

Mendiola, Doris

Subject: FW: 02-28-14 EnergySolutions LLC Comments on Conceptual Example of Proposed Risk Management Regulatory Framework Policy Statement
Attachments: CD14-0044 To NRC from Dan Shrum - Conceptual Example of Proposed Risk Management Regulatory Framework Policy Statement 02-27-14.pdf

From: Treesa Parker [mailto:tparker@energysolutions.com]
Sent: Thursday, February 27, 2014 4:29 PM
To: Bladey, Cindy
Subject: 02-28-14 EnergySolutions LLC Comments on Conceptual Example of Proposed Risk Management Regulatory Framework Policy Statement

Please see the attached comments from EnergySolutions. Hard copy will be sent via USPS. Please contact Dan Shrum if you have any questions regarding content.

Thank you,

Treesa Parker
On Behalf of
Dan Shrum
Sr. Vice President, Regulatory Affairs
801-649-2000
dshrum@energysolutions.com

11/25/2013

78 FR 70354

11

RECEIVED

2014 FEB 27 PM 5:57

RULES AND DIRECTIVES
BRANCH
125103

SUNSI Review Complete
Template = ADM - 013
E-RIDS = ADM-03
Add= M. Drovin (mx ds)

February 28, 2014

CD14-0044

Cindy Bladey
Chief, Rules, Announcements, and Directives Branch
Office of Administration
U.S. Nuclear Regulatory Commission
Mail Stop: TWB-05B01M
Washington, D.C. 20555-0001

Subject: Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement

Dear Ms. Bladey:

EnergySolutions is submitting the comments contained in the attachment in response to the subject notice. We appreciate the opportunity to comment on the U.S. Nuclear Regulatory Commission's (NRC) evaluation of risk management concepts in their regulatory programs.

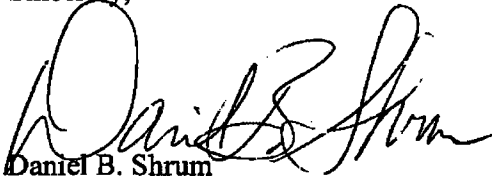
EnergySolutions supports the Commission's initiative to increase the emphasis of risk management in its regulatory approach. Our input is provided in the form of answers to the 26 questions posed in the subject *Federal Register* notice, which are attached. While we believe a risk-based approach could provide significant benefits to all parties, we strongly caution the NRC against adopting a single approach to risk management in light of the diversity of activities that NRC regulates and lack of adequate guidance on how a single approach can uniformly be applied across program offices. As the Commission seeks to establish a "one size fits all" risk management policy statement, EnergySolutions believes the current form of the proposed statement more closely resembles "one size fits none."

There are several critical elements of the RMRF policy that have not been adequately addressed. The policy statement does not clearly define defense-in-depth and does not define the application of defense-in-depth within the RMRF context. As a result, EnergySolutions recommends that the Commission continue to use the current PRA policy statement, but recognize that it could benefit from limited updates. We encourage the NRC to organize additional public workshops focused on improving risk-informed and performance-based regulatory approaches on a targeted basis for each program area (reactors, materials, fuel cycle, waste disposal, and transportation,).



Thank you again for this opportunity to comment. Questions regarding these comments may be directed to me at (801) 649-2109 or dshrum@energysolutions.com.

Sincerely,



Daniel B. Shrum
Senior Vice President
Regulatory Affairs

Comments on Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement

Overall Questions

(1) Is there a need for such a policy statement? If so, why? If not, why not?

Yes. *EnergySolutions* believes that the uses of risk management and defense-in-depth are inconsistent in how they are applied across the NRC's diverse portfolio of activities, and the policy statement itself is poorly understood by key stakeholders.

(2) Do you see any benefits in such a policy statement? If so, what are they? If not, why not?

