DRAFT FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION

[NRC-2009-xxxx]

Draft Safety Culture Policy Statement:

Request for Public Comments

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Issuance of draft safety culture policy statement and notice of opportunity for public comment.

DATES: Comments are requested ~~75~~ 90 days from the date of this *Federal Register* Notice. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date. Please refer to the Supplementary Information section for additional information including questions for which the NRC is requesting comment.

ADDRESSES: Members of the public are invited and encouraged to submit comments by 75 days from the date of this *Federal Register* Notice, by mail to Isabelle Schoenfeld, Office of Enforcement, Mail Stop O-4 A15A, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by e-mail to isabelle.schoenfeld@nrc.gov.

SUMMARY: The NRC is issuing a draft policy statement that sets forth the Commission's expectation that all licensees and certificate holders[1] establish and maintain a positive safety culture that protects public health and safety and the common defense and security when carrying out licensed activities. The Commission defines safety culture as that assembly of characteristics, attitudes, and behaviors in organizations and individuals, which ~~that~~ establishes that~~,~~ as an overriding priority, nuclear safety and ~~nuclear~~ security issues[2] receive the attention warranted by their significance. The Commission also considers nuclear safety and security issues to be equally important in a positive safety culture. The importance of treating safety and security in an equal manner within NRC's regulatory framework is clearly evident in our mission and strategic goals. Experience has shown that certain organizational characteristics and personnel attitudes and behaviors are present in a positive safety culture. These include, but are not limited to, individuals demonstrating ownership and personal responsibility for maintaining safety and security in their day-to-day work activities; the implementation of processes for planning and controlling work activities such that safety and security are maintained; a work environment in which personnel feel free to raise safety and security concerns without fear of retaliation; prompt and thorough identification, evaluation, and resolution of nuclear safety and security issues commensurate with their significance; the availability of the resources needed to ensure that safety and security are maintained; decision-making processes that protect safety and security; clearly defined roles and responsibilities for maintaining safety and security; and the seeking out and implementation of opportunities to improve safety and security. The NRC expects its licensees and certificate holders to foster

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[1] Throughout this document, the phrase "licensee and certificate holders" includes licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals and applicants for a license, certificate, permit, authorization, or quality assurance program approval.

[2] Throughout this document, the terms "safety" or "nuclear safety," "security" or "nuclear security," and "safety culture" are used. These terms refer to matters that are related to NRC-regulated activities, including radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness.

these characteristics, attitudes, and behaviors in their organizations and among individuals who are overseeing or performing regulated activities commensurate with the safety and security significance of their activities and the nature and complexity of their organization and functions.

The NRC is requesting comments on the draft safety culture policy statement and associated questions.

SUPPLEMENTARY INFORMATION:

(1) Background

The Commission has long expressed its expectations for safety culture in previous policy statements. In 1989, the Commission published its "Policy Statement on the Conduct of Nuclear Power Plant Operations" (54 FR 3424; January 24, 1989) to make clear the Commission's expectations of utility management and licensed operators with respect to the conduct of operations. The policy statement stated, "the phrase safety culture refers to a very general matter, the personal dedication and accountability of all individuals engaged in any activity which has a bearing on the safety of nuclear power plants." The policy statement further stated that the Commission issued the policy statement to help foster the development and maintenance of a safety culture at every facility licensed by the NRC.

In 1996, the Commission published a policy statement, "Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation" (61 FR 24336; May 14, 1996), to set forth its expectations that licensees and other employers subject to NRC authority will establish and maintain safety-conscious environments in which employees feel free to raise safety concerns, both to their management and to the NRC,

without fear of retaliation. This policy statement applied to NRC-regulated activities of all licensees and their contractors and subcontractors. A safety conscious work environment is an important attribute of safety culture and is one of the safety culture characteristics in the draft safety culture policy statement.

The importance of a positive safety culture for activities involving civilian uses of radioactive materials and other potential hazards has been demonstrated by a number of significant, high-visibility events world-wide that have occurred in the 20-year period since the Commission published its 1989 policy statement addressing safety culture in nuclear power plants. The events occurred across multiple industries including at nuclear power plants, fuel cycle facilities and in other industries such as chemical processing plants and aerospace. Examples of nuclear industry events include those that occurred at the Davis-Besse Nuclear Power Station and the Peach Bottom Atomic Power Station. Workers at the Davis-Besse Nuclear Power Station discovered a cavity in the reactor pressure vessel head caused by boric acid corrosion. The corrosion developed over a period of several years but was not discovered before the cavity developed. The licensee's analysis of the event identified weaknesses in the station's safety culture as the root cause of the event. It particularly noted that management prioritized "production over safety." At the Peach Bottom Atomic Power Station, personnel behaviors adverse to the security of the plant were identified, specifically, inattentiveness by security officers.

