of assistance in this matter. Gloria and Michael can be reached at 202-223-1670.

Sincerely,

Cassandra Foens, M.D., FACR
Chair, Federal Regulatory Committee
American College of Radiology

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