Yes. Clearly defining how risk techniques can and should be used for each program area (e.g., reactors, materials, fuel cycle facilities, and disposal facilities,) for regulatory control would be useful in developing consistency among key participants. Additionally, clearly defining and providing examples of how defense-in-depth can be used in each regulatory area is a fundamental component of consistent and uniform regulation.

(3) How could the proposed RMRF policy statement be made more useful to licensees and/or certificate holders, applicants and other stakeholders?

In its current form, *EnergySolutions* does not believe the proposed RMRF policy statement is written clearly enough to ensure uniform application across all NRC activities. The utility of the policy statement would be greatly enhanced through the identification and designation of specific regulatory areas that have similar risk attributes and are amenable to similar analytical techniques. Each area can then be evaluated for suitable risk informing techniques and useful examples can be provided as to how these techniques would be useful in a specific area.

(4) Is the policy statement sufficiently flexible to address the specific program area activities (e.g., reactor versus transportation) with regard, for example, to the type of risk analyses, to the defense-in-depth principles?

No, the policy statement does not clearly address how it will be uniformly applied across various program area activities, and does not adequately define how the RMRF will be applied with existing defense-in-depth principles. Sufficient flexibility of the RMRF policy statement can only be achieved by its appropriate integration with existing defense-in-depth principles.

Defense-in-depth is generally stated in regulation as a "philosophy" or a "concept," and the term is used in only a few regulatory requirements

statements. Defense-in-depth has historically been demonstrated through the use of conservative assumptions and treatment of uncertainties in the selection of frequency and dose limits for use in defining and selecting licensing basis events (LBEs), performing deterministic analyses of design basis accidents (DBAs), performing safety classifications of Structures, Systems, and Components (SSCs), and developing special treatment requirements. Generally speaking, regulatory requirements are simply stated as “defense-in-depth shall be maintained,” with emphasis in the guidance on the use of risk-informed assessment to establish how much defense-in-depth is enough. In practice, defense-in-depth is generally applied through redundant and compounded conservatism assumptions in both design and programmatic areas. As a result of compounded conservatisms, defense-in-depth can lead to undue regulatory burdens on licenses. EnergySolutions believes that the lack of clarity in how the RMRF will incorporate defense-in depth has a serious potential to lead to even greater regulatory burden without providing safety improvements or reduction of risk.

It is important to recognize that the regulatory history of defense-in-depth came together over a long period of time during which Light Water Reactors (LWR) were the dominant technology undergoing regulatory review. A large body of defense-in-depth experience and insight was not developed for advanced, non-LWR designs because few non-LWR applications were reviewed by the NRC. This is also true of waste management practices. As such, much of the terminology and attributes used in the regulatory discussion on defense-in-depth is explicitly directed at LWR technology making it likely that while the RMRF might be appropriately applied to NRC activities involving LWR technologies, the same cannot be expected for other activities across the Agency.

EnergySolutions recommends that the Commission plan a series of workshops across the program offices aimed at explicitly identifying how the RMRF will be applied congruently with defense-in-depth, and to clearly articulate how the framework will be consistently applied across the Agency’s broad range and diverse program activities. Input should be solicited from a variety of stakeholders.

(5) What implementation challenges do you foresee?

The fundamental principle of risk management is informed decision making. This implies that the decision maker should have all pertinent information available and have the ability to balance a variety of factors to include mission, operations, and safety. Because of the complexity of the information involved in nuclear reactor and waste disposal risk management, risk decision criteria should be kept the finest level

of granularity possible. The Commission has not yet taken adequate steps to identify appropriate decision criteria.

As the RMRF currently stands, it is going to be difficult, if not impossible to consistently apply across diverse agency activities due to a significant level of ambiguity in the language used to differentiate defense-in-depth and the RMRF, and a lack of clear guidance on how the two will be applied congruently. Updating the current policy statement and addressing defense-in-depth as a separate matter would be a better approach.

