

Mendiola, Doris

Subject: FW: ACMP comments on revised draft safety policy statement
Attachments: 10-19-10_ACMP_Revised_Draft_Safety_Culture_Policy_Statement_Comments_75FR57081_DocketNRC-2010-0282.pdf

From: Lynne Fairobent [mailto:lynne@aapm.org]
Sent: Tuesday, October 19, 2010 11:52 PM
To: Sieracki, Diane; Schwartz, Maria; Zimmerman, Roy
Cc: Corbi Foster; Christopher Serago
Subject: ACMP comments on revised draft safety policy statement

9/17/2010
75 FR 57081
21

All:

I am attaching comments by the ACMP related to the revised draft safety culture policy statement.

Please enter these in the docket since the docket is officially closed in regulations.gov and I can't upload them.

If you have questions, please contact me.

Lynne

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Call =
cm. Schwartz (mcs)



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Submitted Electronically

October 19, 2010

Cindy K. Blady
Chief
Rules, Announcements, and Directives Branch (RADB)
Division of Administrative Services
Office of Administration
Mail Stop: TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Docket ID NRC-2010-0282; Revised Draft Safety Culture Policy Statement: Request for Comments [75 FR 57081]

Dear Ms. Blady:

The American College of Medical Physics (ACMP) is a professional organization composed of medical physicists who provide clinical support to both diagnostic imaging and radiation oncology programs within the United States. ACMP is pleased to provide the following comments in response to the September 17, 2010 Federal Register Notice (FRN) (75FR57081) regarding the Revised Draft Safety Culture Policy Statement.

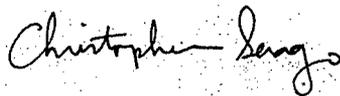
ACMP agrees with the comments filed by the American Association of Physicists in Medicine on October 19, 2010. In summary:

1. It is the responsibility of the licensees and certificate holders for developing and maintaining a strong safety program.
2. It is critical that a common language of safety culture traits and behaviors exist between NRC and each category of licensee.
3. ACMP concurs with the revised definition.
4. ACMP concurs with excluding the term "security" from the definition including security in the definition denigrates other equally important processes that protect the patient, the public, and the environment.
5. Safety culture is not an appropriate subject for rulemaking.

6. NRC needs to acknowledge for medical institutions that patient safety is first and foremost and that the use of radioactive materials in the practice of medicine is to enhance diagnosis or treatment of disease while ensuring that the patient receives the best medical care.
7. Although it is laudable to try and have a single definition that can apply to all categories of licensees, it is equally important to note that implementation of the traits and behaviors as they apply to the specific licensee categories may differ.
8. NRC must define:
 - a. The characteristics that, in the agency's view, define a positive safety culture, and
 - b. The metrics for assessing a licensee's program against those characteristics.
 - c. Without specific definition, the interpretation of a positive safety culture remains subjective.
9. ACMP believes the next critical step is to develop specific actionable characteristics and behaviors specific to each license category. This next level or "third tier," once developed will provide more meaning in the individual licensee category and relate the general characteristics to specific behaviors and indications of a strong safety culture in that particular field.
10. NRC must work closely with the Agreement States to prioritize this effort relative to other regulatory issues.
11. NRC should conduct workshops, in coordination with the Agreement States, specific to each category of licensee to clarify NRC's approach to safety culture and ensure that its expectations are clearly understood.
12. NRC should refrain from including safety culture issues in inspection reports and assessments until such time that the final policy has been issued, relevant coordination with the regulated community and Agreement States has occurred, and implementing guidance is issued to ensure that NRC's expectations are clear.
13. NRC's safety culture scheme should be clarified that if medical licensees can demonstrate the extent to which current requirements and practice meet the "intent of the NRC safety culture policy", they should not have to use methods and terminology developed by NRC staff who might have limited understanding of methods and requirements currently used by healthcare organizations.

Please feel free to contact me if you have additional questions.

Sincerely,



Christopher Serago, Ph.D., FAAPM, FACMP, FACR
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cc: Mr. Roy Zimmerman, U.S. Nuclear Regulatory Commission
Ms. Diane Sieracki, U.S. Nuclear Regulatory Commission