

POLICY ISSUE NOTATION VOTE

January 5, 2011

SECY-11-0005

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: PROPOSED FINAL SAFETY CULTURE POLICY STATEMENT

PURPOSE:

To request Commission approval to publish the final safety culture policy statement in the *Federal Register*.

SUMMARY:

In response to Staff Requirements Memorandum (SRM)-COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture," dated February 25, 2008, and SRM-SECY-09-0075, "Safety Culture Policy Statement," dated October 16, 2009, the U.S. Nuclear Regulatory Commission (NRC) staff published a draft safety culture policy statement in the *Federal Register* in November 2009 for a 90-day public comment period, which was subsequently extended until March 1, 2010, in response to requests by several stakeholders. After evaluation of the public comments received and the staff's additional outreach efforts, including public workshops, public meetings and teleconferences, and participation in various industry forums, the staff published a revised draft safety culture policy statement in the *Federal Register* in September 2010 for a 30-day comment period. The many activities the staff engaged in, including consideration of the comments from the September 2010 *Federal Register* notice (FRN) and stakeholder input from an additional public meeting, informed the development of the final safety culture policy statement through a spectrum of views and provided the necessary foundation for a safety culture policy applicable to the entire nuclear industry. Additionally, the staff developed the Statement of Policy cognizant that individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing regulated materials, while the Commission, as the regulatory agency with an independent oversight role, reviews the performance of those individuals and organizations through its inspection and assessment processes. The staff recommends that the Commission approve the final safety culture policy statement ([Enclosure 1](#)).

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BACKGROUND:

In February 2008, the Commission issued SRM-COMGBJ-08-0001, which directed the NRC staff to expand the Commission's policy on safety culture to address the unique aspects of security and to ensure that the resulting policy is applicable to all licensees and certificate holders. The Commission also directed the staff to answer several additional questions, including: (1) whether safety culture as applied to reactors needed to be strengthened; (2) how to increase attention to safety culture in the materials area; (3) how stakeholder involvement can most effectively be used to address safety culture for all NRC and Agreement State licensees and certificate holders, including any unique aspects of security; and (4) whether publishing the NRC's expectations for safety culture would be best accomplished in one safety and security culture statement or in two separate statements while still considering the safety and security interface.

To address the Commission's direction, the staff reviewed domestic and international documents related to safety culture and considered NRC experience and lessons learned. Additionally, the staff sought insights and feedback from external stakeholders by providing information in a variety of forums, such as several stakeholder organization meetings, newsletters, and teleconferences, and by publishing questions developed to address the Commission direction in the February 9, 2009, FRN, "Safety Culture Policy Statement: Public Meeting and Request for Public Comments." Additionally, the staff developed draft characteristics of a positive safety culture and presented them at a February 2009 workshop, "Development of a Policy Statement(s) on Safety and Security Culture," which involved participation from a broad range of stakeholders, including representation from the Agreement States. Mindful of the increased attention to the important role of security, the staff also sought input from the workshop participants on whether there should be a single safety culture policy statement or two policy statements addressing safety and security independently while considering the interface of both. Before providing its recommendations to the Commission, the staff developed a draft definition of safety culture that modified the definition developed by the International Atomic Energy Agency's (IAEA) advisory group, the International Nuclear Safety Group, to make it applicable to all NRC-regulated activities and to address security.

Based on its review and stakeholder feedback, in SECY-09-0075, "Safety Culture Policy Statement," dated May 18, 2009, the staff provided for Commission approval and publication in the *Federal Register* a single draft safety culture policy statement. The draft safety culture policy statement acknowledged the significance of both safety and security, and the interface of both. Additionally, in response to the Commission's questions, the staff: (1) concluded that the NRC's oversight of safety culture as applied to reactors has been strengthened, is effective, and continues to be refined in accordance with the existing Reactor Oversight Process (ROP) self-assessment process; (2) described actions taken and planned for increasing attention to safety culture in the materials area; and (3) described actions taken and planned for most effectively using stakeholder involvement to address safety culture, including any unique aspects of security, for all NRC and Agreement State licensees and certificate holders.

In SRM-SECY-09-0075, the Commission directed the staff to: (1) publish the draft safety culture policy statement for no fewer than 90 days; (2) continue to engage a broad range of stakeholders, including the Agreement States and other organizations with an interest in nuclear safety, to ensure that the proposed final policy statement presented to the Commission considers a broad spectrum of views and provides the necessary foundation for safety culture

applicable to the entire nuclear industry; (3) make the necessary adjustments to encompass security within the statement; (4) seek opportunities to comport NRC terminology, where possible, with that of existing standards and references maintained by entities regulated by the NRC; and (5) consider incorporating suppliers and vendors of safety-related components in the safety culture policy statement.

DISCUSSION:

Outreach and Efforts to Develop Common Terminology

As part of its effort to actively engage stakeholders, including the Agreement States, the NRC held a second safety culture workshop February 2–4, 2010, that provided a venue for interested parties to comment on the draft safety culture policy statement. The additional goal of this 3-day workshop was for panelists representing a broad range of stakeholders to reach alignment, using common terminology, on a definition of safety culture and a high-level set of characteristics (renamed “traits” during the workshop) that describe areas important to a positive safety culture. The workshop panelists, with the assistance of the other workshop attendees, developed both ([Enclosure 2](#)).

From the February 2010 workshop through the close of the second public comment period on the revised draft safety culture policy statement on October 18, 2010, and into November 2010, the staff participated on panels and made presentations at various industry and organization forums. The staff conducted these activities to provide information to stakeholders about the development of the safety culture policy statement, to obtain additional input, and to ascertain whether the draft definition and traits developed at the February 2010 workshop accurately reflect a broad range of stakeholders’ views. In response to Commission direction in SRM-SECY-09-0075, the staff focused significant attention on meetings involving the Organization of Agreement States and NRC materials licensees ([Enclosure 3](#)).

On July 15, 2010, the NRC held a public teleconference with the panelists who participated in the February 2010 3-day workshop to discuss the status of outreach activities associated with the development of the safety culture policy statement. At that meeting, the panelists reiterated their support for the definition and traits developed at the February 2010 workshop as a result of their outreach with their industry colleagues. This position aligns with the comments that staff received at the various outreach activities. On September 16, 2010, the staff held an additional teleconference to provide information on the initial results of a validation study conducted by the Institute for Nuclear Power Operations (INPO). The study was conducted, in part, to see whether and to what extent the factors that came out of INPO’s safety culture survey supported the traits identified in the February 2010 workshop. The INPO factors do support the traits ([Enclosure 4](#)).

Based on its review and stakeholder feedback, the staff published the revised draft safety culture policy statement in the *Federal Register* on September 17, 2010, for a 30-day public comment period. The NRC held a public meeting on September 28, 2010, in the Las Vegas Hearing Facility, Las Vegas, NV, which was simultaneously broadcast in the Commission Hearing Room in Rockville, MD, and over the internet via web streaming in order to allow remote participation. The goals of the September FRN and meeting were to provide additional opportunities for stakeholders to comment on the revised draft policy statement, including the revised definition and traits, and to discuss the information gathered from the outreach activities

that had occurred since the February 2010 workshop. Additionally, a representative from INPO presented information on the validation study that INPO conducted as part of its efforts to help establish a technical basis for the identification and definition of areas important to safety culture. A member of the Office of Nuclear Regulatory Research also presented findings related to the oversight of the INPO study.

Development of the Proposed Final Policy Statement

The proposed final Statement of Policy is based on the staff's implementation of the Commission's direction in SRM-COMGBJ-08-0001 and SRM-SECY-09-0075; the staff's evaluation of the public comments received on the November 2009 and the September 2010 FRNs; information exchanged during the public meetings held in February 2009, and February, July, and September 2010; the views expressed by stakeholders during the Commission briefing in March 2010; and informal dialogue with various stakeholders during the staff's additional outreach efforts from the February 2010 workshop until November 2010. In addition, the staff considered all comments received after the public comment period ended on October 18, 2010 ([Enclosure 5](#)).

