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Draft Safety Culture Policy Statement: Request for Public Comments

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Comment on FR Doc # E9-26816

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Submitter Information

Name: Laura Thevenot
Address:
8280 Willow Oaks Corporate Dr.
Fairfax, VA, 22031
Submitter's Representative: Laura Thevenot
Organization: American Society for Radiation Oncology

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General Comment

Please see attached comment letter of American Society for Radiation Oncology

Attachments

NRC-2009-0485-DRAFT-0014.1: Comment on FR Doc # E9-26816

SUNSI Review Complete
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March 1, 2010

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Michael T. Lesar
Chief, Rulemaking and Directives Branch (RDB)
Division of Administrative Services
Office of Administration
Mail Stop: TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

**Re: Comments on Docket ID NRC-2009-0485; Draft Safety Culture Policy Statement:
Request for Public Comments (74 FR 57525)**

Dear Mr. Lesar:

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 draft safety culture policy statement (74 FR 57525). 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 in bringing 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 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'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 Responses to Specific NRC Questions

1. **The draft policy statement provides a description of areas important to safety culture, (i.e., safety culture characteristics). Are there any characteristics relevant to a particular type of licensee or certificate holder (if so, please specify which type) that do not appear to be addressed?**

ASTRO believes that the pursuit of a single definition of safety culture that can apply to all categories of licensees comes with significant limitations. Medical applications using radioactive materials differ from other applications because they focus on the safety of the patient and providing the best medical care—and this difference must be captured in safety culture characteristics.

ASTRO generally supports incorporation of the following traits and behaviors based on those developed by participants at the February 2-4, 2010 workshop, but with more emphasis on how those traits would look in practice:

- **Problem Resolution and Metrics.** The organization ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- **Personal Responsibilities and Attitudes.** The organization makes clear that anyone at any time can stop procedures if they feel that something may be amiss, and the organization fosters the feeling of ownership of procedures among all involved.
- **Processes and Procedures.** The organization uses recognized, effective tools for planning the control of work activities such that safety is maintained.
- **Continuous Learning.** Organizational learning is embraced.
- **Leadership Safety Behaviors.** Leaders demonstrate commitment to safety.
- **Effective Safety Communication.** The organization evaluates lines of communication when designing work activities to assure effective communication.
- **Encouraging Reporting of Problems.** The organization maintains a safety conscious work environment in which personnel feel free to raise concerns without fear of retaliation.
- **Respectful work environment.** Trust and respect permeate the organization.

2. **Are there safety culture characteristics as described in the draft policy statement that you believe do not contribute to safety culture and, therefore, should not be included?**

ASTRO believes that the policy statement should be limited to “safety” and not address “security” issues. While ASTRO acknowledges the importance of security of materials, it believes that professionals in safety and security disciplines use differing approaches to achieve risk mitigation or protection of public health and safety, and combining safety and security concepts in a single policy may result in confusion and inefficiency.

3. **Regarding the understanding of what the Commission means by a “positive safety culture,” would it help to include the safety culture characteristics in the Statement of Policy section in the policy statement?**

ASTRO believes that the NRC should include characteristics that in the agency’s view define a positive safety culture, as well as the standard of measurement the agency will use for assessing a licensee’s program against those characteristics. ASTRO is concerned that without further defining “positive safety culture,” an objective assessment of what constitutes compliance with that concept will not be feasible. ASTRO is further concerned with using such vague generalities to assess programs’ compliance with the policy. If the policy is to be enforced, clear and accepted metrics associated with the standards must be developed.

4. **The draft policy statement includes the following definition of safety culture: “Safety culture is that assembly of characteristics, attitudes, and behaviors in organizations and individuals which establishes that as an overriding priority, nuclear safety and security issues receive the attention warranted by their significance.” Does this definition need further clarification to be useful?**

Rather than moving forward with the draft definition contained in the November 6, 2009 Federal Register notice, ASTRO recommends that the NRC adopt the following definition of safety culture developed by the stakeholders at the workshop:

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.

However, even with the workshop statement, to be useful, the statement needs clear guidelines on how it would be interpreted in real situations. Neither statement provides information that would be useful in practice.

5. **The draft policy statement states, “All licensees and certificate holders should consider and foster the safety culture characteristics (commensurate with the safety and security significance of activities and the nature and complexity of their organization and functions) in carrying out their day-to-day work activities and decisions.” Given the diversity among the licensees and certificate holders regulated by the NRC and the Agreement States, does this statement need further clarification?**

ASTRO believes that this statement needs further clarification 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 agencies and organizations, including independent accrediting bodies. Many of these requirements are consistent with the goals of NRC's safety culture policy. ASTRO believes that as long as medical licensees can demonstrate the extent to which current requirements and practice meet the intent of the NRC policy, they should not be required to comply with another set of methods and terminology developed by the NRC, or be required to establish a separate training and record keeping system to demonstrate compliance with the NRC policy.

6. How well does the draft safety culture policy statement enhance licensees' and certificate holders' understanding of the NRC's expectations that they maintain a safety culture that includes issues related to security?

While ASTRO acknowledges the importance of fostering and advancing a positive safety culture, ASTRO is concerned that the policy statement alone does not enhance the licensees' and certificate holders' understanding of NRC's expectations. The policy statement does not convey what the NRC means by safety culture or how the NRC will evaluate licensees' and certificate holders' compliance with the policy statement. Moreover, ASTRO believes the NRC should inform stakeholders as to its future course of actions. Stakeholders need to know if development of the policy statement will be followed by rulemaking, or how the NRC intends to assess safety culture during performance-based inspections.

7. In addition to issuing a safety culture policy statement, what might the NRC consider doing, or doing differently, to increase licensees' and certificate holders' attention to safety culture in the materials area?

As previously stated, ASTRO urges the NRC to work within the existing and substantial quality assurance infrastructure of medical institutions to avoid duplicating methods and systems already employed. Many initiatives are underway within ASTRO, the AAPM, other organizations and several major universities to strengthen the quality and safety structures in radiation oncology. The support of the NRC with these initiatives would be helpful.

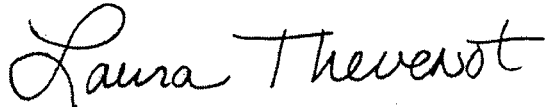
8. How can the NRC better involve stakeholders to address safety culture, including security, for all NRC and Agreement State licensees and certificate holders?

ASTRO commends the NRC for holding the February 2-4 workshop to solicit input from stakeholders representing all licensee categories, and recommends that the NRC continue to engage stakeholders in addressing issues related to the development of a safety culture policy statement or other safety culture issues. Working within the activities noted above would be a strong and effective action on the part of the NRC.

Conclusion

ASTRO advocates a pragmatic, measured approach to the development of a safety culture policy statement that takes into account the patient-centric nature of medical uses of radioactive materials. Further, ASTRO believes the policy statement must be informed by the NRC's intended use of the policy, and cannot be developed without consideration of how the NRC will implement, assess, or enforce compliance to its tenets. Thank you for affording ASTRO this opportunity to provide comments on the draft safety culture policy statement. Please contact Richard Martin at 703-839-7366 or richardm@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