An example of implementation challenges can clearly be seen in a comparison of current risk management approaches used for nuclear reactors which rely on PRA with nuclear fuel facilities that predominantly rely on Integrated Safety Analysis (ISA). In contrast to nuclear reactors, fuel cycle facilities rarely have similar systems and equipment. Because of the uniqueness of the facilities and the proprietary natures of their systems, the fuel cycle industry has not created shared databases of reliability information that are considered paramount to PRA approaches within the nuclear power reactor industry. For fuel cycle facilities, this information would need to be developed over time at a significant cost using scarce specialized human resources to enable PRAs. Also in contrast to reactors, fuel facility processes are typically much less interdependent. The differences in interdependency at a fuel cycle facility significantly reduce the need and value added for PRA approaches that are considered standard practice for nuclear reactor facilities.

EnergySolutions does not believe the White Paper defines risk-informed sufficiently to support consistent application across program offices while providing sufficient flexibility to support variability in risk assessment approaches. In order to develop the strategic vision described in the RMRF, it is essential that the Commission establish a comprehensive understanding of the meaning and application of both risk-informed and defense-in-depth in each program area.

Risk-informed, performance based regulations do not provide straight-forward criteria or thresholds for enforcement actions that are associated with traditional deterministic approaches. Enforcement of the RMRF still requires a significant investment in identification of appropriate performance-based measures of success. *EnergySolutions* does not believe the RMRF should be promulgated until these measures have been identified and vetted by a diverse group of stakeholders.

- (6) A policy statement generally states the Commission's expectation regarding a particular subject. How to meet the Commission's expectation is not included in the policy statement. If approved by the Commission, the staff plans to develop associated implementation guidance. What should be the scope and extent of this guidance to be helpful? For example,**

a. For program area of interest, what would be the appropriate decision criteria for determining adequate defense-in-depth?

Assessment of adequacy in a performance-based approach requires formulation of parameters or metrics of performance that directly or indirectly serve as objective indicators of achievement of functional objectives to the desired levels. One approach to assessing adequacy of defense-in-depth requires identifying performance parameters, establishing objective criteria, and incorporating flexibility in a performance-based approach. The decision criteria should include a clear definition of "safety margin" as the difference between two system states, the first of which is the expected state and the other is one in which a safety concern exists, or is an undesirable state for some other reason. If the magnitude of the safety margin is sufficient to support a performance-based approach, it may be possible to subdivide and apportion it in such a way as to consider multiple objectives. Performance measures can be proposed representing margins which can be subdivided, and appropriate decision criteria identified, within a performance-based approach. This one example of an approach highlights significant areas where the Commission needs to still provide guidance to ensure adequacy of defense-in-depth. As a result, *EnergySolutions* believes the Commission needs to more fully explore approaches to identifying and implementing appropriate decision criteria to determine adequate defense-in-depth and recommends the Commission consider a public workshop to receive stakeholder input from across the program offices.

b. What specific issues or actions should the guidance address in order to implement the policy statement for a particular program area (of interest)?

Program area workshops would be needed to develop such information.

(7) Does the proposed policy statement appropriately integrate security considerations into the RMRF? If not, why not?

Physical security plans for all licensees are designed to protect against sabotage and to promote the common defense and security. *EnergySolutions* believes that security considerations are more appropriately integrated into the proposed policy statement for reactors than for fuel cycle facilities. Unlike power reactors where permanent barriers and controls such as containment are built into the design and operation, defense-in-depth and risk-informed performance based safety requirements will vary considerably for each fuel cycle facility. Defense-in-depth and risk informed safety measures are continuing processes at most fuel cycle facilities, not one permanently established by the initial design.

An example of a failure to appropriately apply risk considerations can be seen in the ongoing rulemaking for enhancing ISFSI security requirements which has not been proposed in a risk-informed approach, but rather, layers another regulation upon existing regulations. There is still much work to be done to meet the Commission's goal of implementation of an agency-wide risk management framework that includes risk-informed security threats. Thus we do not find that the proposed policy statement appropriately addresses security considerations.