Other licensees have had recurring problems resulting in violations of NRC regulations. Through a Commission confirmatory order, a fuel cycle facility licensee~~, Nuclear Fuel Services, Inc.,~~ committed to having a third-party assessment of its safety culture to determine the causes of its continuing problems ~~and~~ in order to ~~taking~~ establish appropriate corrective actions. The third-party assessment identified weaknesses in ~~every~~ areas

important to safety culture. In addition, weaknesses in the safety culture of licensees and certificate holders have contributed to unscheduled events or incidents that the Commission has determined to be significant from the standpoint of public health and safety. Examples linked to characteristics and attitudes in organizations and individuals associated with weak safety cultures include inadequate procedures; procedures not being followed; inadequate supervision; decision-making that does not ensure that safety and security are maintained; and ineffective problem identification, evaluation, and resolution. They have included medical misadministrations (such as giving iodine-131 to lactating females that resulted in the uptake by their infants and multiple events associated with prostate brachytherapy treatment) and overexposures arising from the loss of control of radiography or well logging sources.

(2) <u>Statement of Policy</u>

It is the Commission's policy that a strong safety culture is an essential element for individuals, both internal to the NRC and external, performing or overseeing regulated activities. As such, the NRC will include appropriate means to monitor safety culture in its oversight programs and internal management processes. {PBL Edit} The NRC defines safety culture as that assembly of characteristics, attitudes, and behaviors in organizations and individuals, which ~~that~~ establishes that~~,~~ as an overriding priority, nuclear safety and ~~nuclear~~ security issues receive the attention warranted by their significance. ~~The Commission also considers nuclear safety and nuclear security issues to be equally important in a positive safety culture.~~ Further, it is important for all organizations ~~licensees and certificate holders~~ to provide personnel in the safety and security sectors with an appreciation for the importance of each, emphasizing the need for integration and balance to achieve optimized protection. Safety and security activities are closely intertwined, and it

is critical that consideration of these activities be integrated so as not to diminish or adversely affect either safety or security. A safety culture that accomplishes this would include all nuclear safety and ~~nuclear~~ security issues associated with NRC-regulated activities including radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness issues among the issues that receive attention as a matter of priority.

The Commission's regulations are designed to protect both the public and workers against radiation hazards from the use of radioactive materials. The Commission's scope of responsibility includes regulation of commercial nuclear power plants; research, test, and training reactors; nuclear fuel cycle facilities; medical, academic, and industrial uses of radioactive materials; and the transport, storage, and disposal of radioactive materials and wastes. The Commission carries out these responsibilities in numerous ways including through such regulatory activities as inspecting licensed and certified facilities and activities; collecting, analyzing, and disseminating information about operational safety and security; investigating nuclear incidents; and developing policy and providing direction on safety and security issues.

The Commission believes that, because licensees and certificate holders use or provide services related to the use of radioactive material, they bear the primary responsibility for safely handling and securing these materials. It is, therefore, each licensee's and certificate holder's responsibility to develop and maintain a positive safety culture, which ~~that~~ establishes that nuclear safety issues and nuclear security issues, as an overriding priority, receive the attention warranted by their significance. Therefore, licensees and certificate holders should foster a positive safety culture in their organizations and among individuals who are overseeing or performing regulated activities. However, as the

regulatory agency, the Commission has an independent oversight role (through inspection and assessment processes) including addressing licensees' and certificate holders' performance related to areas important to safety culture.

(3) **Safety Culture Concept**

In 1991, as a result of the 1986 Chernobyl accident, the International Nuclear Safety Group (INSAG) emphasized the concept of safety culture for the nuclear industry in its report, INSAG-4, "Safety Culture." INSAG is an advisory group to the International Atomic Energy Agency (IAEA). The INSAG-4 definition of safety culture is, "that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."

Implied in the INSAG definition of safety culture is the recognition that every organization is continually faced with resolving conflicts among its goals for cost, schedule, and quality (or safety). The organization's members (groups and individuals) also face conflicts among different goals in performing their jobs. Management establishes the framework (management systems, programs, processes) and communicates its priorities for resolving conflicts among different goals. Members of the organization work within that framework and are influenced by management's priorities, but they have their own beliefs and attitudes about what is important and make individual choices on how to proceed when faced with multiple competing goals. The INSAG definition emphasizes that in a positive safety culture, the goal of maintaining nuclear safety receives the highest priority in the organization's and individuals' decision-making and actions when faced with a conflict with other organizational or individual goals.

