

SAFETY CULTURE IN THE MATERIALS AREA

In the February 25, 2008, Staff Requirements Memorandum (SRM) for COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture," the Commission directed the staff to review specific issues related to safety culture in consideration of the safety culture components of the reactor oversight process and fuel facility pilot and their potential applicability to other U.S. Nuclear Regulatory Commission (NRC) licensees. This enclosure addresses the following specific SRM question for consideration: how to increase attention to safety culture in the materials area.

Conclusion

The staff has taken initial steps to increase attention to safety culture in the materials area. In its efforts to develop the draft safety culture policy statement, the staff conducted numerous outreach activities with a variety of materials licensees including holding a public workshop in February 2009 and having a breakout session dedicated to materials users. However, the staff recognizes more needs to be accomplished in this area. In order to further engage materials users following Commission approval to publish the draft policy statement, the staff intends to take the following actions:

- (a) hold a public meeting to solicit input on the draft policy statement and use the publication of the draft policy statement and the public meeting to obtain additional stakeholder views on how the NRC can increase attention to safety culture in the materials area and
- (b) continue to engage the Agreement States on how best to increase the attention that the Agreement States and Agreement State licensees give to safety culture including requesting the Agreement States to share the draft policy statement with their licensees.

The staff's conclusion, to continue to engage the Agreement States is consistent with recommendations from stakeholders. The staff would, at a minimum, use Webinar or Web-streaming technology to reach licensees and certificate holders in different geographic regions but does not plan to hold multiple workshops on the draft policy statement. The staff will also continue to discuss with Agreement States ways to increase the attention of materials licensees to safety culture and will convey to Agreement States those suggestions that specifically concern them.

Review

As part of developing the draft policy statement, the staff conducted outreach activities with a wide variety of material licensees. This provided the NRC with a unique opportunity to begin increasing the attention to safety culture among licensees and certificate holders.

The staff sought stakeholder input on how the NRC should increase attention to safety culture in the materials area. This includes the public workshop on the development of a policy statement held on February 3, 2009, previously mentioned in Enclosure 2. Ten different organizations including licensees, State regulators, and non-governmental organizations were represented on the workshop panels discussing the three topics. The use of Webinar at the workshop allowed greater participation by smaller licensees and certificate holders, State government

representatives, and other stakeholders. The staff devoted one session of the workshop to the question of how to increase attention to safety culture in the materials area and to several related but more specific questions. Public input was also sought on these questions through the January 23, 2009, and February 9, 2009, *Federal Register* Notices (74 FR 4260 and 74 FR 6433), respectively, and on NRC's public safety culture Web site (<http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>).

As noted above, the Agreement States administer the vast majority of materials licenses. In conducting its review, the staff recognized that this requires additional consideration on how best to meet the Commission's direction regarding increasing attention to safety culture in the materials area. For example, although the NRC may express its expectations for Agreement States in a policy statement, these expectations would not be a matter of compatibility. A policy statement would announce the Commission's views on safety culture including security and would contribute towards elevating awareness of the issue to State regulatory authorities and NRC and State licensees. Hence, while issuing a policy statement effectively announces the NRC's views and expectations relating to safety culture and would be an effective tool to help the NRC increase attention to safety culture at NRC licensees and at the Agreement States, it must rely on the Agreement States to provide this outreach to their licensees because the NRC does not regulate these licensees. If, however, the Commission decides that Agreement States licensees' safety culture actions should be a matter of compatibility, then additional rulemaking would be required. A more detailed discussion of compatibility is provided in Enclosure 8.

Agreement States cannot be required to implement the policy statement, and the policy statement is not binding on Agreement State licensees. Therefore, it is important to continue to work with the Agreement States as the Commission continues to develop its policy on safety culture so as to more fully encompass materials licensees. The staff is continuing to develop a strategy to accomplish the Commission's objective of increasing attention to safety culture in the materials area and will provide the Commission with recommendations for accomplishing this objective when it provides a draft final policy statement for Commission consideration. This will allow the staff to develop recommendations that consider (1) additional stakeholder input including additional insights from the Agreement States and (2) insights arising from further progress on the safety culture pilot program initiated by the Office of Nuclear Materials Safety and Safeguards through the efforts to develop the revised fuel facility oversight process and through subsequent efforts to apply insights to other material licensees and certificate holders. In addition, having a draft policy statement available may assist stakeholders in developing suggestions for ways to increase attention to safety culture. The staff will continue to evaluate the comments and recommendations that have been received when developing the longer-term recommendations.