The following paragraphs provide the specific information that was used in the development of the proposed final policy statement, including the changes that were made to the November 2009 draft policy statement:

1. The Statement of Policy adopts the February 2010 workshop definition and traits of a positive safety culture; thus, neither the definition nor the traits include the term "security." The involved NRC program offices expressed varying views on the removal of the term "security" from the definition and traits. After internal discussion, alignment was reached on adopting the workshop definition and traits because the views in favor of removing this term resonated with most of the staff and were strongly supported by stakeholders. Stakeholder support was based on the view that an overarching safety culture addresses both safety and security and does not need to single out security in the definition any more than it would single out other essential programs, such as radiation protection or emergency preparedness. To ensure that security is appropriately encompassed within the Statement of Policy, the staff added a preamble to the traits in the Statement of Policy and retained the robust discussion of security contained in the November 2009 FRN, including the importance of considering the interface of safety and security in the proposed final policy statement. The staff discussed the removal of the term "security" during the Commission briefing in March 2010.
2. The Statement of Policy includes the traits (i.e., high-level descriptions of areas important to a positive safety culture). The staff expressed different views on whether or not to include the traits in the Statement of Policy and carefully considered the pros and cons of doing so in reaching its recommendation.

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 included more detail than the traits included in the proposed final Statement of Policy. The basis for the staff's original decision to include the

characteristics in another section of the draft policy statement but not in the actual draft Statement of Policy was threefold. First, it would keep the draft Statement of Policy brief and concise; second, it would maintain the draft Statement of Policy at a high level; and third, it would not invalidate the characteristics' standing as part of the draft policy statement to place them in another section of the policy statement. Although SECY-09-0075 included a differing professional opinion supporting inclusion of the characteristics in the draft Statement of Policy, the decision was made at that time 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 itself. Some commenters indicated that they would prefer not to include the characteristics in the actual Statement of Policy or that they agree with the original decision to include the characteristics in their own section of the policy statement. Several comments indicated that adding the characteristics to the Statement of Policy itself would help to clarify the Commission's expectations.

As part of the effort to develop common terminology, the stakeholders at the February 2010 workshop replaced the term "characteristics" with the term "traits." The traits developed at the February 2010 workshop provide a high-level description of the areas important to a positive safety culture. As such, the traits do not have 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 and, at the same time, 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 in the larger policy statement visually supports their standing as part of the Commission's expectation that these are the areas that the regulated community should consider as it addresses a 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 positive safety culture.

3. Implementation is not directly addressed in the policy statement which sets forth the overarching principles of a positive safety culture. If the Commission approves the Statement of Policy and provides direction to the staff, the program offices responsible for licensing and oversight of the affected entities will work with their constituents, who bear the primary responsibility for safely handling and securing regulated materials, to address next steps and specific implementation issues ([Enclosure 6](#)).
4. The Statement of Policy recognizes the diversity of the various organizations that are included and the fact that some organizations have already spent significant time and resources in the development of programs and policies to support a positive safety culture. The Statement of Policy notes that the Commission is aware of this and will take this information into consideration as the regulated community addresses the Statement of Policy.
5. Because there were questions about the Commission's use of a policy statement rather than a regulation to achieve its goals, the staff provided a brief discussion of these

differences in the September 2010 FRN, noting that policy statements, though not enforceable, can be used to express the Commission's expectations and guide the activities of the NRC staff and the regulated community. The September 2010 FRN concluded this discussion by noting that, although the option to consider rulemaking exists, the Commission believes at this time that developing a policy statement is a more effective way to engage the broad scope of entities NRC regulates.

6. The Statement of Policy incorporates vendors and suppliers of safety-related components. Some stakeholders raised concerns about how implementation would be carried out, particularly in cases where vendors and suppliers are located outside NRC jurisdiction. Additionally, they indicated that including these entities might have a negative impact on licensees' ability to work with some vendors or suppliers. However, there was significant support for the position that vendors and suppliers of safety-related components should develop and maintain a positive safety culture in their organizations for the same reasons as other NRC-regulated entities.
7. While the majority of comments on the September 2010 FRN indicated that neither the Statement of Policy nor the traits should discuss complacency, the staff's evaluation of the comments from both the November 2009 and September 2010 FRNs led the staff to conclude that complacency should be considered in a positive safety culture. To accomplish this, the staff added the trait, "Questioning Attitude," to the traits included in the Statement of Policy.

Internal and External Safety Culture Interface

In response to Commission direction in 2008 to identify potential improvements of the NRC's internal safety culture, the staff formed the Internal Safety Culture Task Force from October 2008 to May 2009, which developed a set of recommendations for continuous improvement, provided in SECY-09-0068, "Report of the Task Force on Internal Safety Culture," dated April 27, 2009. The staff is implementing the task force recommendations, as noted in SECY-10-0009, "Internal Safety Culture Update," dated January 26, 2010. Separately, the NRC's Office of the Inspector General conducts an independent Safety Culture and Climate Survey every three years, the last one in May 2009. The NRC is taking a combination of agency-wide and office-specific actions to address the areas for improvement identified by the staff's analysis of the results of the survey.

Once the safety culture policy statement is finalized, the agency will evaluate its internal safety culture activities and initiatives to ensure consistency with the underlying tenets expressed in the Statement of Policy. In order to ensure effective coordination, the staff supporting both internal and external safety culture activities will continue to work together closely and share information, experiences, and resources on an ongoing basis.

COMMITMENTS:

The staff will continue to seek ways to engage a broad range of stakeholders, including the Agreement States and other organizations with an interest in nuclear safety, in the roll-out phase of the policy statement.

The Office of Enforcement (OE) will continue to work with the program offices after the Policy Statement's expected issuance, supporting roll-out, communications, and training efforts, as appropriate.

RECOMMENDATIONS:

The staff recommends that the Commission approve the proposed final safety culture policy statement for publication in the *Federal Register*.

RESOURCES:

Most of the offices have not specifically budgeted for safety culture roll-out activities in 2011 and 2012; therefore, if the Commission directs the staff to move forward at this time, these offices will have to go through the planning, budgeting, and performance management process. OE has budgeted two full-time equivalents (FTE) for 2011 and 2012 for external safety culture activities. The Office of Federal and State Materials and Environmental Management Programs (FSME) anticipates that 0.5 FTE (0.2 FTE in FSME, 0.1 in Region I, 0.1 in Region III, and 0.1 in Region IV) would be required in the byproduct materials program for the commitments described in this paper in 2011 and 2012. The Office of New Reactors estimates that it would need up to 1.5 FTE to evaluate possible revisions to existing guidance for the construction oversight process and to develop implementation review guidance for new reactor vendors and suppliers. The Office of Nuclear Security Incident Response plans to ask for 0.3 FTE for implementation in 2013. The Office of Nuclear Reactor Regulation does not anticipate the need for additional FTE for implementation.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

/RA Michael F. Weber for/

R. W. Borchardt
Executive Director
for Operations

Enclosures:

1. NRC Final Safety Culture Policy Statement
2. Definition and Traits of a Positive Safety Culture
3. Stakeholder Outreach Activities
4. NEI/Institute for Nuclear Power Operations Safety Culture Construct Validation Study
5. Public Comments
6. Implementation

NUCLEAR REGULATORY COMMISSION

[NRC-2010-0282]

Final Safety Culture Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Final Safety Culture Policy Statement.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is issuing this Statement of Policy to set forth its expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. The Commission defines Nuclear Safety Culture as *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.* This policy statement applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority.

DATES: This policy statement becomes effective upon publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Roy P. Zimmerman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; 301-415-2741.

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

A. Previous Policy Statements and Events Involving Safety Culture

The NRC has long recognized the importance of a safety-first focus in nuclear work environments for public health and safety. The Commission's emphasis on a safety-first focus is reflected in two previously published NRC policy statements. The 1989 "Policy Statement on the Conduct of Nuclear Power Plant Operations" (54 FR 3424; January 24, 1989), applies to all individuals engaged in activities that affect the safety of nuclear power plants, and provides the Commission's expectations of utility management and licensed operators with respect to the conduct of operations. The 1996 "Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation" (61 FR 24336; May 14, 1996), applies to the regulated activities of all NRC licensees and their contractors and subcontractors, and provides the Commission's expectations that licensees and other employers subject to NRC authority establish and maintain safety-conscious work environments in which employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation. This Safety Culture Statement of Policy, in conjunction with the previous policy statements, is intended to emphasize the importance the NRC places on the development and maintenance of a positive safety culture for all regulated activities.

