

Public Comments

Summary

The *Federal Register* notices (FRNs) from the November 2009, and September 2010 generated 76 comments from affected stakeholders and members of the public. The staff's evaluation concluded that several of the comments were statements of agreement with the information included in the draft and revised safety culture policy statements and did not require further action. A few of the comments raised issues that the staff considered during the development of the policy statement but ultimately concluded were not applicable to the policy statement (e.g., that "by virtue of its all encompassing applicability, the policy must be taken as a strategic utterance") or misunderstood or disregarded the concept of a policy statement in this application (e.g., that a policy statement is "largely inadequate for purposes of establishing broad-reaching performance standards"). The staff used the remaining comments to inform the development of the proposed final policy statement.

The chart at the end of Enclosure 6, "Implementation," "Tiers," illustrates the three tiers that are referenced in this enclosure which include: first, the development of an overarching definition of safety culture (tier one); second, the development of the traits that describe areas important to a positive safety culture (tier two), and third, application of the policy statement which includes next steps and implementation of the policy statement (tier three).

November 2009 FRN: Evaluation of Public Comments on the Draft Safety Culture Policy Statement

The draft safety culture policy statement was published in the *Federal Register* on November 6, 2009, for a 90-day comment period. The FRN requested comments on the draft policy statement and specifically asked for comments on eight questions included in the FRN. The agency extended the original 90-day comment period to March 1, 2010, in response to stakeholder requests. The NRC received 52 responses within the 115-day comment period.

In May 2010, an internal working group held a planning meeting to determine how to best address the comments received on the November 2009 FRN. The working group included representatives from the program offices, including the Office of Nuclear Security and Incident Response, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Regulatory Research, the Office of Nuclear Reactor Regulation, the Office of Federal and State Materials and Environmental Management Programs, the Office of New Reactors, and the Office of the General Counsel. The working group agreed that the Office of Enforcement (OE) would summarize the nature and scope of the comments before each meeting, and that each meeting would focus on one or more of the questions included in the November 2009 FRN. Between May and June 2010, the working group held four meetings to discuss the comments.

OE staff assessed the responses and either organized them into themes or addressed them as a specific comment. That is, if many comments addressed a common issue, the staff identified a theme. If the comment did not fall into one of the themes, it was addressed as a specific comment.

These themes and comments were discussed during the meetings, followed by one of three possible recommendations:

1. No further action is needed or the subject of the comment was being addressed elsewhere.
2. Further discussion and guidance is needed from the NRC steering committee, composed of division directors from each office, before a recommendation can be made.
3. The working group will recommend a modification to the policy statement for the steering committee's consideration.

On May 12, May 18, May 25, and June 15, 2010, the working group met to review the public comments received on the November 2009 FRN. The comments generally fell into three themes: (1) guidance—more guidance is needed on implementation issues; (2) policy vs. regulation—the NRC's choice to use a policy statement, which is voluntary, rather than an enforceable regulation; and (3) security—the term "security" should not be called out specifically in the definition of safety culture.

- Guidance: Many commenters requested additional guidance on implementing the policy statement (e.g., more information was requested on training requirements, resources needed, and the NRC's expectations regarding implementation). The working group recommended that, although the NRC program offices will address the issues raised by these comments in the offices' oversight and inspection documents (a "third-tier" activity that is very specific based on the activity and type of regulated activity involved), the final FRN should include some clarification with the proposed final Statement of Policy.
- Policy vs. Regulation: Because of the number of comments addressing the NRC's use of an "enforceable policy statement," there was clearly some confusion about the difference between a regulation and a policy statement. The working group suggested that it would be helpful to include a discussion in the policy statement on when and how the Commission uses a policy statement and the difference between a policy statement and a regulation.
- Security: The draft policy statement included security in the traits and in the discussion in the policy statement. The February 2010 workshop panelists were aware of this but chose not to include the term "security" in the definition and traits that they developed. Several comments indicated agreement with this recommendation. Other commenters indicated that, if security was included in the definition and traits, they would like more guidance on what that would mean for them. Based on its evaluation of the comments, the working group recommended adoption of the workshop definition that does not include the term "security," but also recommended adding the term "security" to the traits that were developed at the workshop. This issue resulted in extensive discussion and required resolution by the steering committee. As discussed below, ultimately this resulted in adoption of the February 2010 workshop definition and traits, neither of which contains the term "security;" however, a preamble to the traits was included that addresses the significance of security as one of the NRC's regulatory pillars.

