ENERGY*SOLUTIONS*

January 6, 2012 CD12-0002

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

11/22/2011
76 FR 72220
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Subject: Incorporation of Risk Management Concepts in Regulatory Programs, Docket ID NRC-2011-0269

Dear Ms. Bladey:

Energy*Solutions* 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 evaluation of risk management concepts in their regulatory programs.

Energy*Solutions* 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 eight questions posed in the subject *Federal Register* notice, which are attached. While we believe a risk-based approach could provide significant benefit to all parties, we would caution the NRC against adopting a single approach to risk management in light of the diversity of activities that NRC regulates. In that regard as described more fully in the attached responses, we propose that the NRC hold a series of workshops with stakeholders for the program areas cited in the FR notice (fuel cycle, reactors, materials, medical, transportation, waste management).

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to me at (240) 565-6148 or temagette@energysolutions.com.

Sincerely,

Thomas E. Magette, P.E.
Senior Vice President
Nuclear Regulatory Strategy

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RESPONSES TO QUESTIONS

1. **Do you believe there is a common understanding and usage of the terms risk-informed, performance-based, and defense-in-depth within the NRC, industry, and other stakeholders? Which terms are especially unclear?**

   Energy*Solutions* does not believe that there is a common understanding or usage of the terms risk-informed and performance-based across the various offices of the NRC. Generally speaking, it does not seem that the same level of confusion applies to defense-in-depth, most likely because the term has been in use across the nuclear industry for many decades. The other terms, particularly risk-informed, do not enjoy the same distinction. The same level of confusion (or lack thereof in the case of defense-in-depth) extends to an even greater extent outside the Commission.

   A good example comes from the December 1, 2011 meeting of the Advisory Committee on Reactor Safeguards (ACRS), during which members of the ACRS and NRC staff disagreed about the use of the term risk-informed. In discussions over proposed changes to the *Branch Technical Position on Concentration Averaging and Encapsulation*, there was significant disagreement over whether the staff approach was risk-informed. The difference of opinion was not resolved over the course of the meeting, which serves to illustrate the point that there is ongoing confusion over the meaning and use of the term.

2. **What are the relevant lessons learned from the previous successful and unsuccessful risk-informed and performance-based initiatives?**

   The multi-agency development of the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) guidance for the decontamination and release of decommissioning sites provides a good example of a risk-informed, performance-based initiative. This guidance allows flexible application of environmental restoration and monitoring techniques (risk-informed) while providing a clear performance standard (25 mrem) that the licensee can focus on achieving and the NRC can measure success against (performance-based).

   Another case, the multi-agency effort to develop release standards, provides an example of an initiative that was successful in some ways (the development of the standard) but not in others (adoption of the standard). For many years, NRC has cited Regulatory Guide 1.86 in license conditions for surface activity guidelines to release buildings, materials, equipment, and items.[1] Unfortunately, Regulatory Guide 1.86 limits are based on the limits of detection for equipment at the time of development (1974), which are not dose-based or risk-informed.

   In recognition of limitations associated with application of Regulatory Guide 1.86, the Health Physics Society, in conjunction with the American National Standards Institute (ANSI), published their recommended standard, *ANSI N13.12-1999 - Surface and Volume Radioactivity Standards for Unconditional Release*, which contains a dose-based regulation for clearance of equipment and materials having residual radioactivity. This was a consensus standard with ANSI Committee membership including DOC, DOE, DOD, EPA, NRC and

[1] U.S. Nuclear Regulatory Commission, "Termination of Operating Licenses for Nuclear Reactors," Regulatory Guide 1.86, Washington, D.C., 1974.

the U.S. Public Health Service. This is a good example of the application of a risk-informed approach, as the standard uses a primary dose criterion of 1 mrem/yr to determine release criteria and survey methodologies for the unrestricted release of items or materials that may contain residual levels of radioactivity.