The accident at the Chernobyl nuclear power plant in 1986 brought attention to the importance of safety culture and the impact that weaknesses in safety culture can have on safety performance. Since then, the importance of a positive safety culture has been

demonstrated by a number of significant, high-visibility events worldwide. In the United States, incidents involving the civilian uses of radioactive materials have not been confined to a particular type of licensee or certificate holder as they have occurred at nuclear power plants and fuel cycle facilities and during medical and industrial activities involving regulated materials. Assessments of these incidents revealed that weaknesses in the regulated entities' safety cultures were an underlying cause of the incidents or increased the severity of the incidents. The causes of these incidents included, for example, inadequate management oversight of process changes, perceived production pressures, lack of a questioning attitude, and poor communications. One such incident indicated the need for additional NRC efforts to evaluate whether the agency should increase its attention to reactor licensees' safety cultures. This resulted in important changes to the NRC's Reactor Oversight Process (ROP). Commission paper SECY-06-0122, dated May 24, 2006, (ML061320282) describes the NRC's safety culture activities at that time and the outcomes of those activities.

Following the terrorist attacks of September 11, 2001, the Commission issued orders enhancing security at facilities whose operations, if attacked, could have an impact on public health and safety. During the early years of implementation of these security enhancements, several violations of the Commission's security requirements were identified in which the licensee's failure to cultivate a positive safety culture impacted the effectiveness of the licensee's security program. The most visible of these involved security officers sleeping in a "ready room" while on shift at a nuclear power plant. Most of the weaknesses involved inadequate management oversight of security, lack of a questioning attitude within the security organization, complacency, barriers to raising concerns about security issues, and inadequate training of security personnel.

B. Commission Direction

In February 2008, the Commission issued Staff Requirements Memorandum (SRM), SRM-COMGBJ-08-0001 (ML080560476), directing the NRC staff to expand the Commission's policy on safety culture to address the unique aspects of security and to ensure the resulting policy is applicable to all licensees and certificate holders. The Commission directed the staff to answer several additional questions including: (1) whether safety culture as applied to reactors needed to be strengthened; (2) how to increase attention to safety culture in the materials area; (3) how stakeholder involvement can most effectively be used to address safety culture for all NRC and Agreement State licensees and certificate holders, including any unique aspects of security; and (4) whether publishing the NRC's expectations for safety culture and for security culture would be best accomplished in one safety/security culture statement or in two separate statements while still considering the safety and security interfaces.

In response to Commission direction, the NRC staff reviewed domestic and international safety-culture-related documents and considered NRC lessons learned. Additionally, the staff sought insights and feedback from external stakeholders. This was accomplished by providing information in a variety of forums, such as stakeholder organization meetings, newsletters, and teleconferences, and by publishing questions developed to address Commission direction in the February 9, 2009, *Federal Register* notice (FRN) entitled "Safety Culture Policy Statement: Public Meeting and Request for Public Comments." (ML090260709)

In February, 2009, the NRC held a public workshop on the "Development of a Policy Statement on Safety Culture and Security Culture" in which a broad range of stakeholders participated, including representatives from the Agreement States (Meeting Summary: ML090930572). The staff developed draft characteristics (subsequently referred to as "traits") of a positive safety culture and presented them at the workshop. Mindful of the increased

attention to the important role of security, the staff also sought input from the workshop participants on whether there should be a single safety culture policy statement or two policy statements addressing safety and security independently while considering the interface of both. Before providing its recommendations to the Commission, the staff developed a draft definition of safety culture in which it modified a definition from the International Atomic Energy Agency's advisory group, the International Nuclear Safety Group, to make it applicable to all NRC-regulated activities and to address security.

Based on its review and stakeholder feedback, in SECY-09-0075, "Safety Culture Policy Statement," dated May 16, 2009 (ML091130068), the NRC staff provided a single draft safety culture policy statement for Commission approval. The draft policy statement acknowledged the importance of safety and security, and the interface of both, within an overarching culture of safety. Additionally, in response to the Commission's questions, the staff: (1) concluded that the NRC's oversight of safety culture as applied to reactors has been strengthened, is effective, and continues to be refined in accordance with the existing ROP self-assessment process; (2) described actions taken and planned for increasing attention to safety culture in the materials area; and (3) described actions taken and planned for most effectively obtaining stakeholder involvement to address safety culture, including any unique aspects of security, for all NRC and Agreement State licensees and certificate holders.

In SRM-SECY-09-0075 (ML092920099), the Commission directed the staff to: (1) publish the draft safety culture policy statement for no fewer than 90 days; (2) continue to engage a broad range of stakeholders, including the Agreement States and other organizations with an interest in nuclear safety, to ensure the final policy statement presented to the Commission reflects a broad spectrum of views and provides the necessary foundation for safety culture applicable to the entire nuclear industry; (3) make the necessary adjustments to

encompass security within the statement; (4) seek opportunities to comport NRC terminology, where possible, with that of existing standards and references maintained by those that the NRC regulates; and (5) consider incorporating suppliers and vendors of safety-related components in the safety culture policy statement.

C. Development of the Final Policy Statement

On February 2-4, 2010, the NRC held a second safety culture workshop to provide a venue for interested parties to comment on the draft safety culture policy statement. The additional goal of the workshop was for panelists representing a broad range of stakeholders to reach alignment, using common terminology, on a definition of safety culture and a high-level set of traits (previously referred to as “characteristics”) that describe areas important to a positive safety culture. The workshop panelists represented a wide range of stakeholders regulated by the NRC and/or the Agreement states including medical, industrial, and fuel cycle materials users, and nuclear power reactor licensees, as well as the Nuclear Energy Institute, the Institute of Nuclear Power Operations (INPO), and members of the public. The workshop panelists reached alignment with input from the other meeting attendees on a definition of safety culture and a high-level set of traits describing areas important to a positive safety culture.

Following the February 2010 workshop, the NRC staff evaluated the public comments that were submitted in response to the November 2009 FRN. Additionally, the staff participated on panels and made presentations at various industry forums in order to provide information to stakeholders about the development of the safety culture policy statement and/or to obtain additional input and to ascertain whether the definition and traits developed at the workshop accurately reflect a broad range of stakeholders’ views. These outreach activities included, for example, participation in a Special Joint Session on Safety Culture at the Health Physics Society Annual Meeting, and presentations on the development of the safety culture policy

statement at the Annual Fuel Cycle Information Exchange, the Conference of Radiation Control Program Directors' Annual National Conference on Radiation Control, the Institute of Nuclear Materials Management's Annual Meeting, the Second NRC Workshop on Vendor Oversight for New Reactors, and the Organization of Agreement States Annual Meeting. In response to Commission direction in SRM-SECY-09-00075, the staff focused attention on attending meetings involving the Organization of Agreement States and other materials licensees.

In July 2010, the NRC held a public teleconference with the panelists who participated in the February 2010 workshop to discuss the status of outreach activities associated with the development of the policy statement. At the July meeting, the panelists reiterated their support for the definition and traits developed at the February 2010 workshop as a result of their outreach with their industry colleagues. This position aligns with the comments the staff received during the various outreach activities. In September 2010, the staff held an additional teleconference to provide information on the initial results of a validation study conducted by INPO, which was conducted, in part, to see whether and to what extent the factors that came out of INPO's safety culture survey support the February 2010 workshop traits. The factors support the traits developed at the workshop.

Based on its review and stakeholder feedback, the staff published the revised draft safety culture policy statement (ML102500563) on September 17, 2010, for a 30-day public comment period. Because public comments reflected some misunderstanding regarding the Commission's use of a policy statement rather than a regulation or rule, the September FRN provided clarification, pointing out that 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 can express the Commission's expectations of others; however, they are not regulations or

rules and are not accorded the status of a regulation or rule within the meaning of the Administrative Procedure Act. The Agreement States, which are responsible for overseeing their materials licensees, cannot be 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.

This Statement of Policy has been developed to engage individuals and organizations performing regulated activities involving nuclear materials and share the Commission's expectations regarding the development and maintenance of a positive safety culture.

The NRC held a public meeting in September 2010, in the Las Vegas Hearing Facility, Las Vegas, Nevada, which was simultaneously broadcast in the Commission Hearing Room, Rockville, Maryland, and over the internet via web streaming in order to allow remote participation. The goals of the September FRN and meeting were to provide additional opportunities for stakeholders to comment on the revised draft policy statement, including the definition and traits developed at the February 2010 workshop, and to discuss the information gathered from the outreach activities that had occurred since the February 2010 workshop. Additionally, a representative from INPO presented information on the validation study INPO conducted as part of INPO's efforts to help establish a technical basis for the identification and definition of areas important to safety culture. A member of the Office of Nuclear Regulatory Research also presented findings related to the oversight of the INPO study.