The Commission modified the INSAG definition of safety culture which refers to "nuclear plant safety." The Commission is strongly committed to promoting positive safety cultures among its nuclear reactor licensees; however, the Commission regulates many other organizations and processes involving civilian uses of radioactive materials. These regulated activities include 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 nuclear power plants. The Commission also regulates 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. Therefore, by revising the INSAG definition of safety culture to replace "nuclear plant safety" with "nuclear safety," the Commission is emphasizing that it expects all of its licensees and certificate holders to place the highest priority on nuclear safety commensurate with the risks inherent in the regulated activities.

The Commission also modified the INSAG definition to adequately capture or communicate the equal importance of nuclear security and nuclear safety in a positive safety culture. Following the terrorist attacks of September 11, 2001, the Commission increased its attention to the important role of security in regulated facilities whose operations can have an impact on public health and safety. The Commission issued orders enhancing security at its NRC-regulated facilities to further ensure public health and safety and the common defense and security. One of the insights gained from the greater emphasis on security is the importance of incorporating security considerations into a safety culture and effectively managing the safety and security interface. In general, the safety and security interface refers to the organizational and individual awareness that the functions and goals of safety and security must be considered together so that actions to achieve either set of functions

and goals do not inadvertently compromise the other. Therefore, to emphasize the equal importance of nuclear security and nuclear safety in a positive safety culture, the Commission has added "nuclear security" to the safety culture definition. The NRC's modified INSAG definition is provided in the Statement of Policy section above.

(4) Stakeholder Outreach

The Commission's February 28, 2009, Staff Requirements Memorandum (SRM)-COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture," stated in part that the staff should, as part of its public stakeholder outreach, reach out to all types of licensees and certificate holders. In the development of the draft policy statement, the NRC staff sought insights and feedback from stakeholders. This was accomplished by providing information in a variety of forums such as stakeholder organization meetings, newsletters, and teleconferences and by publishing questions in *Federal Register* Notices entitled "Safety Culture Policy Statement: Public Meeting and Request for Public Comments" (74 FR 4260; January 23, 2009, and 74 FR 6433; February 9, 2009) that were related to the Commission's SRM. In addition, a significant stakeholder outreach activity was accomplished by a public workshop held on February 3, 2009, at NRC Headquarters in Rockville, Maryland. The staff reviewed and considered the stakeholder feedback derived from these different forums and incorporated it into the development of the draft policy statement and recommendations.

(5) Safety and Security Culture

In SRM-COMGJB-08-0001, the Commission also considered whether publishing the NRC's expectations for safety and security culture is best accomplished in one safety/security

culture statement or in two separate statements, one each for safety and security, while still considering the safety and security interface.

Based on a variety of sources including document reviews and stakeholder feedback, the Commission concluded there is no one definitive view of this issue, but the results weighed heavily toward a single policy statement to be titled a "Safety Culture Policy Statement." Document reviews and stakeholder feedback suggested that a single policy statement (1) builds on the fact that safety and security have the same ultimate purpose of protecting people and the environment from unintended radiation exposure and (2) encourages attention to the ways safety and security interface. For these reasons, the Commission determined that t~~T~~he term "safety culture" should include both safety and security. ~~be considered as all encompassing because there would be no need for security pertaining to the use of radioactive material if it were not for radioactive material used by licensees and certificate holders.~~

Safety and security have been the primary pillars of NRC's regulatory programs. However, in the current heightened threat environment, there has been a renewed focus on security, and the staff has implemented a number of efforts to enhance security and strengthen the safety and security interface. It is important to understand that both safety and security share a common purpose of protecting public health and safety. In today's environment, safety and security activities are closely ~~intertwined~~, and it is critical that consideration of these activities be integrated so as to compliment each other and not ~~to~~ diminish or adversely impact either safety or security. Further, it is important for licensees and certificate holders to provide personnel in the safety and security sectors with an appreciation for the importance of each, emphasizing the need for integration and balance to achieve optimized protection. The importance of both safety and security in an equal

and balanced manner within NRC's regulatory framework is clearly evident in the Commission's mission and strategic goals.

