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9/17/2010
75FR57081

Comment On: NRC-2010-0282-0002
Revised Draft Safety Culture Policy Statement: Request for Comments

Document: NRC-2010-0282-DRAFT-0007
Comment on FR Doc # 2010-23249

(11)

Submitter Information

Name: Thomas Houghton
Address:
1776 I st NW Suite 400
Washington, DC, 20006
Organization: Nuclear Energy Institute

General Comment

October 18, 2010

Ms. Cindy K. Blady
Chief, Rules, Announcements and Directives Branch (RADB)
Division of Administrative Services
Office of Administration
Mail Stop TWB-05-B01M
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Revised Draft Safety Culture Policy Statement: Request for Comments, 75FR57081, Docket NRC-2010-0282

Project Number: 689

Dear Ms. Blady:

On behalf of the nuclear industry, the Nuclear Energy Institute (NEI) offers the following comments in response to the September 17, 2010 Federal Register Notice (FRN) (75 Fed. Reg. 57081) regarding the Revised Draft Safety Culture Policy Statement. The industry appreciated the opportunity to participate with other stakeholders in the public meeting held September 28, 2010, and many of our comments reflect the outcome of that meeting.

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The attachment to this letter provides our response to the five questions posed in the FRN. In addition, we

SUNSI Review Complete Template = ADM-013

Add = M. Schwartz (mes)

provide comments in five key areas:

• The regulated licensees and certificate holders bear the primary responsibility for developing and maintaining a strong nuclear safety culture.
• A Commission Policy Statement is the appropriate regulatory action for safety culture.
• It is critical that a common language of safety culture traits and behaviors exist between the NRC and each of its unique regulated entities.
• In developing follow on activities, the Commission needs to consider the effect of the policy statement and related NRC activities on the diverse population of materials licensees and certificate holders who have unique needs and have not been interacting with the NRC on safety culture issues for as long as power reactors have.
• Application of the policy to vendors and suppliers of safety-related components should be limited to those who are performing work at an applicant's, licensee's or certificate holder's facility due to duplication with existing quality controls with no commensurate increase in safety.

Again, the

Attachments

NRC-2010-0282-DRAFT-0007.1: Comment on FR Doc # 2010-23249
NRC-2010-0282-DRAFT-0007.2: Comment on FR Doc # 2010-23249

NUCLEAR ENERGY INSTITUTE

Thomas C. Houghton
DIRECTOR
SAFETY-FOCUSED REGULATION
NUCLEAR GENERATION DIVISION

October 18, 2010

Ms. Cindy K. Blady
Chief, Rules, Announcements and Directives Branch (RADB)
Division of Administrative Services
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Subject: Revised Draft Safety Culture Policy Statement: Request for Comments, 75FR57081, Docket NRC-2010-0282

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The attachment to this letter provides our response to the five questions posed in the FRN. In addition, we provide comments in five key areas:

- The regulated licensees and certificate holders bear the primary responsibility for developing and maintaining a strong nuclear safety culture.
- A Commission Policy Statement is the appropriate regulatory action for safety culture.
- It is critical that a common language of safety culture traits and behaviors exist between the NRC and each of its unique regulated entities.

[1] NEI is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

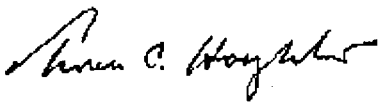
1776 I Street, NW | Suite 400 | Washington, DC | 20006-3708 | P: 202.739.8107 | F: 202.533.0149 | tch@nei.org | www.nei.org

- In developing follow on activities, the Commission needs to consider the effect of the policy statement and related NRC activities on the diverse population of materials licensees and certificate holders who have unique needs and have not been interacting with the NRC on safety culture issues for as long as power reactors have.
- Application of the policy to vendors and suppliers of safety-related components should be limited to those who are performing work at an applicant's, licensee's or certificate holder's facility due to duplication with existing quality controls with no commensurate increase in safety.

Again, the industry appreciates the opportunity to provide comments for your consideration as you proceed to finalize a policy statement on the NRC's expectations for a positive nuclear safety culture.

If you have any questions, please contact me (202-739 8107; tch@nei.org) or Janet Schlueter for materials licensee issues (202-739-8098; jrs@nei.org).

Sincerely,



Thomas C. Houghton

Attachment

c: Mr. Roy Zimmerman, OE, NRC
Mr. David Solorio, OE/CRB, NRC
Ms. Diane Sieracki, OE/CRB, NRC

NUCLEAR ENERGY INSTITUTE (NEI) COMMENTS ON THE NRC REVISED DRAFT SAFETY CULTURE POLICY STATEMENT

On behalf of the nuclear industry, the Nuclear Energy Institute (NEI)[1] offers the following comments on the NRC's September 17, 2010 Revised Draft Safety Culture Policy Statement. (See notice of public comment opportunity at 75 Fed. Reg. 57081). We appreciate the opportunity to comment on the revised draft.

I. General Comments

NEI's general comments on the revised draft policy statement are set forth in Section I. NEI's specific comments responding to the questions posed by the agency in the Federal Register Notice (FRN) are set forth in Section II.

A. NRC Licensees and Certificate Holders Have Primary Responsibility for Ensuring a Positive Safety Culture

The draft Policy Statement states the NRC's expectation that "individuals and organizations performing or overseeing regulated activities involving nuclear materials bear the primary responsibility for safely handling and securing these materials." 75 Fed. Reg. 57084. And, it is the Commission's expectation that they "establish and maintain a positive safety culture." Id. At 57083.

Industry agrees that the regulated industry should take the lead on safety culture. To that end, the operating power reactor community has developed and is piloting a rigorous approach to assessing and ensuring the effectiveness of nuclear safety culture activities. We believe that implementation of this approach will permit the NRC to modify its current burdensome substantive cross cutting issues method of oversight of nuclear safety culture in the Reactor Oversight Process, while maintaining its appropriate oversight role. In our view, the reactor industry approach employs a more robust, holistic and integrated look at indications of safety culture than that used by the inspection staff. We believe that this approach will provide greater assurance to the NRC that a positive safety culture is being maintained while employing fewer NRC resources. NRC staff are observing and commenting on the pilot program.

Details of the power reactor industry's proposed approach are available in NEI 09-07, *Fostering a Strong Nuclear Safety Culture*, which was provided to the NRC June 2, 2009 in a letter from T. Houghton to F. Brown. Appropriate methods that other licensees and certificate holders might use should be discussed by the NRC and the affected

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organizations during workshops targeted for specific licensee categories. The NRC should also work with existing industry tools and resources (e.g., professional organization websites, meetings and training providers) to establish and communicate its expectations to materials licensees and certificate holders well in advance of implementing the final policy statement. NEI is available to assist in this regard.

B. An NRC Statement of Policy is the appropriate Regulatory Action to Address Safety Culture

Industry believes that a nuclear safety culture policy statement is the appropriate regulatory vehicle for the Commission to use. As noted above, NRC licensees and certificate holders bear the responsibility for facility safety and will support a policy statement that provides the potential for even safer operations. We do not believe that safety culture is an appropriate subject for NRC rulemaking. On this point, we strongly concur with the NRC's observation in the draft Policy: "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." 75 Fed. Reg. 57085. As discussed with the NRC staff, industry plans to participate in NRC efforts to develop any implementation guidance.

C. A Common Language of Nuclear Safety Culture Is Needed

The safety culture workshop conducted by NRC on February 2-4, 2010 was an excellent beginning toward a common language of nuclear safety culture. We believe that the basic definition and characteristics of safety culture developed at the workshop are appropriate for use by the NRC, its licensees and certificate holders, and other NRC stakeholders. Once this high level of agreement and understanding of what is meant has been achieved, we believe the next critical step is to develop specific characteristics and behaviors at the level of the uniquely different industries (operating reactors, new construction, fuel facilities, radiography, etc.) that the NRC regulates. This "third tier," as it were, will provide more meaning in the individual industries and relate the general characteristics to specific behaviors and indications of a strong safety culture in those industries. NEI recommends that this level of development begin for the power reactor industry in the near future, and we are prepared to commence this work immediately. It is essential that the NRC, in its oversight role of safety culture, and reactor licensees, in their training of staff and assessment of safety culture, use the same terminology. This same degree of alignment will be necessary for the remaining categories of NRC facilities at the appropriate time.

D. Effect of the Draft Policy Statement and related NRC Activities on NRC Materials Licensees and Certificate Holders

As the NRC is aware, the level of NRC licensees' familiarity with the safety culture

concept varies widely. To broaden understanding across the nuclear industry, we believe the NRC needs to conduct workshops, in coordination with the Agreement States. Such outreach efforts would be particularly useful to the wide variety of NRC materials users. The focus of these efforts should be to inform the NRC's approach to safety culture and help ensure that the agency's expectations are reasonable, do not have an unintended negative impact on safety, and are clearly articulated and understood. Additionally, we urge the NRC to provide clear guidance to licensees as to how the NRC plans to provide oversight of safety culture in its inspection programs. The NRC should also work closely with the Agreement States to prioritize this effort relative to other regulatory issues. Finally, the NRC should refrain from including safety culture issues in inspection reports and assessments until such time that the final policy has been issued, relevant coordination with the regulated community and Agreement States has occurred, and implementing guidance is issued to ensure that the NRC's expectations are clear and appropriate.

Additionally, we recommend that the NRC work through the February 2010 stakeholder workshop planning committee to solicit input on how best to involve stakeholders for further development of the final policy, safety culture characteristics, "third tier" characteristics, implementing guidance and outreach to industry and the Agreement States to ensure an effective nationwide effort on safety culture. For example, based on previous public meetings between the NRC and the fuel facilities, it is industry's understanding that implementation of the Safety Culture policy would be further discussed, defined and incorporated into possible enhancements to the current oversight process for fuel facilities. With regard to the Agreement States, the NRC should create additional opportunities, such as the Organization of Agreement States' annual meeting, to prioritize this effort since they have limited, and in many cases, declining resources for a new regulatory initiative and are currently working with the NRC on other higher priority initiatives, e.g., National Source Tracking System, Web-Based Licensing and the License Verification System. With regard to other regulated entities, it is conceivable that several workshops will be needed to convene the wide variety of industries to effectively meet our mutual goal of ensuring that an adequate safety culture exists at regulated facilities nationwide.

E. Applicability of the Draft Policy Statement to Vendors and Suppliers of Safety-Related Components

With respect to vendors and suppliers of safety-related components, NEI believes it is appropriate for the NRC to limit the application of the policy statement to those who are performing work at an applicant's, licensee's or certificate holder's facility. While the tenets of safety culture obviously are beneficially incorporated into the operation of these vendors and suppliers, broader application of the NRC's policy statement is likely to impose additional administrative burdens without significantly improving safety or, possibly, improving it at all. The NRC itself implicitly recognized the potential difficulty

associated with applying the policy to vendors and suppliers of safety-related components, stating, "while implementation issues (particularly in cases where such vendors and suppliers are outside of NRC jurisdiction) may be complicated," most comments support vendors maintaining a positive safety culture.

NEI's suggestion that the policy statement be applied to suppliers and vendors in a more limited fashion is based on two grounds. First, the objective of safety culture is already achieved by existing regulations to ensure the quality and functionality of safety-related components. For example, 10 CFR Part 50 Appendix B imposes stringent audit and quality control measures that ensure safety-related products meet safety specifications. In addition, 10 CFR Part 21 requires manufacturers of safety-related products to notify customers and the NRC of defects even after shipment and receipt of the product. Given that these vendors and suppliers produce physical components, the objectives embodied in the safety culture policy statement are already achieved by, and therefore are in essence duplicative of, the quality reviews and testing requirements specific to safety-related components. In other words, imposing safety culture obligations at a product-driven manufacturing facility is likely to be duplicative of existing regulations and processes, and therefore likely will not result in increased public health and safety.

Second, as a practical matter, the obligations potentially associated with the NRC's expectations for safety culture are likely to negatively affect the commercial viability of U.S. suppliers. This is likely to be the case for smaller suppliers or for those for whom the nuclear product line is only a small portion of their business. New administrative requirements would result in a cost premium being imposed on products being supplied by U.S. vendors. This would put U.S. manufacturers at a disadvantage to foreign suppliers, as licensees thereby may be driven to procure components from international companies outside of the NRC's jurisdiction. Imposing an additional and unwarranted burden on U.S. companies will make them less viable and drive business overseas without a commensurate increase in safety.

II. NEI Responses to Questions for Which NRC Is Seeking Input

(1) The revised definition of Nuclear Safety Culture is: "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." Should this be retained, as currently written, or should it be revised?

NEI believes this definition, developed by a panel of stakeholders, should be retained as written. It is written in plain English, calls for a collective commitment by leaders and individuals, and appropriately emphasizes the goal of protection of people and the environment. The scope of this definition is appropriate. We generally concur with the NRC staff's assessment of the need for changes between the initial and revised definitions, discussed at 75 Fed. Reg. 57084. Additionally, the implementing guidance should clarify the term "leaders" since it could be interpreted to mean union leadership, or others without responsibility for day-to-day plant operations.