II. Public Comments

The November 2009 FRN and the September 2010 FRN generated 76 comments from affected stakeholders and members of the public. The staff's evaluation concluded that many of the comments were statements of agreement on the information included in the draft and

revised safety culture policy statements and did not require further action. A few of the commenters raised issues that the staff considered during the development of the policy statement, but ultimately concluded that the issues were either not applicable to the policy statement, for example, that “by virtue of its all encompassing applicability, the policy must be taken as a strategic utterance;” or either misunderstood or disregarded the concept of a policy statement in this application, for example, that a policy statement is “largely inadequate for purposes of establishing broad-reaching performance standards.” The remaining comments informed the NRC staff’s development of the final policy statement. These were grouped into the following themes:

1. The NRC should adopt the definition and traits developed during the February 2010 workshop. This theme encompassed additional comments indicating that retaining the term “security” in the definition and traits of a positive safety culture may be confusing to many licensees, particularly materials licensees.
2. The traits from the February workshop should be included in the Statement of Policy in order to provide additional clarity as to its intent.
3. More guidance is needed on the NRC’s expectations as to how the policy statement will be implemented. This encompassed the additional theme that stakeholders would like to be actively involved in the process of developing this guidance and that the continued use of workshops with the various licensees would be helpful.
4. A discussion should be included in the policy statement that addresses the diversity of the regulated community. Additionally, the Commission should acknowledge the efforts already underway as the regulated community addresses the Statement of Policy.
5. How does the NRC plan to “enforce” adherence to the policy statement?
6. Comments on the draft policy statement were generally supportive of including vendors and suppliers of safety-related components in the Statement of Policy, but reflected

concern about jurisdictional issues, as well as the impact that including vendors and suppliers in the Statement of Policy might have on licensees' ability to work with these entities.

7. During its evaluation of the public comments on the draft safety culture policy statement, the staff felt that a trait addressing complacency should be added to the February 2010 workshop traits. Several months later, the results of an INPO study indicated that the trait "Questioning Attitude" had strong support with operating nuclear plant personnel. This trait resonated with the staff as an approach for addressing complacency for all regulated activities. At the September 2010 public meeting, as part of a larger presentation providing the results of the INPO validation study, the staff added a question about whether to include this trait. Additionally, the September 2010 FRN specifically asked whether complacency should be addressed in the Statement of Policy. Although the responses to this question varied, the staff concluded it should be considered in a positive safety culture and included the concept of complacency in the Statement of Policy under the trait, "Questioning Attitude." "Questioning Attitude" is described in the 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."

This policy statement is being issued after careful consideration of the staff's evaluation of the public comments received on the November 2009 and September 2010 FRNs; the public meetings held in February 2009, and February, July, and September 2010; the views expressed by stakeholders during the Commission briefing in March 2010; and the informal dialogue with the various stakeholders during the staff's additional outreach efforts from the February 2010 workshop until the second public comment period ended on October 18, 2010.

The following paragraphs provide the specific information that was used in the development of the final policy statement, including the changes that were made to the November 2009 FRN:

1. The Statement of Policy adopts the 2010 February workshop definition and traits of a positive safety culture. The term “security” is not included in either the definition or the traits. The Commission agrees that an overarching safety culture addresses both safety and security and does not need to single out “security” in the definition. However, to ensure that security is appropriately encompassed within the Statement of Policy, a preamble to the traits has been added and the robust discussion of security, including the importance of considering the interface of safety and security that was included in the draft Statement of Policy, has been retained in the Statement of Policy.
2. The Commission agrees that including the traits in the Statement of Policy will serve to clarify the intent of the policy. The draft policy statement published in the November 2009 FRN did not include the characteristics (now described as “traits”) in the actual Statement of Policy. The staff developed the draft characteristics based on a variety of sources, including the 13 safety culture components used in the ROP. The characteristics included significantly more detail than the traits included in the Statement of Policy. The staff’s basis for the original decision to include the characteristics in another section of the draft policy statement but not in the actual draft Statement of Policy was three-fold: 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 as part of the draft policy statement to place them in another section of the draft policy statement. The November 6, 2009 FRN that contained the draft policy statement specifically requested comments on whether the characteristics should be included in the Statement of Policy. Some commenters

indicated that they would prefer not to include the traits in the actual Statement of Policy or that they agree with the original decision to include the traits in their own section of the policy statement. However, several commenters indicated that adding the traits to the Statement of Policy itself would help to clarify the Commission's expectations.

Because the traits in question were developed by the stakeholders at the February 2010 workshop to provide a high-level description of the areas important to a positive safety culture, the level of detail that was included in the draft characteristics is not present in the traits. Thus, even with inclusion of the traits, the Statement of Policy remains brief and concise; in addition, this approach 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 the policy statement visually supports their standing as part of the Commission's expectation that these are areas that members of the regulated community should consider as they develop a positive safety culture. 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 positive safety culture.

3. Implementation is not directly addressed in this policy statement, which sets forth the overarching principles of a positive safety culture. This discussion is not included because the Commission is aware of the diversity of its regulated community (which includes, for example, industrial radiography services; hospitals, clinics and individual practitioners involved in medical uses of radioactive materials; research and test reactors; large-scale fuel fabrication facilities; as well as operating nuclear power plants and the construction of new facilities where operations will involve radioactive materials with the potential to affect public health and safety and the common defense and security) and recognizes that implementation will be more complex in some settings than others. The NRC program offices responsible for licensing and oversight of the affected

entities intend to work with their constituents, who bear the primary responsibility for safely handling and securing regulated materials, to address the next steps and specific implementation issues. Nevertheless, before implementation issues are addressed, the regulated community can begin assessing their activities to identify areas for enhancement. For example, industry representatives could begin to identify tacit organizational and personal goals that, at times, may compete with a safety-first focus and develop strategies for adjusting those goals. Some monetary incentive or other rewards programs could work against making a safe decision. Current training programs may not address safety culture and its traits or how those traits apply to day-to-day work activities. Identification of both strengths and weaknesses related to safety culture in the regulated community will be helpful in understanding implementation strategies.

4. The final Statement of Policy includes a statement that the Commission recognizes the diversity of the various organizations that are included in the Statement of Policy and the fact 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 will take these efforts into consideration as the regulated community addresses the Statement of Policy.
5. Because there seemed to be some questions about the Commission's use of a policy statement rather than a regulation, the staff provided a brief discussion of the differences in the September 17, 2010 FRN, pointing out that policy statements, while not enforceable, guide the activities of the NRC staff and express the Commission's expectations. The Commission reiterates the conclusion of the discussion provided in the September FRN that while the option to consider rulemaking exists, the Commission

believes at this time, that developing a policy statement is a more effective way to engage stakeholders.

6. Vendors and suppliers of safety-related components have been included in this Statement of Policy. A few stakeholders have raised concerns about how implementation would be carried out, particularly in cases where vendors and suppliers are located outside of NRC jurisdiction. However, the Commission believes that vendors and suppliers of safety-related components should develop and maintain a positive safety culture in their organizations for the same reasons that other NRC-regulated entities should do so.
7. The final Statement of Policy adds the trait “Questioning Attitude” to the traits developed at the February 2010 workshop as an appropriate vehicle for addressing complacency.

III. Statement of Policy

The purpose of this Statement of Policy is to set forth the Commission’s expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The Commission encourages the Agreement States and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy, within their regulated communities. The NRC will include appropriate means to monitor safety culture in its oversight programs and internal management processes.

The Commission defines Nuclear Safety Culture as *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*. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. The Commission, as the regulatory agency with an independent oversight role, reviews the performance of those individuals and organizations through its inspection and assessment processes, including their performance as it relates to areas important to safety culture.

Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort vs. safety. It should be noted that although the term “security” is not expressly included in the following traits, safety and security are the primary pillars of the NRC’s regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The following are traits of a positive safety culture:

- (1) Leadership Safety Values and Actions - Leaders demonstrate a commitment to safety in their decisions and behaviors;
- (2) Problem Identification and Resolution - Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
- (3) Personal Accountability - All individuals take personal responsibility for safety;
- (4) Work Processes - The process of planning and controlling work activities is implemented so that safety is maintained;
- (5) Continuous Learning - Opportunities to learn about ways to ensure safety are sought out and implemented;
- (6) Environment for Raising Concerns - A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
- (7) Effective Safety Communication - Communications maintain a focus on safety;
- (8) Respectful Work Environment - Trust and respect permeate the organization; and
- (9) Questioning Attitude - Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

There may be traits not included in this Statement of Policy that are also important in a positive safety culture. It should also be noted that these traits are not necessarily inspectable and were not developed for that purpose.

The 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. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent

significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy.

Dated at Rockville, Maryland this ___ day of _____

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Definition and Traits of a Positive Safety Culture

Summary

The U.S. Nuclear Regulatory Commission's (NRC's) definition of safety culture and the identification of traits that describe a positive safety culture have evolved since the development of the draft safety culture policy statement published on November 6, 2009, in the *Federal Register*. Participants in the February 2010 workshop modified the original definition and characteristics, which were renamed "traits." Based on ongoing outreach activities and staff discussions, the staff modified the traits developed at the workshop to clarify them; however, the staff did not make any substantive changes. The staff published the definition and traits resulting from the workshop in the *Federal Register* on September 17, 2010, for a 30-day public comment period (although the staff considered comments received after October 18, 2010). The *Federal Register* notice (FRN) also contained the revised draft Statement of Policy.

November 2009 *Federal Register* Notice

The definition of safety culture in the November 2009 draft policy statement is based on the definition of safety culture put forward by the International Nuclear Safety Group (an advisory group of the International Atomic Energy Agency). The staff modified that definition to make it applicable to all NRC-regulated activities and to address security. The staff developed safety culture characteristics (i.e., high-level descriptions or attributes that contribute to a positive safety culture) based on a variety of sources, including the 13 safety culture components used in the Reactor Oversight Process. Additionally, the characteristics explicitly communicated the central role of security considerations and were intended to be generically applicable to the wide range of entities and activities the NRC regulates. Enclosure 7 of SECY-09-0075, "Safety Culture Policy Statement," dated May 18, 2009, provides an overview of the development of the draft safety culture characteristics. The draft safety culture policy statement provided the following definition of safety culture:

The NRC defines safety culture as that assembly of characteristics, attitudes, and behaviors in organizations and individuals that establishes that, as an overriding priority, nuclear safety and security issues receive the attention warranted by their significance.

The draft statement identified the characteristics of a positive safety culture as summarized below:

- Problem Identification and Evaluation—The organization ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- Work Practices—Personnel demonstrate ownership for nuclear safety and security in their day-to-day activities.
- Work Planning and Control—Processes for planning and controlling work activities are implemented such that safety and security are maintained.

- Continuous Learning Environment—The organization maintains a continuous learning environment in which opportunities to improve safety and security are sought out and implemented.
- Licensee Decision-making—The organization’s decisions ensure that safety and security are maintained.
- Safety Conscious Work Environment—The organization maintains a safety conscious work environment in which personnel feel free to raise safety and security concerns without fear of retaliation.
- Accountability—Roles, responsibilities, and authorities for safety and security are clearly defined and reinforced.
- Resources—The organization ensures that the personnel, equipment, tools, procedures, and other resources needed to ensure safety and security are available.

February 2010 Workshop

Participants in the 3-day safety culture workshop held in February 2010 revised the definition of safety culture (<http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>). The 16 panelists who represented medical, industrial, and fuel cycle materials users, operating power plant licensees, the Nuclear Energy Institute, the Institute of Nuclear Power Operations, and members of the public, reached alignment on a definition with broad applicability. The workshop panelists also agreed on eight traits (originally called “characteristics”) that describe a positive safety culture. Although many of these traits were similar to the original list of characteristics the staff provided in the 2009 FRN, there were some differences. The workshop participants developed the following definition of safety culture:

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.

The participants aligned on the following traits:

- 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.
- Personal Responsibilities and Attitudes—Everyone is personally responsible for nuclear safety.
- Processes and Procedures—Processes for planning and controlling work activities are implemented such that safety is maintained.
- Continuous Learning—Organizational learning is embraced.

- Leadership Safety Behaviors—Leaders demonstrate commitment to safety.
- Encouraging Report of Problems—The organization maintains a safety conscious work environment in which personnel feel free to raise concerns without fear of retaliation.
- Effective Safety Communication—Effective communication is essential to maintain focus on safety.
- Respectful Work Environment—Trust and respect permeate the organization.

September 2010 *Federal Register* Notice

Following the February 2010 workshop, the staff evaluated the public comments received in response to the November 2009 FRN. Additionally, the staff participated on panels and made presentations at various industry forums in order to provide information to stakeholders about the development of the safety culture policy statement, obtain additional input, and ascertain whether the definition and traits developed at the February 2010 workshop accurately reflected the views of a broad range of stakeholders. The definition developed at the workshop was widely endorsed at industry forums and in the public comments. The NRC staff revised the workshop traits to make them clearer but made no substantive changes. Additionally, the staff added a preamble to the traits explaining what a trait is and noted that although the term “security” is not expressly included in the traits, consideration of both safety and security issues commensurate with their significance is an underlying principle of the Statement of Policy.

The FRN published on September 17, 2010, included the following revised draft definition:

The Commission defines Nuclear Safety Culture as 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.

The FRN also included the following preamble before the revised traits:

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production vs. safety, schedule vs. safety, and cost of the effort vs. safety. It should be noted that although the term “security” is not expressly included in these traits, safety and security are the primary pillars of the NRC’s regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

The FRN listed the following traits of a positive safety culture:

- Leadership Safety Values and Actions—Leaders demonstrate commitment to safety in their decisions and behaviors.
- Problem Identification and Resolution—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- Personal Accountability—All individuals are personally responsible for safety.
- Work Process—The process of planning and controlling work activities is implemented so that safety is maintained.
- Continuous Learning—Opportunities to learn about ways to ensure safety are sought out and implemented.
- Environment for Raising Concerns—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination.
- Effective Safety Communication—Communications maintain a focus on safety.
- Respectful Work Environment—Trust and respect permeate the organization.

Proposed Final Safety Culture Policy Statement

At the September 28, 2010, public meeting in Las Vegas, NV, the staff specifically asked the participants to consider adding a trait addressing the importance of individuals and organizations performing regulated activities to have a questioning attitude. Participants expressed no specific support for or against this idea at the meeting. However, several comments in response to the November 2009 and September 2010 FRNs indicated that the policy statement should address the problem of complacency, and the staff agreed with that position. Therefore, the staff added “Questioning Attitude” as the ninth trait to address complacency more directly (i.e., by having a questioning attitude and challenging existing conditions, individuals can avoid complacency). The staff did not change the other traits, the definition of safety culture, or the preamble from the September 2010 FRN.

Stakeholder Outreach Activities

Summary

The proposed final policy statement benefits from consideration of a spectrum of views and provides a foundation for a policy statement on safety culture that is applicable across the array of activities regulated by the U.S. Nuclear Regulatory Commission (NRC). As directed by the Commission in Staff Requirements Memorandum (SRM)-SECY-09-0075, "Safety Culture Policy Statement," dated October 16, 2009, the staff has engaged a broad range of stakeholders, including the Organization of Agreement States (OAS) and other organizations with an interest in nuclear safety, throughout the development of the policy statement. The staff efforts to develop common terminology (i.e., safety culture terminology that can be used by the NRC and stakeholders) provided additional opportunities to further engage stakeholders. Although there has already been a substantial amount of outreach in the nuclear power plant area (for example, through the Reactor Oversight Process), the more recent initiative to develop a safety culture policy statement applicable to all licensees and certificate holders has significantly increased the outreach to materials stakeholders, including those located in the Agreement States. These efforts have contributed to the staff's progress in achieving the Commission's objective of increasing attention to safety culture in the materials area. The staff will continue to identify opportunities to discuss safety culture with materials licensees and certificate holders with the objective of advancing the progress they have made in increasing the attention that they give to safety culture.

Outreach Activities

February 2009 Public Workshop

On February 3, 2009, the NRC held a public workshop on the "Development of a Policy Statement(s) on Safety and Security Culture," in which a broad range of stakeholders participated. The purpose of this workshop was to obtain public input on the draft definition and characteristics of a positive safety culture that the staff had developed. Additionally, mindful of the increased attention to the important role of security, the staff also sought input from the workshop participants on whether there should be a single safety culture policy statement or two policy statements addressing safety and security independently while considering the interface of both. The staff also sought input on the additional questions the Commission posed to the staff in SRM-COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture," dated February 25, 2008. Ten different organizations, including OAS, licensees, and nongovernmental organizations, were represented on the workshop panels discussing the three topics. The use of a 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. The workshops also addressed the questions of whether (1) the NRC should combine its expectations for safety and security in one policy statement or keep its expectations in separate documents, and (2) safety culture as applied to reactors needed to be strengthened. The staff also sought public input on these questions through the January 23 and February 9 *Federal Register* notices (FRNs) (74 FR 4260 and 74 FR 6433), respectively, and on the NRC's public safety culture Web site (<http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>).

