21

1/9/2017
82FR 2399-2

Duran-Hernandez, Doris

From:	Wu, Irene
Sent:	Thursday, March 23, 2017 5:48 PM
To:	Cervera, Margaret; Davis, Gina; Gordon, Craig; Jimenez, Manuel; Lewin, Aron; Lohr, Edward; London, Lisa; Purdy, Gary; Quinones, Ernesto; Randy Crowe; Reed, Elizabeth; Sherrie Flaherty; Trussell, Gregory; White, Duncan
Cc:	Duran-Hernandez, Doris
Subject:	FW: Comments on NSTS Category 3
Attachments:	2017-03-10_Fairobent_comments_NSTS.pdf

Comments from Lynne Fairobent

From: Lynne Fairobent [mailto:lynne.fairobent@gmail.com]
Sent: Thursday, March 23, 2017 5:34 PM
To: White, Duncan <Duncan.White@nrc.gov>; Wu, Irene <Irene.Wu@nrc.gov>
Subject: [External_Sender] Comments on NSTS Category 3

Duncan and Irene:

So sorry that I did not get these uploaded before March 10th. I hope that there is still time to consider them.

I heard you did a great job at AAPM this week.

Lynne

--
Lynne A. Fairobent

E-mail: lynne.fairobent@gmail.com
Phone: 703-626-8556

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= Irene Wu (IWW1)

March 10, 2017

Cindy Bladey
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment: Category 3 Source Security and Accountability (NRC-2016-0276)

Dear Ms. Bladey:

Thank you for the opportunity to provide comments to the U.S. Nuclear Regulatory Commission (NRC) regarding Category 3 source security and accountability. As acknowledged in the January 9, 2017 Federal Register notice (82 FR 2399), this is not a new issue. The NRC first published the proposed rule on "Expansion of NSTS [National Source Tracking System] in the Federal Register on April 2008 (73 FR 19749).

Numerous radiation oncology facilities employ high-dose-rate remote after loader (HDR) systems in the treatment of disease, particularly for gynecological, prostate, and breast cancers. The additional tracking and potential security, beyond that currently in force through U.S. Nuclear Regulatory Commission (NRC) (10 CFR Part 37) and equivalent Agreement State regulations, would impose additional costs on these treatment facilities; costs which would result in significant increases in the cost of medical care for these patients. Many of these cancer care facilities are freestanding and it is likely that a significant number of these institutions would be forced to halt HDR treatments, denying care to many patients.

Hospitals and health systems are already experiencing financial hardship due to changes in the way healthcare is delivered and paid for in this country. Adoption of this proposed regulation may make it more difficult for facilities to maintain their existing equipment and could potentially require them to purchase newer machines even though their current equipment has not outlived its usefulness. Most of the nominally equivalent replacement equipment fails to provide the quality treatments of the current equipment, and in some cases, can pose a safety hazard for patients.

In the end, patients may have less access to the latest treatment options or they will pay dramatically more to obtain the benefits of those treatment options. Even if one presumes that third-party payers (government and commercial) will adjust their reimbursement rates to reflect these higher costs, historically it can take two years or longer for these payment adjustments to make their way through the system. In the meantime, facilities will have incurred the costs to perform the upgrade and often must wait two or more years to obtain reimbursement rates that reflect those added costs. This alone could create a significant cash-flow problem for many institutions. Oftentimes these devices and equipment are the only option for treatment of certain cancers or tumors. Imposing barriers to facilities for housing this type of diagnostic and treatment equipment will significantly reduce the physical number of these pieces of equipment which gives patients fewer options at a higher cost.

Tracking Category 3 Radioactive Sources

The current regulatory system allows NRC and Agreement States to identify licensees that possess Category 3 sources, and to monitor the location and movement of the sources through the licensing and inspection program. Is it the current regulatory system that is not sufficient or is it that there are not adequate resources to establish a more rigorous pre-licensing, inspection and enforcement program to ensure licensee compliance with existing requirements without increasing the regulatory burden on the licensees. I believe that the latter is possibly true and therefore both NRC and Agreement States may need additional resources to ensure the existing regulatory system remains effective.

Robustness of System Capacity

During the 2009 discussions on include Category 3 sources in the NSTS, the robustness of the system was raised. I continue to be concerned on whether the system can handle the additional Category 3 sources. Including Category 3 sources will increase not only the total number of sources in the system but the number of licensees needing to interact with NSTS.

At the January 31, 201, public meeting at NRC headquarters, NRC stated there are currently approximately 1,400 Category 1 and 2 licensees representing approximately 75,000-80,000 sources. NRC staff also stated that there are approximately 5,500 Category 3 licensees of NRC and Agreement state licensees (NRC ~ 600 licensees of the 5,500 cat 3). However, this does not indicate how many additional sources would be added to the Licensee Verification System (LVS) or the NSTS.

In 2009, the discussion indicated that before including Category 3 sources, a detailed impact analysis should be performed for the expansion of NSTS to include Category 3 reflecting the significantly larger number of licensees impacted. To date, I don't believe this impact analysis has been conducted nor made publicly available. Prior to a staff recommendation to the Commission is made, the results of this should be completed and provided for public comment.

If Category 3 sources are added, will the system become diluted thus masking the ability to focus on sources of risk significance.

Adequate Resources

It is unclear whether NRC and the Agreement State have or will have adequate resources to handle the increased workload if Category 3 sources are added to the system. It is also unclear what the resource burden would be on Category 3 licensees. More and more demands are being made to medical licensees which could impact patient safety. There has been no discussion as to how these requirements will be paid for. I urge NRC to complete a cost/benefit analysis addressing the regulatory burden prior to a final decision.

System Accessibility and Cybersecurity Vulnerability

At the January 31, 2017 meeting, NRC staff stated that roughly 30 - 40 percent of category 1 and 2 licensees do not electronically upload the data. Licensees have chosen instead to fax or email their data which must then be uploaded to the system, thus causing a delay in the information and introducing errors in data entry.

In today's world, the issue of cyber security cannot be ignored. Although part of the argument for including Category 3 sources in to provide better traceability of radioactive sources, does it truly make sense to put all information into one database? Has an analysis of the vulnerability of the system been conducted? I urge NRC and the Agreement States to consider the potential from a cybersecurity risk and to provide the results prior to a final decision.

Conclusion

My view on the need to include Category 3 radioactive sources in enhanced security regulations has not changed since 2009. I believe that if someone wants to circumvent any system, they may be able to. The question that needs to be answered, if the current system any less safe and secure that the proposed changes? There has not been sufficient justification provided to demonstrate the new proposed requirements would result in a more secure regulatory system.

I believe that the current regulatory system provides for the safe use of radioactive materials. Until a true cost/benefit and risk analysis is conducted, I do not believe there is sufficient justification to implement the changes proposed.

Thank you for the opportunity to comment. If you have any questions or require additional information, please contact me at lynne.fairobent@gmail.com.

Sincerely,

Lynne A Fairobent

Lynne A. Fairobent