The NRC conducted a workshop February 2-4, 2010 which asked a group of sixteen panelists, representing NRC licensees and certificate holders and other interested stakeholders, to address the NRC draft safety culture policy and its eight proposed characteristics. Panelists included representatives from the nuclear medicine, materials, industrial applications, labor, fuel cycle, new construction and operating reactor industries, as well as a member of the public, an attorney specializing in employee concerns and an Indian Community Tribal Council member. The workshop consisted of initial panel sessions, followed by separate breakout sessions (for reactors and new construction; materials – medical; and materials – Industrial and Fuel Cycle) in which additional input and suggestions were provided by an even broader audience of stakeholders and licensee and certificate holders.

The workshop's goal was to develop a single unifying definition for "Safety Culture" that would be applicable to the full range of licensees and certificate holders and could be used in the development of a final safety culture policy statement. The panel had available an earlier proposed draft definition, the Institute of Nuclear Power Operations (INPO) definition and several other definitions, including the International Atomic Energy Agency (IAEA). The definition which was developed is the subject of this question.

The panel felt this definition best represents what nuclear safety culture means to the community of NRC licensees and certificate holders and would be most useful in expanding the understanding and importance of nuclear safety culture in their communities. Thus the panel recommended this definition to the Commission.

After over six months of discussion, the industry continues to believe this definition will

meet the needs of the Commission in communicating what it means by "nuclear safety culture."

(2) Does including the safety culture traits in the SOP itself clarify your understanding of what the Commission means by a positive safety culture? If not, what additional guidance do you think is needed?

Yes, we believe that the inclusion of the traits in the SOP does clarify understanding of what the Commission means by a positive safety culture. It is important to note, however, that the SOP appropriately states: "The traits of a positive safety culture include, *but are not limited to*: ..." (emphasis added). This is important, because ongoing research may indicate other traits which may also be important to consider. Also, the next step, after development of the SOP with its definition and traits, is to develop industry segment specific common language to be used by the regulator and its licensee/certificate holder community. This is commonly referred to as a "third tier," below the definition and general traits. It may be that there are additional traits specific to particular industry segments, but not others, which should be added to the third tier.

We believe the eight traits developed by the stakeholders at the February workshop are applicable to all communities and should be retained in the SOP. Based on our six month outreach to our communities, we have not identified any additional traits which we believe are needed and would apply to all communities. The development of implementation guidance, training for NRC staff and inspection manual revision are critical to ensuring that industry is aware of and can meet NRC's expectations while not inadvertently compromising the safety of facility operations, their workers and members of the public. The guidance should also recognize that non-satisfactory performance on one trait does not, in and of itself, translate to an inadequate safety culture.
Finally, NRC should be mindful of the need for "plain language" in the guidance. It is essential that the NRC convey its message clearly and concisely so that every individual with a role in maintaining an adequate safety culture understands and applies the policy. Industry will support continued open and transparent dialogue on such matters and recognizes that this effort will require an ongoing commitment of resources by NRC, the Agreement States and regulated entities.

(3) Does the revised draft SOP provide a clear statement of the NRC's expectations that the regulated community should maintain a safety culture that includes balanced consideration of safety and security? If not, what changes or additions should be made?

The revised draft SOP does provide a clear statement of the NRC's expectations for a balanced consideration of safety and security. Like the other panelists at the February NRC workshop, NEI supports excluding the term security from the definition and the

enumerated traits. The staff discusses in the Draft Policy the various valid reasons supporting this omission; see 75 Fed. Reg. 57085. On this point, we note the NRC staff has developed a preamble to the discussion of the safety culture traits which explains that despite the omission of the term "security," both safety and security are "the primary pillars of the NRC's regulatory mission." We agree with that statement.

However, we continue to believe that there is an overemphasis on security in the SOP. Security is only one of several key programs and activities, such as emergency preparedness, quality assurance, occupational and public radiation safety, etc., which require a positive nuclear safety culture to be effective in protecting the public and the environment. Effective defense in depth requires a positive safety culture be applied to all areas, not just security, and not security more than others. Furthermore, there can be potential interface issues in other programs and potential conflicts, which must be addressed under the more general context of nuclear safety. No individual program or element of defense in depth should be singled out as more important than any other.

(4) Should a discussion regarding complacency be added to the SOP and/ or to the traits that describe areas important to safety?