February 2010 Workshop

On February 2–4, 2010, the NRC held a 3-day public workshop. This workshop was part of the staff's efforts to further engage all NRC-regulated entities as well as OAS, Native American Indian Tribes, and organizations and individuals interested in nuclear safety. The goals of the February 2010 workshop were to (1) provide an additional opportunity for comments on the draft policy statement and (2) develop a common definition of safety culture and a high-level set of traits describing areas important to a positive safety culture. Before the meeting, the staff engaged a broad range of interested stakeholders to obtain their input on the most effective way to organize the meeting, including, for example, the composition and role of the panel members. The staff also discussed the goals of the workshop with the interested stakeholders.

The workshop participants represented a broad range of stakeholders regulated by the NRC or the Agreement States, including medical, industrial, and fuel cycle materials users and nuclear power reactor licensees, as well as the Nuclear Energy Institute (NEI), the Institute of Nuclear Power Operations (INPO), and members of the public. The workshop panelists reached alignment, with input from the other meeting attendees, on a common definition of safety culture and a high-level set of traits describing areas important to a positive safety culture. The NRC and OAS, as co-regulators, took a facilitative role during the workshop. The presentations that were made at the workshop, the workshop summary, and the products from the workshop can be found on the NRC's safety culture Web page at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

The approach the staff took (i.e., engaging stakeholders from the planning stages of the February 2010 workshop through the workshop itself) allowed the various stakeholders to reconcile differences in their needs and interests and develop, using common terminology, a draft definition and a draft set of traits that can be widely embraced. The staff believes that stakeholder involvement during the development of the policy statement has increased the prospects for the common terminology to be embraced and used by NRC stakeholders. This observation is based on (1) the comments made by members of the external panel at the March 30, 2010, Commission meeting, (2) the comments on the draft policy statement and revised draft policy statement, and (3) the comments made at the public meetings.

July 15, 2010, Public Meeting

On July 15, 2010, the NRC held a public meeting with panelists who participated in the February 2–4, 2010, workshop to discuss the status of the activities associated with the development of the draft safety culture policy statement, which included, for example, the review of public comments, outreach activities, and a discussion of the definition and traits of safety culture. The details of that discussion can be reviewed in the materials for the July 15, 2010, public meeting, at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

September 16, 2010, Public Meeting/Teleconference

On September 16, 2010, the staff held an additional public meeting/teleconference to provide information on the initial results of a validation study conducted by INPO, which was conducted, in part, to see whether and to what extent the factors that came out of INPO's safety culture

survey support the February 2010 workshop traits. The factors support the traits developed at the workshop. A discussion of the validation study is found in Enclosure 4.

September 28, 2010, Public Meeting

The September 28, 2010, public meeting offered an additional opportunity for stakeholders to provide input on the revised draft policy statement included in the FRN seeking public comments for a 30-day period that began on September 17, 2010. The public meeting took place in the NRC Hearing Facility in Las Vegas, NV. This location provided the information technology and capabilities that allowed a large number of people to attend in two separate locations and also view the meeting via Web stream. The second location was at NRC Headquarters in Rockville, MD. Six of the panelists from the February 2010 workshop provided short presentations related to the definitions and traits, outreach activities, and any challenges they anticipate will need to be addressed when implementation begins. An additional interested stakeholder from the American Association of Physicists in Medicine provided comments concerning the next steps or implementation phase. A presentation related to the INPO validation study was provided and generated discussion. The agenda, presentation materials, and meeting summary can be found on the NRC's safety culture Web page at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

Additional Outreach Activities

Following the February 2010 workshop, in addition to the NRC public meetings, the staff participated on panels and made presentations at various industry forums in order to provide information to stakeholders about the development of the safety culture policy statement, obtain additional input, and ascertain whether the draft definition and traits developed at the workshop accurately reflect a broad range of stakeholders' views. For example, on June 30, 2010, the staff cosponsored a special session on safety culture with the Health Physics Society at the American Conference on Radiological Safety and 22nd Biennial Campus Radiation Safety Officers Meeting. The Health Physics Society, as an affiliate member of the International Radiation Protection Association, is participating in efforts to develop guiding principles for promoting radiation safety culture. Through this session, the NRC was able to obtain increased visibility for its efforts relating to safety culture including an area of mutual interest (i.e., increasing the awareness of the relationship between safety culture and radiation safety).

Additional outreach activities included presentations on the development of the safety culture policy statement at the Annual Fuel Cycle Information Exchange, the Conference of Radiation Control Program Directors Annual National Conference on Radiation Control, the Institute of Nuclear Materials Management's Annual Meeting, the second NRC Workshop on Vendor Oversight for New Reactor Construction, and the OAS annual meeting. The attached chart lists the outreach activities the staff engaged in after the February 2010 workshop through November 2010.

Continued Involvement of External Panel Members within Their Organizations

Since the February 2010 workshop, the NRC staff has encouraged external panel members to continue their involvement with their organizations in ways that contribute to the increased attention to safety culture among materials licensees and certificate holders. Organizations

such as the NEI, the Health Physics Society, the Institute of Nuclear Materials Management, and the American Association of Physicists in Medicine shared information on safety culture with their membership through cosponsored special sessions on safety culture or by adding NRC staff presentations on safety culture to their meeting programs. The session on safety culture at the OAS 2010 annual meeting also included a presentation by a member of OAS. Information on safety culture was included in newsletters and discussed as part of OAS' other activities (e.g., electronic mail bulletins, meetings with NRC or Agreement State licensees, seeking the views of their membership). Safety culture is also being discussed by external panel members and byproduct materials licensees in other forums, including other NRC public meetings.

Continuing and Future Outreach Activities

The staff will continue to conduct widespread discussions concerning safety culture with external stakeholders whenever the opportunities arise. During several NRC management drop-in meetings with members of the industry and other external stakeholders, for example, safety culture has been an important topic of discussion. NRC management is consistently communicating the NRC's interest in the development of a positive safety culture with licensee representatives.

The staff has continued to engage the Agreement States during the development of the policy statement and continues to discuss safety culture in the periodic teleconferences with OAS and CRCPD and in other forums, including the 42nd National Conference on Radiation Control, the 2010 annual meeting of OAS, and the Mid-Atlantic States Radiation Control Conference. The staff will continue to work with the Agreement States on appropriate ways to increase the attention given to safety culture in the materials area. This will include the sharing of information and cooperation during the development of guidance documents that discuss safety culture. For example, the staff has begun updating the volumes of NUREG-1556, "Consolidated Guidance about Materials Licenses." The Agreement States are involved in this effort. The steering committee for the update to this series is co-chaired by an OAS representative. As the staff develops guidance that addresses safety culture, such as in the NUREG-1556 series, licensees and certificate holders will have an opportunity to provide comments or to participate in meetings associated with the guidance development.

During the development of the revised fuel cycle oversight process, the staff focused on developing a methodology for incorporating safety culture into its oversight processes through the Office of Nuclear Material Safety and Safeguards (NMSS) Safety Culture Pilot, which was implemented in 2007. This multiyear effort required working with both internal and external stakeholders on items related to safety culture. Through numerous interactions with internal and external stakeholders, the staff proposed in SECY-10-0031, "Revising the Fuel Cycle Oversight Process," dated March 19, 2010, that safety culture be an important aspect of the revised fuel cycle oversight process. Subsequent Commission direction on SECY-10-0031 directed that the staff should provide incentives for licensees to maintain strong corrective action programs, which would be consistent with the Commission's ongoing safety culture initiatives.

Through the staff's ongoing work with Commission-directed activities, such as the revised fuel cycle oversight process (SRM-SECY-10-0031, "Revising the Fuel Cycle Oversight Process," dated August 4, 2010) and the Extended Storage and Transportation Plan

(SRM-COMDEK-09-0001, "Revisiting the Paradigm for Spent Fuel Storage and Transportation Regulatory Programs," issued February 2010), the staff will appropriately incorporate safety culture into the evaluation of those activities, commensurate with Commission direction on the overall agency safety culture policy statement. Development of these tasks will certainly require outreach and interaction in various areas, which will include safety culture.