Unfortunately, while the development of the standard is a success story, it has not been widely adopted by agencies or across Agreement State programs, and in at least one, has been rejected outright. More significantly, the NRC has also not adopted a dose-based clearance standard. This severely limits the usefulness of the standard given the potential complications stemming from interstate transfer and use of materials unconditionally released.

Another example with mixed results comes from the attribution of residual waste from incineration. After several years of process evaluation and discussion, the Tennessee Department of Environment and Conservation (TDEC), Division of Radiological Health granted an amendment to Energy*Solutions*' radioactive materials license to permit attribution of incinerator hearth ash to Energy*Solutions* as processor residual waste (as defined in Tennessee Regulation 1200-02-05, Schedule RHS 8-33 – state equivalent to Appendix G of 10 CFR 20). The technical basis included the inability to separate ash into distinct batches associated with each input charge, changes in radionuclide composition (partitioning) during incineration, and changes in physical and chemical form of the resultant waste. This is an example of successful application of risk-informed decision-making.

Unfortunately, this licensing decision has not been accepted by several other Agreement State programs and Interstate Compacts for reasons unrelated to health and safety concerns. As a result, manual cleanout and decontamination work inside the incinerator prior to burning wastes originating in these states is required. This results in additional occupational radiation exposure and introduces industrial safety concerns for no health and safety benefit. The lack of consistent recognition and acceptance of a risk-informed decision demonstrates the difficulty to be expected in implementing risk-informed regulation across multiple regulatory agencies.

A final example of the unsuccessful application of risk-informed regulation is found in 10 CFR 61.58. This regulation enables the Commission to accept alternate classification of the disposal of low-level radioactive waste as long as the licensee demonstrates compliance with the performance objectives in 10 CFR 61 Subpart C. This approach is sound, and in fact provides a good model for following elsewhere in the Commission's regulations. Unfortunately, it has been only marginally successful because the NRC regulates no LLW sites and the regulation has not been adopted by some of the Agreement States that do regulate active LLW disposal sites.

3. What are the relevant lessons learned from the previous successful and unsuccessful deterministic regulatory actions?

Energy*Solutions* recognizes that historically, deterministic requirements have served to provide a sound basis for robust facility designs. Deterministic requirements are inherently more straight-forward. It is clear to a licensee what is required for compliance and for an inspector to assess compliance. The cost of this simplicity is the imposition of requirements that in some cases provide no commensurate benefit to public health and safety.

An example of an unsuccessful deterministic regulatory action is the application of certain Part 61 requirements at Energy*Solutions*' Clive facility. The Clive facility is located in the west desert of Utah and is underlain by groundwater that is highly-saline and non-potable. Thus the site is well suited for waste isolation. Deterministic license regulations require a deterministic inadvertent intruder scenario (e.g., assuming a member of the public moves onto the site at some point in the future, digs a drinking-water well, grows a garden, and constructs a home). This requirement is imposed despite the fact that to consume the groundwater at Clive would be fatal because of its salinity. To satisfy this deterministic requirement, Energy*Solutions* expends resources to demonstrate compliance with a standard that provides no associated protection of public health and safety.

4. **What are the key characteristics for a holistic risk management regulatory structure for reactors, materials, waste, fuel cycle, and security?**

In order to develop the strategic vision described in the *Federal Register* notice, it is important that the Commission establish a comprehensive understanding of the meaning and application of these terms. Nonetheless, Energy*Solutions* believes that it is important to recognize that while there may be merit in implementing a holistic risk management regulatory structure, the same regulatory approach may not apply uniformly to the regulation of reactors, materials, waste, fuel cycle, and security. Avoiding a one-size-fits-all approach would be crucial in the successful implementation of a holistic risk management structure.

In order to assemble an overarching management framework, Energy*Solutions* recommends NRC conduct public workshops specific to individual program areas to solicit input from affected stakeholders. We also suggest that prior to the workshops, the NRC develop, at a minimum, proposed definitions for the terms risk-informed, performance-based, and defense-in-depth.