Sections I and II

- (8) Are these two sections (Background and Development of Risk Management Regulatory Framework Policy Statement) informative? Do they provide useful information in helping to clarify the need, purpose, goals, etc. of the policy statement in Section III?**

They are useful however they are not clear on how to balance defense-in-depth and risk considerations. This balancing will need to be addressed area by area to provide a clear discussion of how risk informed techniques can be used in conjunction with defense-in-depth in each area.

What information is not necessary and what type of information should be added if any?

Examples developed through targeted workshops with professionals in each program area will be needed to achieve the stated goals.

- (9) Is the purpose and goal of the proposed conceptual policy statement clear? If not, where is clarification needed?**

The goal to improve regulatory approaches used for program areas is clear. However, the discussion and explanation of how to improve approaches for each program area is deficient. A structured decision-making model for a fuel cycle facility analysis is not the same as for a reactor or waste disposal facility. Each program area should be examined on its own and program area workshops would likely be needed to clearly define how risk informed analytical techniques apply and how defense-in-depth can be used appropriately in that program area.

- (10) Is the proposed conceptual RMRF policy statement useful in clarifying the Commission's intent to use a risk-informed and performance-based defense-in-depth approach in performing its regulatory function? If not, what needs to be clarified?**

The policy statement is not clear. It confuses the relationship between risk-informed approaches and defense-in-depth. As noted in the NTTF recommendation 1, NRC should establish a logical, systematic and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations. The statement does not indicate how to balance defense-in-depth and risk considerations in the major program areas. As noted above, we believe that workshops targeted to the regulatory communities responsible for each program area would be a useful approach to develop examples suitable for guidance on how to balance defense-in-depth and risk considerations in any given program area. A one size fits all approach is not appropriate.

Section II

- (11) Should the current PRA policy statement (60 FR 42622, August 16, 1995) be replaced or subsumed/ incorporated into this policy statement?**

The PRA policy statement should be updated clearly articulating how the NRC views use of risk informing techniques for each of the major regulatory areas. The Commission should seek to establish a policy that will support efficient and effective oversight.

- (12) What would be the benefit? What would be the detriment?**

The intent of the PRA policy statement and the proposed policy statement are too similar to be addressed in separate documents. Should the Commission continue to pursue the RMRF, the policy should be clearly stated in one policy statement. The benefit of so doing would be to clearly articulate the Commission's expectations for the application of risk-informed decision-making. Failure to do so would waste resources in an effort to achieve consistency between two separate policy statements that overlap.

Section III.B

- (13) If subsumed, is the proposed manner of incorporating the PRA statement reasonable? If not, why not?**

No. If the Commission moves forward with a comprehensive RMRF policy statement, then the PRA statement should be replaced with a statement that more explicitly captures the regulatory requirements as applied to each program area.

The shortcomings of the PRA statement can once again be illustrated using the example of risk assessment requirements for a fuel cycle facility versus a reactor facility. Conducting a PRA is a complex, resource intensive undertaking. Properly done, a PRA relies on extensive databases that include

information on equipment reliability, test data for equipment performance under adverse conditions, as well as an understanding of plant operations and conditions and their relative importance to the risk at the facility. This data has been established over time at numerous reactor sites.

While no reactor may be identical to another, all have similar systems. As mentioned earlier, fuel cycle facilities rarely have similar systems and equipment. For fuel cycle facilities, the needed databases would be costly and difficult to develop while providing little additional safety benefit due to the lack of inter-dependent systems and other differences from reactors. Industry supported ISA as the preferable risk approach for fuel facilities long before (over 10 years) the NRC made a determination that application of ISA methods to recycling facilities is indeed consistent with NRC policy. The significance of this is that the PRA statement in its current form requires resource intensive oversight by NRC staff to evaluate the potentially broad range of risk assessment approaches across diverse program activities in order to make determinations on the consistency of these approaches with the Commission's policies.

