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Draft Safety Culture Policy Statement: Request for Public Comments

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RULES AND DIRECTIVES
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General Comment

AAPM comments are attached

Attachments

NRC-2009-0485-DRAFT-0015.1: Comment on FR Doc # E9-26816

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March 1, 2010

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

Re: Docket ID NRC-2009-0485; Draft Safety Culture Policy Statement: Request for Public Comments [74 FR 57525]

Dear Mr. Lesar:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to provide the following comments in response to the November 6, 2009 Federal Register Notice (FRN) (74FR57525) regarding the Draft Safety Culture Policy Statement. AAPM commends the NRC for holding a facilitated workshop to solicit input from all licensee categories. The workshop was well conducted and every participant had a chance to express their viewpoint. Many of our comments reflect the outcome of that workshop.

The enclosure to this letter provides our response to the eight questions posed in the FRN. In addition AAPM offers comments in the following key areas:

- The consensus result of the February workshop should be given serious consideration as an alternative to NRC's proposed definition.

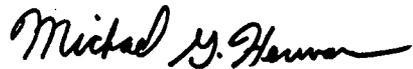
¹ The American Association of Physicists in Medicine's (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

Mr. Lesar
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- It is the licensees and certificate holders that are primarily responsible for developing and maintaining a strong nuclear safety program.
- It is critical that a common language of safety culture traits and behaviors exist between the NRC and each category of licensee.
- Consistent with the stakeholders' panel, the policy statement should be limited to "safety" and not include a reference to "security".

If the AAPM can supply any additional information to the Commission or the NRC staff in support of this issue, please do not hesitate to contact Lynne Fairbent, AAPM Manager of Legislative and Regulatory Affairs at 301-209-3364. Thank you in advance for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Michael G. Herman". The signature is written in a cursive, flowing style.

Michael G. Herman, Ph.D., FAAPM, FACMP

1 Attachment



**Attachment to AAPM's Comment re: Docket ID NRC-2009-0485;
Draft Safety Culture Policy Statement: Request for Public Comments
[74 FR 57525]**

General Comments

NRC Sponsored Stakeholders' Forum - Consensus Definition of Safety Culture

AAPM appreciated the opportunity to participate in the February 2-4, 2010 facilitated workshop. The goal of the workshop was to develop a single definition of "Safety Culture" that would be applicable to all categories of licensees and certificate holders and could be used in development of a final safety culture policy statement by the NRC. After reviewing several examples of draft safety policy culture statements including that in November 6, 2009 Federal Register Notice (FRN), the panelists developed the following definition:

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.

Although not perfect, the consensus of the panelists was that the above definition would be beneficial in increasing the understanding and importance of what is "safety culture." Therefore, the panelists recommended that this definition to the Commission in place of the proposed definition in the FRN.

AAPM concurs with the panelists and recommends that that Commission consider this definition in place of the proposed FRN definition. Also, AAPM notes that it is extremely important to emphasize that the term "protection of people" in the above definition includes "patients".

NRC Sponsored Stakeholders' Forum - Draft Supporting Traits (Characteristics) and Behaviors

During the course of the workshop, the participants also developed supporting traits and behaviors which they felt would provide the best communication to all categories of licensees and stakeholders of what was meant by the above definition. They are:

1. **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.

2. **Personal Responsibilities and Attitudes.** Everyone is personally responsible for nuclear safety.
3. **Processes and Procedures.** Processes for planning and controlling work activities are implemented such that safety is maintained.
4. **Continuous Learning.** Organizational learning is embraced.
5. **Leadership Safety Behaviors.** Leaders demonstrate commitment to safety.
6. **Effective Safety Communication.** Effective Communication is essential to maintain focus on Safety.
7. **Encouraging Reporting of Problems.** The organization maintains a safety conscious work environment in which personnel feel free to raise concerns without fear of retaliation.
8. **Respectful work environment.** Trust and respect permeate the organization.

It is important to note that the panelists believe that the above traits and behaviors will be easier to convey the understanding and implementation of safety culture in each of their respective industry.

Licensee and Certificate Holder Primary Responsibility

The Statement of Policy states “licensees and certificate holders... bear the primary responsibility for safely handling and securing materials. It is therefore each licensee’s and certificate holder’s responsibility to develop and maintain a positive safety culture...” AAPM agrees that the regulated community should take the lead on safety culture. 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. What is appropriate for a commercial nuclear reactor is not necessarily appropriate for medical licensees. Therefore, AAPM recommends that the NRC conduct specific meetings with each of the license categories such as the medical community to develop appropriate methodologies unique to their industry.

Common Understanding

The safety culture workshop conducted February 2-4 of this year was an excellent beginning toward a common understanding of nuclear safety culture. AAPM believes that the basic definition and characteristics developed during the workshop are appropriate for the NRC, its licensees and certificate holders, and all of the other NRC stakeholders. However, we believe the next critical step is to develop specific actionable characteristics and behaviors specific to each license category that the NRC regulates; for example, medical, industrial, operating reactors, new construction, fuel facilities, etc. 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.