5. **Should the traditional deterministic approaches be integrated into a risk management regulatory structure? If so, how?**

We believe it is both inevitable and appropriate that the Commission integrate deterministic and risk management approaches. Continuation of some deterministic regulation avoids the cost and delay associated with an agency-wide, comprehensive regulatory reevaluation. A combined regulatory management strategy is appropriate for some regulated activities, for example transportation, particularly given the desire of both DOT and NRC to improve conformance with international transport regulation.[2]

The acceptability of a package design used for repeated routine shipments is most efficiently judged against a specific set of deterministic criteria. However, the option of evaluation for acceptability under a risk-informed, performance-based system for domestic transportation should be made available for interested generators and processors. Currently, a licensee can use 10 CFR 71.41(d) (e.g., the Lacrosse Reactor Vessel Package) to demonstrate the acceptability of a single-use package under special circumstances. Expanding the applicability of 10 CFR 74.41(d) beyond single use would be one way the NRC could

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[2] DOT. "Hazardous Materials Regulations; Compatibility With the Regulations of the International Atomic Energy Agency," U.S. Department of Transportation, Federal Register 76:156, August 12, 2011.

combine deterministic and risk-informed approaches and further the NRC goal of achieving a risk-informed, performance-based management structure.

Another example of how the two approaches could be integrated in is the area of LLW disposal. A performance based approach to LLW disposal would evaluate a LLW system in a deterministic fashion, and investigate the uncertainties in a probabilistic fashion to inform the analysis. A performance assessment could be conducted to provide a reasonable assurance that performance objectives are met while using deterministic and probabilistic tools to help understand the risk on a site and waste-specific basis. The performance objectives should include worker protection, protection of the public via all dose pathways, and intruder protection, including an assessment of the probability of a spectrum of intruder scenarios.

6. **What are the challenges in accomplishing the goal of a holistic risk management regulatory structure? How could these challenges be overcome?**

There will be many challenges involved in creating the strategic vision of a risk management regulatory structure. Among them are:

NRC Resource Allocation – The staff recently presented the Commission with an analysis in response to COMGEA-11-0001 regarding the use of expert judgment that recommended "no further action at this time." Their basis was lack of resources. The Commission currently is struggling to apply resources to the implementation of the Fukushima Task Force. It will be a significant challenge to identify and deploy resources for such a comprehensive initiative, particularly given that resources already are in such short supply.

Agreement State Resource Allocation – Agreement States should be involved in both the development and implementation of the contemplated regulatory scheme and would be challenged in both regards. State budgets are under significant pressure, which would restrict the ability of this important group of stakeholders to participate in the initiative. At the implementation stage, they may be challenged to interpret and apply regulations that differ dramatically from those they historically have implemented; particularly if they have not meaningfully participated in the development of revised regulations.

Establishing Measures of Success – Risk-informed, performance-based regulatory schemes will not provide the straight-forward pass or fail criteria that most often are associated with deterministic approaches. Thus, they will require the promulgation of performance-based measures of success, which will likely prove to be a challenging task. A good example of such performance objectives are the performance objectives in 10 CFR 61 Subpart C. But even this example is controversial because the performance objectives, particularly 10 CFR 61.42 which addresses the inadvertent intruder, have been interpreted in a non-risk-informed fashion (intruder probability of 1) and because there is no clear standard of success (the current regulations specify no dose standard that must be met).

Consistency in Interpretation and Application – If licensees are given latitude to determine how they will meet established performance objectives, it is reasonable to expect a diverse set of approaches will evolve, increasing the regulatory agency burden and effort to ensure each receives fair treatment while also ensuring adequate safety. In order to avoid the situation exemplified by the Agreement State refusal to accept TDEC's approval of incinerator hearth ash attribution (presented in response to Question 2), state agencies not

only will require access to significant technical resources equipped to recognize and address interactions and promulgation of cross-disciplined uncertainties, but will need clear guidance. Notwithstanding this, it is likely that a restrictive Agreement State compatibility category will be required to ensure consistent interpretation, which will in itself increase controversy.