In addition to these themes, five specific comments warranted further consideration and discussion. Many commenters indicated that leadership is the most important contributor to safety culture. Although all of the traits are considered important, the working group

recommended moving the trait “Leadership Safety Values and Actions” to the top of the traits list to give it visual prominence and importance.

A sentence in 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.” Many comments indicated that the word “consider” implied that fostering safety culture was too optional and may not be taken seriously enough. The working group recommended removing the words “consider and” so that the sentence would read “All licensees and certificate holders should foster the safety culture characteristics...in carrying out their day-to-day work activities and decisions.” Ultimately, based on several iterations of the language, the staff did not include this sentence in the proposed Statement of Policy. Instead, the proposed final Statement of Policy states, “[T]he Commission expects that all individuals and organizations performing regulated activities will take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments.

One comment stated that complacency often results from long-term success and repetition. Although complacency is already indirectly addressed in the traits (e.g., Effective Safety Communication and Personal Accountability), the working group felt that because complacency could erode compliance with regulations and impact safety culture, it should be included more directly in the Statement of Policy.

Several commenters were concerned with the diversity among licensees and how the policy statement addresses this. Although this issue will be addressed in the third tier by the NRC program offices, the working group suggested that the policy statement should be clarified to state that, although the definition and traits apply to all, implementation of the policy statement will vary.

Several comments questioned whether the policy statement would apply to vendors and contractors. Based on other comments in response to the November 2009 FRN as well as comments from the NRC’s 2010 Regulatory Information Conference panel on safety culture, the working group recommended including vendors and contractors in the Statement of Policy, although comments did reflect a concern about implementation.

Resolution of public comments from the November 2009 FRN included adding language to the revised draft safety culture policy statement in the September 2010 FRN as follows:

- **Implementation Comments**

In response to the comments on the November 2009 FRN requesting clarification of the NRC’s plans to implement the Statement of Policy, the September 2010 FRN provided the following discussion:

Presuming the Commission approves the policy statement, the Commission will issue an SRM to provide direction to the staff regarding next steps. The NRC offices that are responsible for overseeing regulated activities will assess their inspection and oversight programs to determine whether (and if so, how) to revise their programs based on the Commission’s direction. The Commission is aware that there are many different settings in which the policy statement will be

implemented and that roll-out will be more complex in some settings than others. For example, the NRC's Reactor Oversight Process (ROP) already addresses safety culture in the inspection of nuclear power reactors. In addition, the power reactor community has ongoing programs and activities in place for assessing safety culture and implementing improvement strategies. This may not be the case with other categories of regulated entities, such as industrial radiography and medical use of isotopes. Variants such as these will be factored into the agency's approach and schedule for implementing the policy statement.

- **Security Comments**

Regarding the comments on the inclusion or deletion of the term "security" in the definition and traits of a positive safety culture, the September 2010 FRN provided the following discussion:

...the panelists at the February workshop aligned on a common definition of safety culture. That definition, however, differs from the draft definition proposed in the November 2009 FRN which defines safety culture as "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." The initial draft definition includes the terms "safety" and "security," underscoring the significance the Commission places on consideration of both within NRC's regulatory framework. In subsequent internal discussions and during the various outreach activities with stakeholders, the February workshop definition, which does not include the term "security", has been well received and thus, has been adopted in the revised draft [Statement of Policy]. The workshop definition is as follows: "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." Deletion of the term "security" was deliberate. The panelists believe that leaving it in the definition would cause unnecessary confusion, particularly for smaller regulated entities that do not have to consider the same security issues as a nuclear power plant or fuel reprocessing facility, for example. Their position is that security, like radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness, falls under an overarching definition of safety and should not be singled out. These views on removing the term "security" from the definition were also expressed by several members of a stakeholder panel during the Safety Culture Commission Briefing on March 30, 2010....

Likewise, the traits that are included in the revised draft SOP, while similar to those proposed by the NRC, do not include the term "security" wherever the term "safety" is used. In recognition of the importance the agency places on security in a post "9/11" environment, the staff developed a preamble to the traits which points out that while the term "security" is not expressly included in each of the traits, safety and security are the primary pillars of the NRC's regulatory mission.

- **Inclusion of the Traits in the Statement of Policy**

In response to the specific question in the November 2009 FRN, comments indicated substantial support for inclusion of the traits in the Statement of Policy in order to clarify the Commission's intent. The Statement of Policy includes the traits (i.e., high-level descriptions of areas important to a positive safety culture). Different views were expressed on whether to include the traits in the Statement of Policy. The staff carefully discussed and considered the pros and cons in reaching the current position.