Summary of Stakeholder Comments on How to Increase Attention to Safety Culture in the Materials Area

There was general agreement that the approach the NRC takes in the policy statement should be flexible enough to address differences among the licensees and certificate holders and should consider risk. A number of commenters recommended taking a graded approach based on the type of licensee and the risk of the activities involved. Although one commenter indicated a preference for having the expectations on security culture prescriptive for academic and medical licensees, some commenters would like the NRC's approach for addressing safety culture to be performance based. That is, the NRC should not dictate specific criteria in this area. There was also general agreement in favor of consistency in the application of the policy

at the NRC and the Agreement States. One commenter suggested that there is complexity associated with having different approaches used by the NRC and the Agreement States and that this makes it more difficult for licensees to use a standard approach in areas such as corrective action programs and a safety conscious work environment. This difficulty arises because the NRC regulates some activities and Agreement States regulate other activities, and different approaches are taken with regard to the oversight of these areas. One commenter asked whether the NRC had considered making the policy a matter of compatibility.

Some commenters suggested that the NRC coordinate more with the Agreement States regarding the NRC's application and implementation of safety culture policy to the materials arena. One commenter suggested that the NRC should reach out more to the regulated community (such as individual doctors and employees) and focus on education and awareness. Another stakeholder suggested that the NRC work with professional societies (i.e., Society for Nuclear Medicine, American Association of Physicists in Medicine, Health Physics Society, American College of Radiology, and American Society for Therapeutic Radiology and Oncology) to have safety culture incorporated into their standards of practice which are then adopted by licensees.

A number of commenters wanted to understand the NRC's expectations regarding oversight. Some commenters suggested that the NRC revise its enforcement approach because the current focus on potential violations without acknowledging the positive aspects of programs could have a negative impact on the site's programs and its safety and security culture. One commenter suggested that the NRC refrain from citing a licensee's self-identified violations, if appropriate corrective action has been taken. Another commenter suggested that the NRC should consider developing different levels of certifications such as a platinum level of safety conscious awareness. A commenter suggested that the NRC should encourage licensees to continue to focus on safety culture and to expect them to conduct activities such as self assessments and audits to improve their performance.

Based on the material stakeholder comments, the staff concluded that there is value in striving towards a common understanding of expectations. The consensus among commenters is that the NRC's safety culture policy expectations should not be different for different types of licensees. However, the approach should also recognize the range of materials licensees and not apply a one-size-fits-all perspective. One commenter suggested that the methods that the NRC uses to share information such as generic communications and licensee newsletters could be used by the Agreement States. Another commenter suggested that the Agreement States could help licensees maintain a safety culture if they were to conduct inspections requested by the licensee.

The Organization of Agreement States/Conference of Radiation Control Program Directors representative raised the following points in the workshop. The approach needs to (1) be performance based, (2) appropriately consider the relative risk of the activities, and (3) be generic enough to address the range of different types of licensees. It was indicated that it would be almost impossible to develop one interpretation for all 36 Agreement States, and in the absence of a single policy, there could be 36 variations of a policy. It was suggested that there is a need for uniformity based on sound policy and that the guidance needs to be simplified and made un-burdensome. There is some skepticism, specifically that the NRC's effort to increase the attention to safety culture may be a reaction to the U.S. Congress at the expense of the States.

The following suggestions were made for moving forward with the development of the policy statement.

- First, the NRC should look at vulnerability versus the actual risk.
- Second, the NRC should look at data for basing its decisions (i.e., how many devices have been stolen/attempted to be stolen before and after the implementation of the increased security requirements).
- Third, the NRC needs to listen to the stakeholders and avoid making the presumption that the NRC knows best.
- Fourth, there is the need to continue with a questioning attitude and to trust but verify.

The staff will continue to consider these and other stakeholder comments during further development of the safety culture policy statement.