While many safety and security activities complement each other or are synergistic, there remain areas where potential conflicts may arise ~~differences~~. It is then imperative that mechanisms be established to resolve these potential conflicts to ~~differences if we must~~ assure the adequate protection of public health and safety and promote the common defens~~e~~e and security. Hence, safety and security have implications for each other in connection with all aspects of nuclear activities. ~~For example, the enhanced risk of a sabotage event has highlighted the importance of integrating safety and security in the field of protection and of identifying areas where they need to complement each other so that a terrorist event can be dealt with in as seamless a fashion as possible.~~

One potential ~~important difference or~~ challenge is the way in which individuals involved in safety and security activities approach the goal of risk mitigation and protection of public health and safety. The safety staff is typically focused on preventing errors that would result in an inadvertent accident while the security staff is focused on preventing deliberate attacks or diversion of certain materials that could cause harm. ~~Another difference is the way in which individuals involved in safety and security activities approach information sharing. The safety staff promotes information sharing and collaboration while the security staff promotes the sensitivity of information and a need to know. These differences as well as any others identified through stakeholder interactions would need to be resolved and managed.~~ Another challenge is that the organization/facility must ensure that the existence of motivated and capable persons with ill intent is recognized and that the importance of nuclear security to prevent such persons from unauthorized access is understood. ~~This~~

~~need for an improved~~ sensitivity ~~to the current threat~~ environment is exacerbated ~~by the significant growth in nuclear utilization worldwide~~. To manage these potential conflicts or challenges, the Agency has recently issued regulations on the safety/security interface. An overarching safety culture policy statement which encompasses security supports and further enhances those regulations.

Based on the above considerations, the Commission concluded that a single policy statement would accomplish its goal that, as an overriding priority, safety issues and security issues receive the attention warranted by their significance. Although, in some cases, issues relating to security might be handled differently than issues related to safety. A single policy statement recognizes there is one overarching culture in an organization; however, safety and security functions and goals must be treated equally within that overarching safety culture.

(6) Characteristics of a Positive Safety Culture

Experience has shown that certain organizational attributes and personnel attitudes and behaviors are present in a positive safety culture. Therefore, in 2006, when the NRC implemented an enhanced reactor oversight process (ROP) that more fully addressed safety culture, it identified and incorporated safety culture components that are overarching characteristics of a positive safety culture. The NRC based its development of the safety culture components on a review of a variety of sources of information including the Institute of Nuclear Power Operations; the IAEA; the Nuclear Energy Agency; the regulatory approaches of other domestic and international organizations; and the organizational behavior, safety culture, and safety climate research literature. The Commission presented

drafts of the safety culture components and aspects in frequent public meetings and modified them in response to stakeholder feedback.

For the purpose of this policy statement, the NRC modified the ROP safety culture components (termed "safety culture characteristics") to explicitly address security in the safety culture characteristics descriptions, create a more generic description for each safety culture characteristic that would apply to the range of NRC licensees and certificate holders, and maintain all the safety culture concepts in the safety culture components. The staff presented the draft safety culture characteristics for stakeholder comment in a February 3, 2009, public workshop and on the NRC's public safety culture Web site (http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html).

Although the safety culture characteristics themselves are applicable to all licensees and certificate holders, there may be other examples that more specifically address the unique characteristics of a licensee's or certificate holder's environment (i.e., unique for medical and industrial applications, operating reactors, research and test reactors, fuel cycle facilities, and new reactor construction environments). Hence, the Commission recognizes that these safety culture characteristics are not all inclusive; other characteristics and attitudes in organizations and individuals may be indicative of a positive safety culture. However, the Commission expects its licensees and certificate holders to consider the extent to which these characteristics and attitudes are present in their organizations and among individuals who are overseeing or performing regulated activities and to take steps, if necessary, to foster a positive safety culture commensurate with the safety and security significance of activities and the nature and complexity of the licensee's or certificate holder's organization and functions.

The following characteristics that are indicative of a positive safety culture, are relevant across the broad range of ~~licensees' and certificate holders'~~ activities carried out by the nuclear industry, the Agreement States and the NRC, and address the importance of nuclear safety and security:

- Personnel demonstrate ownership for nuclear safety and security in their day-to-day work activities by, for example, ensuring that their day-to-day work activities and products meet professional standards commensurate with the potential impacts of their work on safety and security. They proceed with caution when making safety- or security-related decisions and question their assumptions, especially when faced with uncertain or unexpected conditions, to ensure that safety and security are maintained.

- Processes for planning and controlling work ensure that individual contributors, supervisors, and work groups communicate, coordinate, and execute their work activities in a manner that supports safety and security. For example, individuals and work groups communicate and cooperate during work projects and activities to ensure their actions do not interact with those of others to adversely affect safety or security. In addition, managers and supervisors are accessible to oversee work activities, including those of contractors or vendors, and they challenge work activities and work products that do not meet their standards.

