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General Comment

See attached file(s)

Attachments

NRC-2010-0282-DRAFT-0009.1: Comment on FR Doc # 2010-23249

*SUNSI Review Complete
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Call = M. Schwartz (mes)*



October 18, 2010

Electronically submitted VIA: <http://www.regulations.gov>

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Division of Administrative Services
Office of Administration
Mail Stop: TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: Comments on Docket ID NRC-2010-0282; Revised Draft Safety Culture Policy Statement: Request for Public Comments (75 FR 180)

Dear Ms. Blady:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to participate in this information-gathering process by offering the following comments to the U.S. Nuclear Regulatory Commission (NRC) regarding its revised draft safety culture policy statement (75 FR 180). ASTRO commends the NRC's efforts to raise awareness of safety culture issues and to improve safety in the medical use of radioactive materials and in all aspects of radiation use. ASTRO further commends the NRC for bringing in stakeholders from all licensee categories together to develop a meaningful, viable safety culture policy statement.

Introduction

ASTRO is the largest radiation oncology society in the world, with 10,000 members who specialize in treating patients with radiation therapy. 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's highest priority is ensuring that radiotherapy patients receive the safest, most effective treatments, and the Society is committed to improving safety and quality in radiotherapy and reducing the chances of medical errors. ASTRO believes that medical applications using radioactive materials are patient-centric—and this focus differentiates medical use of radiation from all other uses of radiation. Patient safety and practice of medicine decisions must come first. Accordingly, ASTRO urges that any reference to "people" in the definition of safety culture include

"patients," and that specific safety culture characteristics be developed addressing medical stakeholders' patient-safety focus.

ASTRO's Answers to Specific NRC Questions

1. The revised definition of Nuclear Safety Culture is: "Nuclear Safety Culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Should this be retained, as currently written, or should it be revised?

ASTRO supports the NRC's adoption of this Statement of Policy that was developed during the February 2010 workshop and concurs with excluding the term "security" from the definition.

ASTRO's Next Step Recommendations

ASTRO believes the NRC must develop specific actionable characteristics and behaviors for each license category, recognizing the differences of specific use applications. Medical applications using radioactive materials differ from other applications because they focus on the safety of the patient and providing the best medical care. This difference must be captured in safety culture characteristics as well as the metrics used to assess effectiveness. Moreover, ASTRO asserts that the NRC must delineate not only the characteristics that define a positive safety culture, but also the metrics for assessing a licensee's program against those characteristics. Guidelines explaining NRC expectations regarding adoption of safety culture values must also be developed so that stakeholders have both the tools to implement safety culture and the metrics to assess the effectiveness of their programs.

ASTRO believes that the NRC's safety culture scheme should be further clarified to reflect the patient-centric focus of the medical use of radiation and the considerable existing quality assurance infrastructure of medical institutions. ASTRO urges the NRC to work within the existing quality assurance infrastructure of medical institutions to avoid inefficient redundancy that would do little to develop or foster a positive safety culture or improve patient care. Medical institutions administering radiotherapy are already imbued with safety and quality assurance requirements defined by a variety of state and federal agencies, as well as professional organizations and independent accrediting bodies. Many of these requirements are consistent with the goals of NRC's safety culture policy. Medical licensees that can demonstrate the extent to which their current requirements and practices meet the intent of the NRC policy should not be required to comply with another set of methods and terminology developed by the NRC. Such licensees also should not be required to establish a separate training and record keeping system to demonstrate compliance with the NRC policy.

Conclusion

ASTRO supports the need for common standards of safety culture traits and behaviors that apply consistently to each category of licensee. We urge the NRC to work within the existing and substantial quality assurance infrastructure of medical institutions to avoid duplicating methods and systems. ASTRO advocates a pragmatic, measured approach to the development of a safety culture policy scheme that takes into account the patient-centric nature of medical uses of radioactive materials. Thank you for affording ASTRO this opportunity to provide comments on the revised draft safety culture policy statement. Please contact Dave Adler, ASTRO's director of government relations, at 703-839-7362 or davea@astro.org if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer