



John E. Baldacci, Governor Brenda M. Harvey, Commissioner

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March 1, 2010

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

Handwritten notes: 11/06/09, 74 FR 57525

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RULES AND DIRECTIVES
BRANCH
USNRC

RE: Docket ID NRC-2009-0485

Dear Mr. Lesar:

The Maine Radiation Control Program (RCP) has received and reviewed the above referenced document. We appreciate the opportunity to comment on the draft Safety Culture definition. Furthermore the RCP, in conjunction with the Organization of Agreement States (OAS), is always ready to assist licensees in ways to attain and maintain regulatory compliance. We support the effort that the NRC is taking toward the development of a Policy Statement, in lieu of a regulation. We believe that this document will be a great reminder for all, regulators and licensees, that health, safety and security must be incorporated into one's comprehensive radiation protection program.

Our comments to the specific questions listed in the above mentioned document are as follows:

(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?

One area that needs to be addressed, especially in the medical arena is one of "supervision". Materials inspections often point to a lack of physical supervision by authorized users and the overall use of radioactive materials. Since there is no clear definition, enforcement of supervision is difficult. Another area that should be addressed is the incorporation of safety culture in training programs. If this can be included early in an entity's overall "culture", then it becomes easier to follow. Of course this assumes a top down approach, where management actually "practices what they preach."

(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?

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There are many factors that are incorporated into a positive safety culture, that when absent, would adversely affect the overall safety culture of an entity. Therefore, there must be management commitment, including but not limited to resources, to support the program.

- (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?*

Yes, in addition it would make sense to include this in any guidance, training, and other areas of an entity's radiation protection program.

- (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?*

The definition needs to reflect the diverse areas that you are trying to address. The definition that was developed during the public workshop is a great starting point. The only clarification of that definition would be to come up with a term that would make it a high enough priority but not such that for the medical arena they would have to decide whether to save a life or not. In the end, one must balance all the competing ideals to determine what order they feel it deserves, similar to that of the ALARA principle.

- (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?*

Licensees and certificate holders should always consider and foster the characteristics of a safety culture. Maybe remove the word "consider" and include specific guidance on implementation and compliance for all to use.

- (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 which is developed should be clear, concise and to the point. It needs to be kept simple so anyone can understand it and its implementation.

- (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?*

Simple checklists and guidance for implementation should be developed for entities, including regulators, to utilize, especially during audits or inspections.

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

The NRC must continue to involve stakeholder input early and often throughout any potential rulemaking and/or policy statement development. This will ensure that adequate information has been sought before proposing any item that may affect entities.

In closing the RCP supports the development of a policy statement on defining safety culture. By doing this it will not be a matter of compatibility for the States. We look forward to continuing our participation in the process and we firmly believe that early and substantive involvement of the stakeholders is desirable and will only serve to improve the final product.

Thank you for allowing us to comment on this proposed policy statement and again we look forward to the continued participation of the RCP in future NRC initiatives.

Sincerely,

A handwritten signature in black ink, appearing to read "Jay C. Hyland", written over a vertical line that serves as a placeholder for a name.

Jay C. Hyland, P.E., Manager
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