- The organization ~~licensee or certificate holder~~ maintains a safety conscious work environment in which personnel feel free to raise safety and security concerns without fear of retaliation. For example, claims of harassment, intimidation, retaliation, and discrimination are investigated consistent with the regulations regarding employee protection. If an instance of harassment, intimidation, retaliation, or discrimination for

raising a safety or security concern is identified, corrective actions are taken in a timely manner.

- The organization ~~licensee or certificate holder~~ ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected, commensurate with their significance.

- The organization ~~licensee or certificate holder~~ ensures that the personnel, equipment, tools, procedures, and other resources needed to assure safety and security are available. For example, training is developed and implemented or accessed to ensure personnel competence. Procedures, work instructions, design documentation, drawings, databases, and other job aids and reference materials are complete, accurate, and up-to-date.

- The organization's ~~licensee or certificate holder~~ decisions ensure that safety and security are maintained. For example, production, cost, and schedule goals are developed, communicated, and implemented in a manner which demonstrates that safety and security are overriding priorities.

- Roles, responsibilities, and authorities for safety and security are clearly defined and reinforced. For example, personnel understand their roles and responsibilities in maintaining safety and security. Programs, processes, procedures, and organizational interfaces are clearly defined and implemented as designed. Leaders at all levels of the organization consistently demonstrate that safety and security are overriding priorities.

- The organization ~~licensee or certificate holder~~ maintains a continuous learning environment in which opportunities to improve safety and security are sought out and implemented. For example, individuals are encouraged to develop and maintain current their professional and technical knowledge, skills, and abilities and to remain knowledgeable of industry standards and innovative practices. Personnel seek out and implement opportunities to improve safety and security performance.

(7) Implementation of Policy

This policy statement describes areas important to safety culture, but it does not address how the nuclear industry, the Agreement States and the NRC ~~licensee or certificate holder~~ should establish and maintain a positive safety culture in ~~its~~ their organizations. ~~Licensees, and certificate holders~~ The nuclear industry, the Agreement States and the NRC differ in their size and complexity, infrastructure, and organizational frameworks. Therefore, a single approach for establishing and maintaining a positive safety culture is not possible. Nevertheless, the Commission expects that nuclear safety and security issues receive the attention warranted by their significance, and all organizations ~~licensee or certificate holder~~ 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.

QUESTIONS FOR WHICH NRC IS SEEKING INPUT:

(1) The draft policy statement provides a description of areas important to safety culture, (i.e., safety culture characteristics). Are there any characteristics relevant to a particular

type of licensee or certificate holder (if so, please specify which type) that do not appear to be addressed?

(2) Are there safety culture characteristics as described in the draft policy statement that you believe do not contribute to safety culture and, therefore, should not be included?

(3) Regarding the understanding of what the Commission means by a "positive safety culture," would it help to include the safety culture characteristics in the Statement of Policy section in the policy statement?

(4) The draft policy statement includes the following definition of safety culture: "Safety culture is that assembly of characteristics, attitudes, and behaviors in organizations and individuals, which ~~that~~ establishes that~~,~~ as an overriding priority, nuclear safety and ~~nuclear~~ security issues receive the attention warranted by their significance." Does this definition need further clarification to be useful?

(5) The draft policy statement states, "All licensees and certificate holders should consider and foster the safety culture characteristics (commensurate with the safety and security significance of activities and the nature and complexity of their organization and functions) in carrying out their day-to-day work activities and decisions." Given the diversity among the licensees and certificate holders regulated by the NRC and the Agreement States, does this statement need further clarification?

(6) How well does the draft safety culture policy statement enhance licensees' and certificate holders' understanding of the NRC's expectations that they maintain a safety culture that includes issues related to security?

(7) In addition to issuing a safety culture policy statement, what might the NRC consider doing, or doing differently, to increase licensees' and certificate holders' attention to safety culture in the materials area?

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

To ensure efficient consideration of your comments, please identify the specific question numbers with your comments when applicable. When commenting, please exercise caution with regard to site-specific security-related information. Comments will be made available to the public in their entirety. Personal information such as your name, address, telephone number, and e-mail address will not be removed from your submission.

For the Nuclear Regulatory Commission.

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Cynthia A. Carpenter, Director

Office of Enforcement

Dated at Rockville, Maryland, this_____day of_____, 2009.