Any update to the PRA statement should achieve, at a minimum, both safety goals and operational efficiency. The current PRA statement may or may not enhance the first of these two goals, but most certainly challenges the Agency in meeting the latter.

- (14) Should the policy statement establish a Commission expectation that for all program areas, licensees and/or certificate holders are expected to have a risk analysis that is commensurate with the activity and technology?**

No. Some areas that are clearly low risk should be addressed by assuring regulations specify minimum requirements that provide appropriate barrier and controls to prevent contain and mitigate exposures. No additional licensee risk analyses should be required beyond demonstration that the regulations are met. A graded approach should be developed for each program area, and for higher risk licensed activities, some risk informed analysis should be required.

Section III.A

- (15) Do the proposed key elements in the RMRF process represent a complete and reasonable set?**

Yes, overall the RMRF represents a complete and reasonable set of process elements. However, there are still many sub-elements that have yet to be incorporated into the framework including a clear definition of defense-in-depth and the relationship between defense-in-depth and the risk-informed, performance-based approach.

a. If not, what modifications should be made?

The Commission needs to clearly define defense-in-depth, specifically in relation to other elements of the RMRF.

b. Are other elements needed to cover the full spectrum of regulated activities?

EnergySolutions does not believe it is possible to identify all of the elements needed to cover the full spectrum of regulated activities without the benefit of targeted public workshops.

c. Are the elements sufficient to develop a consistent decision-making approach across all regulated activities?

No. The Commission oversees a broad range of activities over which the proposed RMRF will be applied. Successful implementation of the RMRF will be heavily influenced by the Commission's promulgation of guidance that will ensure consistent application of the rule.

Section III.C

(16) Should defense-in-depth be a key aspect of a RMRF? If not, why not?

Yes. Based on the extent to which defense-in-depth is embedded in the regulatory philosophy of the Commission, as well as the design of nuclear reactors, it is inevitable that it will be included in any regulatory framework. It would be counterproductive to consider an approach that did not include defense-in-depth. What is missing is a coherent approach for how to address defense-in-depth in various program areas within the context of RMRF.

(17) Will such proposed draft policy statement be useful in determining the extent of defense-in-depth needed in each program area?

Yes, application of the principal of defense-in-depth can and should be addressed in the policy statement.

(18) Is the approach proposed for characterizing defense-in-depth clear? If not, where is clarification needed? Is the strategy reasonable? If not, why not?

The Commission recognizes that the characterization of defense-in-depth can and should be made more specific for the various program areas to provide a consistent and coherent application of defense-in-depth elements across the NRC. This draft does not provide a consistent and coherent application of defense-in-depth elements for each program area. The strategy should include follow up workshops in each program area to establish how defense-in-depth elements can be applied in each program area.

(19) Is the definition provided for defense-in-depth clear? If not, why not?

The Policy Statement does not include a clear definition of defense-in-depth. The opening paragraph of § 3.C discusses what defense-in-depth employs and how it is implemented, but it nowhere includes a straight-forward definition of the concept. Furthermore, the opening paragraph states that the RMRF will be “based upon” an inclusion of defense-in-depth. We do not believe that it is appropriate to base a risk-informed approach on defense-in-depth, which is at its core a deterministic solution.

Historically, defense-in-depth has relied on redundancy, which may or may not have been the result of a quantitative assessment of the probability of failure of some particular structure, system, or component. Often defense-in-depth was employed to reduce the consequences of an event, not because the probability of the event was high, but because the consequences were intolerable. That is not to say that the application of defense-in-depth was improper or unjustified, just that it was not a risk-based decision.

We proposed the following as a definition for defense-in-depth:

Defense-in-depth is the use of multiple levels of defense to compensate for uncertainty and make a regulated activity more tolerant of failure, external challenge, or malicious acts. Defense-in-depth is intended to ensure that the failure of some or all primary barriers and controls does not result in unacceptable consequences from exposure to radioactive material. Defense-in-depth should be based on a risk-informed approach and should be implemented to reduce or mitigate risk.