No. While it is certainly true, as stated in the FRN, that "Complacency can occur because of long term success and repetition," we do not believe a discussion of complacency should be added to the SOP or traits. As also pointed out in the FRN, "this is already indirectly addressed in the traits (*e.g.,* Effective Safety Communication and Personal Accountability are traits that prevent complacency)." Several other traits such as problem identification and resolution, continuous learning, and environment for raising concerns also combat complacency.

Moreover, while the validation study, discussed in question five below, looked only at the power reactor community, it did not identify complacency as a trait worthy of separate mention. Interestingly, the validation study did identify a "questioning attitude" as a key trait. One could easily point out that a questioning attitude is an excellent tool for battling complacency. Complacency would only be part of the reason a questioning attitude would be a useful trait to consider for the SOP. Because complacency appears to be a sub element of numerous other traits, we believe it should not be called out separately at the SOP level. We will address a questioning attitude in response to the next question.

(5) In late August 2010, the Institute of Nuclear Power Operations (INPO) completed a validation study to assess the extent to which the factors that emerged from analyzing responses to a safety culture survey match the traits that were identified during the February 2010 workshop. Only individuals working at nuclear reactors participated in the survey. The study provides general support for the traits developed at the workshop; however, the study provides a slightly different grouping. Under the validation study,

there are nine traits: (1) Management Responsibility/ Commitment to Safety; (2) Willingness to Raise Concerns; (3) Decision-making; (4) Supervisor Responsibility for Safety; (5) Questioning attitude; (6) Safety Communication; (7) Personal Responsibility for Safety; (8) Prioritizing Safety; and (9) Training Quality. Four of these are consistent with the eight traits developed by the workshop participants, i.e., Management Responsibility is consistent with Leadership Safety Values and Actions; Willingness to Raise Concerns relates to Environment for Raising Concerns; Safety Communication relates to Effective Safety Communication; and Personal Responsibility for Safety is consistent with Personal Accountability. The remaining five traits identified in the study, i.e., Decision-making, Supervisor Responsibility for Safety, Questioning Attitude, Prioritizing Safety, and Training Quality, are not as closely related (although they are not completely dissimilar). This is new information. The NRC is seeking stakeholder comments on this information though the FRN and through the public meeting scheduled for September 28 in Las Vegas.

We believe that there are many potential ways to develop a list of key traits related to nuclear safety culture. The panelists at the February 2–4, 2010 workshop developed their list based on their subject matter expertise in their own industry segment, and came to common agreement on traits that apply across all industry segments based on discussion and consensus. The validation study described was based on a previous industry survey instrument developed by the Utilities Service Alliance using the INPO Principles for a Strong Nuclear Safety Culture, with the addition of questions from NRC staff.

Both approaches have their strengths and were very similar in their results. The following table shows the relationship of the two sets of traits.

Workshop Traits	Survey Factors
Leadership Safety Values and Actions in which leaders demonstrate a commitment to safety in their decisions and behaviors	Management Responsibility Supervisor Responsibility Decision Making Prioritizing Safety
Problem Identification and Resolution in which issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance	
Personal Accountability in which all individuals take personal responsibility for safety	Personal Responsibility

Workshop Traits	Survey Factors
Work Processes in which the process of planning and controlling work activities is implemented so that safety is maintained	
Continuous Learning in which opportunities to learn about ways to ensure safety are sought out and implemented	Training Quality
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	Willingness to Raise Concerns
Effective Safety Communication in which communications maintain a focus on safety	Communication
Respectful Work Environment in which trust and respect permeate the organization	
Not covered by Workshop traits	Questioning Attitude

From this table, it appears that the validation study did not highlight as most significant several of the traits identified by the panel (such as respectful work environment, work processes and problem identification and resolution). The area that the panel did not appear to identify was a questioning attitude. (Note that another comparison could align these sets of traits differently. What is important is that they overlap so well.)

It appears that the trait "questioning attitude" could be missing from the panelists' and the SOP list. Interestingly, the issue of complacency, asked in question four above, could be subsumed under the trait of a "questioning attitude." However, there was not an opportunity for the panel members to discuss any additions or deletions to its list based on the validation study and to develop a consensus opinion.

It may be that a questioning attitude, found to be a trait amongst the power reactor community by the validation study, is a valid high level trait of a positive nuclear safety culture for all communities, but there is no proof to say that it is. We would recommend, therefore, that the list of eight traits identified by the stakeholder subject matter experts be retained as is in the SOP. When the tier three, or individual industry segment, traits are developed, consideration should be given to including a questioning attitude.