The draft policy statement did not include the characteristics (now described as "traits") in the actual draft Statement of Policy. The staff initially developed the draft characteristics based on a variety of sources, including the 13 safety culture components used in the ROP, and the draft characteristics included more discussion and detail than the traits included in the proposed Statement of Policy. The basis for the staff's original decision to include the characteristics in another section of the draft policy statement rather than the draft Statement of Policy was threefold. First, it would keep the Statement of Policy brief and concise; second, it would maintain the Statement of Policy at a high level; and third, it would not invalidate the characteristics' standing to place them in the draft policy statement rather than the draft Statement of Policy. Although SECY-09-0075, "Safety Culture Policy Statement," dated May 18, 2009, included a differing professional opinion supporting inclusion of the traits in the draft Statement of Policy, the decision was made to locate them in another section of the draft policy statement. The November 2009 FRN specifically requested comments on whether the characteristics should be included in the Statement of Policy. Some comments indicated that they would prefer not to include the characteristics in the actual Statement of Policy or that they agreed with the original decision to include the characteristics in policy statement rather than the Statement of Policy itself. Several comments indicated that adding the characteristics to the Statement of Policy itself would help to clarify the Commission's expectations.

The stakeholders at the February 2010 workshop revised the characteristics (renaming them "traits") to provide a high-level description of the areas important to a positive safety culture. Therefore, the traits do not contain the level of detail that was included in the draft characteristics. Thus, even with inclusion of the traits, the Statement of Policy remains brief and concise, yet this approach also provides high-level detail that was not in the draft Statement of Policy. Including the traits in the Statement of Policy rather than as part of a larger policy statement visually supports their standing as part of the Commission's expectation that these are areas that should be considered as the regulated community develops its safety culture framework. Finally, as the Statement of Policy points out, the list of traits was not developed for inspection purposes, nor does it represent an all-inclusive list of areas important to a safety culture.

- **Policy Statement vs. Regulation/Rule Comments**

Because public comments reflected questions regarding the Commission's use of a policy statement rather than a regulation/rule, the September 2010 FRN provided the following clarification:

The Commission may use a policy statement to address matters relating to activities that are within NRC jurisdiction and are of particular interest and importance to the Commission. Policy statements help to guide the activities of the NRC staff and express the Commission's expectations. The NRC's Enforcement Policy, for example, describes the policy and procedures the agency follows in initiating and reviewing enforcement actions in response to violations of NRC requirements.

Policy statements are not regulations/rules and are not accorded the status of a regulation/rule within the meaning of the Administrative Procedure Act (P.L. 79-404), the primary goal of which is to ensure that agencies observe procedural due process (i.e., fairness), in conducting their regulatory and administrative affairs. For example, Agreement States that are responsible for overseeing materials licensees are not required to implement the elements of a policy statement because such statements, unlike NRC regulations, are not a matter of compatibility. Additionally, policy statements cannot be considered binding upon, or enforceable against, NRC or Agreement State licensees and certificate holders.

While the option to consider rulemaking exists, the NRC believes that, at this time, developing a policy statement is a more effective way to engage stakeholders.

- **Additional Recommendations Based on Public Comments**

Based on its evaluation of the public comments, the NRC staff made several additional recommendations. These recommendations were included in the revised draft Statement of Policy or were addressed elsewhere in the September 2010 FRN:

- In SRM-SECY-09-0075, "Safety Culture Policy Statement," dated October 16, 2009, the Commission directed the staff to consider incorporating vendors and suppliers of safety-related components in the safety culture policy statement. Although there is general support from stakeholders for doing so, some stakeholders have raised implementation concerns. These concerns, particularly in cases where such vendors and suppliers are outside of NRC jurisdiction, may involve a complicated path forward. Although the staff is aware of these concerns and will work with its constituents during implementation to resolve these concerns, it has indicated its support for including vendors and suppliers of safety-related components. Thus, the revised draft Statement of Policy indicates that it is applicable to vendors and suppliers of safety-related components.
- Several comments indicated that the Statement of Policy should include a discussion of complacency. Complacency can occur because of long-term success and repetition. Although this is already indirectly addressed in the traits (e.g., Effective Safety Communication and Personal Accountability are traits that prevent complacency), the staff recommended further discussion of complacency in the revised draft Statement of Policy. The NRC asked for comments on whether it is useful to add a discussion on this aspect of safety culture to the Statement of Policy.

September 2010 FRN: Evaluation of Public Comments on the Revised Draft Policy Statement

The NRC published the revised draft policy statement in the *Federal Register* on September 17, 2010, providing a 30-day public comment period ending on October 18, 2010, and soliciting comments on five specific questions. The agency received 24 responses within the 30-day comment period.