(20) Are the key attributes identified reasonable and complete? If not, why not?

Attributes are not identified in the paper. Key elements are identified and they are reasonably clear. However, as noted above, element 4 is not helpful. Mixing risk-informed and defense-in-depth in the same element is confusing. Deliberating on the results of risk-informed analyses first and subsequently considering defense-in-depth based on the analyses would be an appropriate approach.

(21) Are the basic levels of prevention and mitigation reasonable? If not, why not?

Yes.

(22) Are the definitions of prevention and mitigation clear and reasonable? If not, why not?

a. **Are they sufficiently flexible to support all program areas? If not,**

where not?

No. The use of prevention and mitigation needs to be discussed on a program area basis. Without examples by program area it will not be clear how prevention and mitigation are applied successfully.

b. Should and can these levels be further detailed (i.e., more specific) and still be sufficiently flexible to support all program areas?

Yes. It is exactly because this can be achieved that *EnergySolutions* recommends the NRC not pursue a comprehensive RMRF policy statement until further detail is established.

(23) Is it reasonable to expect the levels of defense to be independent such that failure of one level does not lead to failure of subsequent levels? If not, why not?

Yes.

Should the NRC accept different levels of rigor, or different levels of confidence, in demonstrating that there is independence between levels?

Yes.

a. Could the level of rigor vary depending upon the nature of the activity and the risks associate with loss of independence?

Yes. This is the essence of the graded approach, which is reasonable to apply in this context.

b. Are there any other considerations that should be taken into account in determining the acceptable level of rigor or confidence in demonstrating independence between layers?

We are unable to provide additional considerations without the benefit of targeted public workshops to gather this information.

(24) Is it reasonable to expect the following with regards to defense-in- depth:

- a. Ensure appropriate barriers, controls, and personnel are available to prevent and mitigate exposure to radioactive material according to the hazard present, the credible scenarios, and the associated uncertainties; and**
- b. Ensure that the risks resulting from the failure of some or all of the established barriers and controls, including human errors, are maintained acceptably low consistent with the applicable acceptance guidelines.**
- c. Overall, ensure that each regulated activity has appropriate defense-in-depth measures for prevention and mitigation of adverse events and**

accidents.

d. If the expectations of a, b, or c are not reasonable, why not?

The expectations above are too vague to be meaningful. The use of words such as “appropriate,” “credible,” and “acceptably low” are highly subjective and lack explicit direction that is required from the regulation. Clear and concise examples are needed to show what appropriate, credible, and acceptably low mean within the context of specific program areas.

(25) Are the proposed defense-in-depth principles and decision criteria complete? Are they useful in deciding the extent of defense-in-depth needed in a program area? If not, how should they be improved?

No, that they are not complete. As noted above, the policy statement does not provide adequate definitions of defense-in-depth principles and decision criteria. Clear examples of how to address defense-in-depth are needed in each specific program area.

Section III.D

(26) Are the proposed program area specific policy considerations clear and complete? If not, what modifications should be made? Are others needed to cover the full spectrum of regulated activities?

EnergySolutions believes the policy considerations are not complete in their current form as they lack specific examples of how to conduct risk performance analyses by each program area. It should not be the purpose of this policy statement to define what the specific requirements are for each program area; however, it should list considerations that may apply. The extent to which these considerations apply to any specific activity can be addressed in implementing guidance. Additionally, it is unclear how defense-in-depth will be applied to each program area congruently with risk-informed, performance-based analyses.

EnergySolutions recommends that the NRC develop additional guidance on how each consideration should be applied across programs. An example of such a resource would be a reference matrix that includes a comprehensive list of considerations that can then be aligned with every program area to provide an easy-to-understand reference for licensees and stakeholders.