AAPM recommends that this level of development begin in the near future and is prepared to commence this work immediately in the medical area. It is essential that the NRC in its

oversight role of safety culture, and the licensee or certificate holder in its training of staff and assessment of safety culture use the same terminology.

Safety and Security Culture

NRC's proposed definition includes security as well as safety culture. The FRN states that the policy statement "(1) builds on the fact that safety and security have the same ultimate purpose of protecting people and the environment from unintended radiation exposure and (2) encourages attention to the ways safety and security interface."

It is important to note that the February 2-4 workshop panel unanimously rejected the inclusion of the term "security" in the FRN proposed definition. Panelists expressed the concern that the policy statement should focus on nuclear safety and not on any individual aspect of nuclear safety at the highest level of definition. Placing an undue emphasis on just one of the many important aspects such as security is distracting and raises unnecessary questions in the licensee and certificate holders' minds. AAPM concurs with the panelists that security should not be included in the definition of "safety culture." At a minimum it is distracting and denigrates other equally important processes that protect the patient, the public, and the environment.

Questions for Which NRC Is Seeking Input

- 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?**

As discussed above, AAPM believe that the traits and behaviors developed by the February 2-4 workshop more effectively and comprehensively address the areas licensees and certificate holders feel are important to safety culture. We believe their language – plain language -- will mean more to the regulated communities, having been developed by representatives from those communities. However, it is important that NRC 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.

- 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?**

Yes. AAPM believes that NRC should not include security with safety culture. This was also expressed by the panelists during the February 2-4, 2010 workshop. Although security of radioactive materials is important, those involved in safety and security

activities use differing approaches to achieve risk mitigation or protection of public health and safety.

- 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?**

NRC does need to define the characteristics that, in the agency’s view, define a positive safety culture, and the metrics for assessing a licensee’s program against those characteristics. Without specific definition, the interpretation of a positive safety culture remains subjective.

- 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?**

Based on the work during the February 2-4, 2010 workshop, NRC should present the definition developed by the workshop participants in place of the one in the Federal Register. We believe that February 2-4 workshop panel definition is clearer and more useful to the regulated community which is ultimately responsible for establishing an environment that reflects a strong safety culture. Again, we do not believe it is appropriate to include security in the definition.

- 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?**

Yes. It is essential that the diverse communities of licensees and certificate holders regulated by the NRC and the Agreement States develop additional information (in particular specific industry characteristics) to clarify NRC expectations. The draft policy statement developed during the February 2-4 workshop helped to generalize the policy statement for all stakeholders. 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 the implementation of the traits and behaviors as they apply to the specific licensee categories may differ. What is appropriate for a commercial nuclear reactor is not necessarily appropriate for medical licensees. A clear example of the differences in diversity of views was stated by the medical community during the workshop. The medical community representatives indicated that nuclear safety does not pre-empt or override patient safety especially in emergency situations. For example, life saving

measures should always pre-empt the need to decontaminate a patient in the emergency room.

Medical institutions must follow numerous safety requirements defined by a variety of agencies and organizations such as The Joint Commission and independent accrediting bodies. Many of these requirements are consistent with the goals of NRC's safety culture policy. Medical licensees should not be required to establish a separate training and record keeping system to demonstrate compliance with NRC's safety culture policy approach.

AAPM recommends that the NRC's safety culture scheme be clarified to accept 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.

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?

The policy statement alone does not enhance the licensees' and certificate holders' understanding of NRC's expectations on what is meant by safety culture and how they will be assessed against such policy statement. NRC should clarify the future course of actions. For example, does NRC plan to issue regulations related to safety culture? How will safety culture be assessed during performance-based inspections? How does NRC expect the policy statement to be addressed by the Agreement States? As stated above, AAPM does not believe security should be specifically called out in the safety culture definition.

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?

It was stated many times during the February 2-4 workshop that the level of understanding of the concept of safety culture varies greatly with the category of licensee. 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. Guidelines explaining NRC expectations regarding adoption of Safety Culture values must be promulgated. If stakeholders do not understand how to implement Safety Culture, and have metrics to use internally to determine the effectiveness of their efforts, attention will be minimal.

NRC must work closely with the Agreement States to prioritize this effort relative to other regulatory issues. In the absence of adequate Agreement State support for this initiative, the safety culture concept would potentially only be applied to approximately

twenty percent of the byproduct materials users nationwide. Finally, 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.

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

NRC should work through the stakeholder February workshop planning committee to solicit input on how best to involve stakeholders for further development of the policy, characteristics, "third tier" characteristics, implementing guidance and outreach to industry and the Agreement States to ensure a nationwide effort on safety culture. With regard to the Agreement States, NRC should create additional opportunities, such as the Organization of Agreement States annual meeting and others, to prioritize this effort since they have limited and in many cases declining resources for a new regulatory initiative. With regard to regulated entities, it is conceivable that several workshops will be needed to convene the wide variety of regulated activities represented by industry to effectively meet our mutual goal of ensuring that an adequate safety culture exists at regulated facilities nationwide.