The staff largely used the same method to evaluate the comments, preparing a summary that organized the comments into themes or addressed a specific comment.

These themes and specific comments were discussed during two internal meetings on October 25 and 27, 2010. For each theme and comment, the working group made one of two recommendations: (1) no further action was needed; or (2) modification to the revised draft policy statement was appropriate. Many general comments were provided. Most of the public comments, however, fell into two general themes: (1) the Commission should acknowledge the differences between the various licensees, certificate holders, and others; and (2) the agency should provide additional guidance on implementation and include stakeholders in this process.

- Distinction between Licensees: Many individuals commented that the Statement of Policy should recognize the differences between licensees because there are profound differences between many of these organizations. Additionally, the Commission should give credit to those organizations that have already undertaken the development of a safety culture specific to their organization. The medical community, for example, has a patient-centered focus that has existing programs and procedures that have been developed specifically in the furtherance of their safety culture that the Commission should acknowledge during implementation. Further, each industry (e.g., new construction, radiography, fuel facilities) has distinct characteristics and behaviors unique to its industry that the Commission should recognize during implementation of the Statement of Policy. The working group recommended adding discussion in the policy statement acknowledging the difference between licensees; that some organizations have already spent significant time and resources in the development of programs and policies to support a positive safety culture. The Commission is aware of this and will take this information into consideration as the regulated community addresses the Statement of Policy.
- Implementation and Stakeholder Involvement: Many individuals requested more guidance on how the policy will be rolled out. Additionally, there were many requests for continued stakeholder involvement in developing the implementation plans and guidance. Stakeholders requested workshops during which the various program offices would work with their constituents, communicating the NRC's expectations and receiving feedback addressing implementation issues. The working group recommended addressing this request briefly in the proposed final policy statement.

The remaining public comments responded to specific questions addressing: (1) the issue of using a policy statement versus a regulation; (2) the definition of safety culture, including the

use of the term “security” in both the definition and traits. This was resolved by removing the term from the definition and traits but adding a discussion on the importance of security in the (3) the preamble to the traits; (4) whether the traits should be included in the actual Statement of Policy; (5) the question about whether complacency should be more directly addressed in the Statement of Policy; and (6) whether information from the Institute of Nuclear Power Operations (INPO) validation study should be considered.

- Policy Statement: The majority of comments addressing this issue noted that a policy statement was the appropriate regulatory approach for safety culture. One individual said that the policy should be risk-informed. Another said that the policy statement is not enforceable and therefore inadequate. The working group agreed to include a discussion of the difference between a policy and a regulation in the policy statement and to clarify its expectations during the implementation period (which the staff did in the September 2010 FRN).
- Definition: The majority of comments addressing this issue aligned on the definition of safety culture provided in the September 2010 FRN. A few individuals expressed a preference for the phrase “radiation safety culture” rather than “nuclear safety culture” because they felt it would apply to more of the regulated entities in the Agreement States. The working group agreed to retain “nuclear safety culture” in the definition because it reflects the agency’s mission.
- Traits Included in the Statement of Policy: The majority of comments addressing this issue stated that including the traits in the Statement of Policy clarified the Commission’s intent. Two individuals requested more guidance on how the traits will be applied, which the working group agreed is a question that will be addressed during implementation. The staff has included the traits in the proposed final Statement of Policy.
- Preamble to the Traits: The majority of comments stated that the preamble appropriately clarified the necessary balance between safety and security. One individual believed that the revised draft policy statement overemphasizes security and that it should also note other important areas. The staff has included the preamble in the proposed final Statement of Policy.
- Complacency: The majority of comments indicated that complacency should not be discussed in the Statement of Policy or in the traits. However, the staff believes that the concept of complacency should be considered in a positive safety culture and included it in the Statement of Policy under the trait, “Questioning Attitude.” “Questioning Attitude” is described in the proposed final Statement of Policy as a culture “in which individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.”
- INPO Validation Study: Several comments indicated that, regarding the INPO validation study, it was primarily applicable to power reactors. One comment noted that it would take more thought to understand how the INPO results apply to the medical community; while another noted that there was considerable overlap between the INPO results and the workshop traits. The INPO validation study supported “Questioning Attitude” as an important factor to consider in a positive safety culture. The staff considered this factor in light of statements the Commission has made over the past year, which includes the importance of a questioning attitude, as well as the staff’s desire to include the concept

of complacency in the Statement of Policy. In response, as noted in the previous bullet, the staff added an additional trait, "Questioning Attitude," to the list of traits developed at the February 2010 workshop.