Enclosure 1

[7590-01-P]

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