Where it is appropriate, the staff will continue to use its current approaches to increase the awareness of and attention given to safety culture. These approaches include interactions with licensees, public meetings, and using licensee newsletters to discuss safety culture.

Safety Culture Outreach/Conference Dates for Industry/Groups

NRC Responsible Office	Conference Dates	Conference	Conference Location	NRC-Regulated Industry/Groups
NRO	1. May 13, July 1, Aug 19, 2010, 2. June 17, 2010	1. Category III Public Meetings on Construction Inspection 2. NRC Workshop on Vendor Oversight	1. At/near NRC HQ 2. New Orleans, LA	New Construction, Suppliers/Vendors, Research and Test Reactors
NRR	1. June 7–10, 2010 2. June 21–25, 2010 3. July 25–28, 2010 4. September 19– 24, 2010	1. Mid-Atlantic Nuclear Training Group 2. Human Performance, Root Cause and Trending 3. NEI Health Physics Forum 4. Joint Meeting National Organization of Test Research, & Training Reactors	1. Gettysburg, PA 2. Baltimore, MD 3. Clearwater Beach, FL 4. Knoxville, TN	Power Reactors, Research and Test Reactors
NMSS	1. May 4–6, 2010 2. June 23–24, 2010 3. June 29–July 1, 2010	1. NEI Dry Storage Forum (SFST, cask suppliers/vendor/certificate holder/licensee) 2. SFST Licensing Conference 3. Fuel Cycle Information Exchange	1. Baltimore, MD 2. Rockville, MD 3. Bethesda, MD	Fuel Cycle, SFST, Cask Suppliers/Vendors

	4. July 12–15, 2010	4. Institute of Nuclear Materials Management Annual Meeting	4. Baltimore, MD	
FSME	1. April 22, 2010	1. 42 nd Annual National Conference on Radiation Control: Opportunities and Innovations in Radiation Protection	1. Newport, RI	1. Conference of Radiation Control Program Directors
	2. May 24–25, 2010	2. Advisory Committee on the Medical Uses of Isotopes	2. Rockville, MD	2. Medical
	3. May 24, 2010	3. American College of Medical Physics Annual Meeting	3. San Antonio, TX	3. Medical Physicists
	4. June 24–25, 2010	4. Safety in Radiation Therapy: A Call to Action	4. Miami, FL	4. Medical, Medical Physicists, Diagnostic, Therapeutic, and Radio Pharmacy
	5. July 18–22, 2010	5. American Association of Physicists in Medicine	5. Philadelphia, PA	5. American Association of Physicists in Medicine
	6. August 23–26, 2010	6. Organization of Agreement States	6. Portland, OR	6. Organization of Agreement States
	7. October 21, 2010	7. Advisory Committee on the Medical Uses of Isotopes	7. Rockville, MD	7. Medical
	8. November 15, 2010	8. Mid-Atlantic States Radiation Control Conference	8. Newark, DE	8. States and Federal Staff and Radiation Protection Staff

	9. December 13, 2010	9. Advisory Committee on the Medical Uses of Isotopes	9. Teleconference	9. Advisory Committee on the Medical Uses of Isotopes
NSIR	1. Monthly meetings 2. June 21–24, 2010	1. Monthly Nuclear Security Working Group Meetings 2. National Nuclear Security Conference	1. Washington, DC 2. Charlotte, NC	1. Security 2. Security
OE	1. July 11–15, 2010 2. Sept. 20–24, 2010 3. June 27–July 1, 2010	1. Institute of Nuclear Materials Management 2. National Association of Employee Concerns Professionals 3. 55 th Annual Health Physics Society and 22 nd Biennial Campus Radiation Safety Officers Meeting	1. Baltimore, MD 2. Annapolis, MD 3. Salt Lake City, UT	1. Safeguards, Physical Protection, Waste, Packaging, and Transportation 2. Employee Concern Issues 3. Academic, Government, Medical, Research and Development, Analytical Services, Consulting, Industrial

Nuclear Energy Institute/Institute for Nuclear Power Operations Safety Culture Construct Validation Study

Summary

The results of the Nuclear Energy Institute (NEI)/Institute for Nuclear Power Operations (INPO) Safety Culture Construct Validation Study have two important implications. First, the study provided general support for the traits identified by the participants in the February 2010 workshop. Second, the study demonstrated that safety culture traits exhibited within power reactor organizations are meaningfully related to other measures of organizational effectiveness and, more importantly, to safety performance.

Background

In February 2010, the U.S. Nuclear Regulatory Commission (NRC) sponsored a public workshop in Rockville, MD, to develop a common definition of safety culture and a set of traits that describe a positive safety culture that would be meaningful to persons and organizations who engage in NRC-regulated activities. NEI volunteered to sponsor a validation study, to be conducted by INPO, of the traits recommended by the workshop participants. The NRC Office of Enforcement asked the Office of Nuclear Regulatory Research to perform an independent evaluation of INPO's research.

The validation study had several purposes. The first was to confirm research findings from other industries that the safety culture construct incorporates several distinct but related dimensions (i.e., traits) and, second, to identify those dimensions in the nuclear power industry. A third purpose was to assess the extent to which the dimensions of safety culture, or "factors," derived from the study are consistent with the safety culture traits that participants identified during the February 2010 workshop. The study also sought to determine the extent to which the safety culture factors derived from the study correlate with the other measures of organizational and equipment performance to which theory suggests they should be related. For example, researchers considered whether sites with lower scores on a measure of safety culture have higher numbers of allegations than sites that score more positively.

Results

The study's principle component analysis identified nine clearly interpretable factors, shown in bold in the left-hand column of the following table. The table shows the subfactors from the larger survey factors in the left-hand column in normal font. The table also shows the relationship of the factors and subfactors from the survey to the traits identified during the workshop.

Survey Factors and Subfactors	Workshop Traits
1. Management Responsibility for Safety	Leadership Safety Values and Actions in which leaders demonstrate a commitment to safety in their decisions and behaviors
1a. Respectful work environment	Respectful Work Environment in which trust and respect permeate the organization

Survey Factors and Subfactors	Workshop Traits
1b. Continuous improvement—combines items related to problem identification and resolution and organizational learning	Problem Identification and Resolution in which issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance Continuous Learning in which opportunities to learn about ways to ensure safety are sought out and implemented
1c. Performance indicators	
1d. Resources	
1e. Rewards	
2. Willingness to Raise Concerns	Environment for Raising Concerns in which a safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination
2a. Informally	
2b. Formally	
3. Decision-making	
4. Supervisor Responsibility for Safety	
4a. Communication	
4b. Presence/availability	
4c. Coaching	
4d. Alignment with management	
5. Questioning Attitude	
5a. Situation/problem awareness	
5b. Process use	Work Processes in which the process of planning and controlling work activities is implemented so that safety is maintained
5c. Plant knowledge	
6. Safety Communication	Effective Safety Communication in which communications maintain a focus on safety
7. Personal Responsibility for Safety	Personal Accountability in which all individuals take personal responsibility for safety
8. Prioritizing Safety	
9. Training Quality	

These results generally support the validity of the traits identified by workshop participants, although they also indicate that additional traits are also important to a positive safety culture in power reactor organizations. As the table shows, four of the survey factors (Management Responsibility, Willingness to Raise Concerns, Safety Communication, and Personal Responsibility) are consistent with traits identified in the February workshop. Two of the workshop traits (Respectful Work Environment and Work Processes) emerged as subfactors of the Management Responsibility and Questioning Attitude survey factors, respectively. In the survey results, the workshop traits of Problem Identification and Resolution and Continuous Learning were combined into one subfactor, Continuous Improvement, of the Management Responsibility factor. The survey revealed four additional factors (Decisionmaking, Questioning Attitude, Prioritizing Safety, and Training Quality) that workshop participants had not identified as separate traits important to safety culture.

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.

Implementation

Conclusion

The NRC Program Offices responsible for the licensing and oversight of the regulated community will work with their constituents to address specific implementation issues. The “Tiers” chart at the end of this enclosure explains how implementation will be addressed in this process.

Before implementation issues are addressed, the program offices can work with the regulated community, the public, and other stakeholders as the regulated community begins assessing their activities to identify areas for enhancement. For example, community members could begin to identify tacit organizational and personal goals that, at times, may compete with a safety-first focus and develop strategies for adjusting those goals. Some monetary incentive or other rewards programs could work against making a safe decision. Current training programs may not adequately address safety culture and its traits or how those traits apply to day-to-day work activities. Identification of both strengths and weaknesses related to safety culture in the regulated community will be helpful in evaluating implementation strategies.