Treatment of Qualitative Assessment versus Quantitative Analysis – Recently, the NRC staff at the Commission's request addressed the question of whether the staff as part of its oversight of fuel cycle facilities should use qualitative or quantitative analyses (SECY-11-0140, Enhancements to the Fuel Cycle Oversight Process). This matter is still before the Commission; however, the same issues are applicable to the different types of activities that NRC regulates.

Data Availability and Sufficiency – As the NRC moves into the use of risk analyses in more of its regulatory programs, data will be needed, especially for quantitative analyses. It is not clear that data is available of sufficient quality and quantity to support analyses for all activities that the NRC regulates. The cost and effort to obtain the necessary data should be factored into the decision process.

The best way to overcome these challenges is to prioritize those portions of the regulations that could best benefit from a risk-informed, performance-based approach. Energy*Solutions* recommends NRC conduct program area and facility type-specific workshops in which affected stakeholders can provide input. Using this input, NRC could assemble tailored management strategies, appropriately combining the benefits of deterministic and risk management strategies.

7. **What is a reasonable time period for a transition to a risk management regulatory structure?**

The NRC is currently and has for some time been undergoing a transition to risk-informed regulation. A concerted effort to transition to a risk-based structure would be a large-scale effort. Given that significant rulemakings routinely take the Commission many years, it is hard to foresee how such a fundamental change to a risk management structure could be accomplished in less than a decade, if that.

It is not clear that a comprehensive transition is warranted or prudent. It also is not clear that the Commission ultimately intends to propose something so sweeping. While there are advantages to adopting more risk-informed regulations in certain cases, it is equally true that current deterministic approaches suffice in others. Changing regulations is burdensome to both the Commission and its licensees. We propose that the Commission be driven by the input to its Question 8 to identify areas where a risk-informed approach would be most valuable and select those portions of its regulations that merit change. This would also inform the Commission and its stakeholders as to a reasonable schedule. An effort to arbitrarily select an implementation timeline is premature for a variety of reasons, including the lack of definition of risk management regulatory structure, the absence of undue risk to the public health and safety of existing regulations, and the cost to the NRC, its licensees, and other stakeholders of major changes to NRC requirements.

8. From your perspective, what particular areas or issues might benefit the most by transitioning to a risk management regulatory approach?

Energy*Solutions* believes that one part of the NRC regulations that is ripe for full conversion to a risk management regulatory approach is 10 CFR 61, Licensing Requirements for Land Disposal of Radioactive Waste. The current regulations are based on generic analyses of a composite waste stream at an assumed site. This approach was logical when the regulations were promulgated over 30 years ago, but no longer suffices in today's world, where we have the data and means to analyze the disposal of existing waste systems: the actual waste, packaging, disposal methods, and environment of a specific site. There is a rulemaking underway that would make strides in this direction, although as currently envisioned by the staff, it does not fully incorporate a risk-informed approach.

Many aspects of Part 61 would benefit significantly from a performance based approach. For example, as currently constructed, there is a conflict between providing protection for the inadvertent intruder (10 CFR 61.42) and the obligation to minimize occupational exposure (ALARA). Maximizing intruder protection literally results in increased worker dose not only in our processing facilities, but for the workers at other processors' and generators' facilities. A risk-informed approach would recognize this conflict and require risk-based consideration of these impacts.

A transformation of 10 CFR 61 to a risk-managed paradigm would allow licensees to continue operations in a manner that optimally reduces occupational exposures from current activities, while continuing to demonstrate risk-informed, performance-based protection of a hypothetical future inadvertent intruder. Ideally, it also would allow each site to develop performance-based waste acceptance criteria that would enable a more thorough utilization of the disposal asset while still satisfying the performance objectives of Part 61. Risk-informing Part 61 would reduce the unnecessary regulatory burdens resulting from the current deterministic approach.