Office of Nuclear Reactor Regulation (NRR) Next Steps

Beginning in 1989, the NRC published two policy statements concerning safety culture at nuclear power plants. One describes the Commission’s expectations regarding the conduct of operations in control rooms; the second establishes the Commission’s expectation for maintaining a safety conscious work environment (SCWE) in which workers are able to raise nuclear safety concerns without fear. The Reactor Oversight Process (ROP) approach to addressing safety culture takes these policy statements into consideration. In 2003 the Davis-Besse reactor vessel head degradation event led to Commission direction that the staff should monitor efforts to develop objective measures that serve as indicators of possible problems with safety culture. Subsequently, on July 1, 2004, the staff issued SECY-04-0111 which proposed possible options for enhancing oversight of SCWE and safety culture. In response to this SECY, the Commission issued Staff Requirements Memorandum (SRM)-SECY-04-0111 on August 30, 2004, approving several options including to: (1) enhance the ROP treatment of cross-cutting areas to more fully address safety culture; (2) ensure inspectors were properly trained; and (3) develop a process for determining the need for conducting safety culture evaluations of plants in the Degraded Cornerstone Column of the ROP Action Matrix. Since 2006, the NRC’s oversight of safety culture for power reactors through the ROP has included guidance and procedures for inspecting and assessing aspects of licensees’ safety culture. In 2008, several additional changes to the guidance on oversight of safety culture in the ROP were developed as a result of lessons learned from the supplemental inspection conducted at Palo Verde. The staff believes that the current process for monitoring and assessing safety culture is effective within the established framework of the ROP.

The staff continues to enhance ROP guidance documents, as needed, based on lessons learned and stakeholder feedback. Although the staff believes that the existing program already fits within the framework of this policy statement, NRR will continue to work with internal and external stakeholders through the normal processes to be better aligned with the philosophy

and language of the proposed final policy statement and to consider insights from ongoing industry initiatives on safety culture.

Through the Nuclear Energy Institute (NEI) in partnership with the Institute for Nuclear Power Operations (INPO), the nuclear power industry pilot tested a broad initiative to monitor and improve its nuclear safety culture. Four nuclear power plants volunteered to participate in the industry's pilot application of the "Site Nuclear Safety Culture Process," documented in NEI 09-07, "Fostering a Strong Nuclear Safety Culture." NRR agreed to observe three key elements of the safety culture initiatives underway at the pilot plants. To date, NRC staff have observed all four of the pilot applications. Staff plans to observe a revision to the NEI 09-07 process at Hope Creek in February 2011, including the nuclear safety culture assessment process. NRR will continue to work with NEI and INPO to develop a common terminology of safety culture, where appropriate, during the implementation phase of the policy statement.

For research and test reactors (RTRs), the staff plans on addressing safety culture as part of the updates to existing procedures in order to incorporate safety culture guidance into its inspections of RTRs and its evaluation of inspection findings. The staff will seek stakeholder input on these updates. Similarly, NRR will continue to work with NRO, NMSS, and other internal and external stakeholders on inspection guidance to take into account safety culture as it applies to suppliers and vendors.

Office of New Reactors (NRO) Next Steps

NRO has worked closely with NRR in order to develop and implement an approach for documenting and evaluating aspects of safety culture during construction that are consistent with the ROP. This process for construction was documented by NRO in inspection manual chapter (IMC) 0613, "Documenting 10 CFR Part 52 Construction and Test Inspections," and IMC 2505, "Periodic Assessment of Construction Inspection Program Results" (similar to NRR IMC 0305 and IMC 0310). Subsequently, in response to Commission direction, NRO staff established an internal working group to evaluate and possibly revise these construction oversight processes, including how safety culture issues should be addressed. The construction oversight programs continue to go through revisions and evolutions which may result in additional revisions to these IMCs. NRO will await the Commission's final determination on the safety culture policy to look at its construction oversight program and evaluate the need for any necessary modifications to reflect the Commission's vision. Just as in the ROP, the office will learn from self-assessments it conducts and will ensure the appropriate measures are taken to adequately assess the safety culture at construction sites.

A key element to keep in mind is the challenges inherent to the roll-out of such a policy in the realm of construction vendors, given their vast numbers and variety of work capacity and organization. How the office looks at the efforts by the numerous vendors inspected will depend on a number of factors. This will be an ongoing effort that the office will need to resolve; however, there are venues and lessons learned that will be considered to ensure that the different vendor sites have positive safety cultures.

Office of Nuclear Material Safety and Safeguards (NMSS) Next Steps

After the Commission has acted on the proposed final Statement of Policy, NMSS will evaluate the oversight programs for fuel cycle facilities, independent spent fuel storage installations

(ISFSI), and cask vendors to identify appropriate means to incorporate safety culture into these programs. The staff's activities will include outreach to the affected licensees and certificate holders to understand measures already in place to develop and maintain a positive safety culture and how best to consider these activities in the oversight programs.

In recent months, the Commission has provided direction to staff on near-term activities related to revising the fuel cycle oversight process. The staff expects to provide a paper to the Commission in March 2011 comparing integrated safety analysis and probabilistic risk assessment methods in the context of fuel cycle facility oversight. In July 2011, the staff expects to provide the Commission a paper describing its development of safety cornerstones for fuel cycle facilities and providing recommendations for next steps in revising the fuel cycle oversight process. The staff will include in that paper recommendations for incorporating safety culture in the oversight process.

Regarding oversight of ISFSIs and cask vendors, in COMSECY-10-0007, "Project Plan for the Regulatory Program Review to Support Extended Storage and Transportation of Spent Nuclear Fuel," dated June 15, 2010, the staff proposes to perform comprehensive reviews and evaluations of the inspection and enforcement programs within the current regulatory program. In conjunction with the reviews proposed in COMSECY-10-0007, the staff will consider appropriate ways to incorporate safety culture in its oversight of these licensed activities. The timing of implementation will consider the integration of the waste confidence rulemaking (ref. SRM on SECY-09-0090, dated September 15, 2010) with the activities described in COMSECY-10-0007. NMSS proposes to conduct a thorough review of its regulatory oversight and enforcement programs in accordance with the Commission direction on the staff's proposed plan in COMSECY-10-0007. Following additional Commission input on this item and the overall agency safety culture direction, the staff will determine appropriate follow-up activities for all spent fuel storage and transportation certificate holders and licensees to ensure there is an effective implementation of a corrective action process that identifies, follows, and corrects conditions adverse to quality. This is especially true with regard to determining the cause of a problem and the elimination of both the problem's recurrence or the occurrence of a similar problem. NMSS could potentially modify the inspection requirements to review licensee and certificate holders' implementation of an effective safety culture program (ensuring a safety/quality conscious work environment).

Office of Federal and State Materials and Environmental Management Programs (FSME) Next Steps

After the final policy statement is complete, FSME will evaluate its oversight programs in light of the final policy statement. Although the policy statement is not a matter of compatibility, FSME will work with the Agreement States as FSME reviews the oversight programs for byproduct materials licensees.

As a first step, FSME is looking for ways to introduce safety culture into the NUREG-1556 series, "Consolidated Guidance about Materials Licenses," and the FSME revision to IMC 1246, "Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Area." The latter document will be given a new number and will apply specifically to the byproduct materials program. Although FSME is looking for ways to introduce safety culture into these documents, addressing safety culture is not the primary reason for updating these documents. The work on these updates has begun. FSME is involving the Agreement States in these efforts so that the NRC can learn from the best practices in the Agreement States.

The update of the NUREG-1556 series is anticipated to take about three and one-half years. The first three volumes — portable gauges, fixed gauges, and industrial radiography — are scheduled to be completed in early 2011. The extent to which safety culture is introduced into any particular volume of the NUREG-1556 series will be influenced by the timing of its completion and the Commission action on the proposed final policy statement. We will continue to learn as we update the different volumes of the NUREG-1556 series and will have more time to look at how best to introduce safety culture into guidance in light of the final policy statement. Although we may be able to include more detail on safety culture as we work on the subsequent volumes, FSME will make other changes, as appropriate, in its oversight programs and future updates to these documents consistent with the outcomes from FSME's longer-term efforts to evaluate its oversight of byproduct materials licensees.

TIERS

