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U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001

Comments on NRC–2011–0269 Incorporation of Risk Management Concepts in Regulatory Programs

The Penn State Breazeale Reactor (PSBR) appreciates the opportunity to participate in the Commission initiative to develop more a holistic risk informed and performance based regulation framework.

The feedback provided is based on an understanding of research and test reactors (RTR) and the associated regulation as applied to them as well as licensees possessing radioactive sources for other research activities.

Discussion:
The evolution and implementation of risk/performance based approaches in the power reactors has had a long slow evolution. In the original approach of the Commission (AEC) to RTRs, the extraordinary low public risk was well understood and was clearly evident in the regulatory approach. The AEC followed the statutory requirements contained in the Atomic Energy Act (AEA) to "*impose only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations under this Act to promote the common defense and security and to protect the health and safety of the public and will permit the conduct of widespread and diverse research and development.*" The Commission sought to "*exercise its powers in such manner as to insure the continued conduct of research and development and training activities in the fields specified below, by private or public institutions or persons...*"

Over the years, the separation of the responsibilities between DOE and the NRC, loss of expertise, and "regulatory creep" has slowly increased regulation and diminished resource support for RTRs. Fewer resources at the facilities and increasing regulatory burden has contributed to the highly visible result that there are far fewer operating facilities today with more in danger of closing. It is not clear that the Commission (DOE and NRC) have a holistic view of their combined responsibility under the AEA to *insure* the continued operation of these facilities.

A graded approach is used for inspection and rule activities for RTRs. But any new vision for a holistic risk based approach regulation should (for RTRs) start with reexamination of the existing statutory basis for regulation and the risk presented to the health and safety of the public by the facilities.

Given the small source term contained in these facilities and the lack of a stored energy to provide a dispersion driving force, the true risk presented by the facilities is the radiological and industrial safety risk to workers in the facilities, financial risk to the institutions, loss of critical infrastructure if the facility were disabled, and risk to facility and NRC public credibility. The health and safety of the public will not be affected.

Specific 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?*

In general the answer is yes, there is understanding. But an absence of performance metrics leaves the RTR community thinking in terms of a lack of events means that performance is good and additional regulation is therefore unnecessary. This interpretation does not consistently align with the NRC staff when discussions regarding the basis for additional regulation occur. The same can be said for risk informed. The RTR community sees the risk (to the health and safety of the public) as the basis for regulation, but the NRC sees other less tangible risks and political considerations.

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

Stakeholder involvement, thorough analysis and response to stakeholder input, and clear justification of the performance and risk basis for decisions result in better regulation that is understood by the stakeholder.

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

The NRC has a process to involve stakeholders that presents the opportunity for successful regulation. No stakeholder wants additional regulation and it seems (to the regulated) that the decision is to regulate vice seek cooperative compliance with a common goal. Unsuccessful regulation has had unintended consequences when stakeholder feedback is not adequately considered, cost benefit analysis are forced fit, and regulatory deadlines met but without stakeholder buy-in.

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

Simply put:

- Internal communication within the NRC to prevent overlapping regulatory impact
- Concept/Goal/Outcome based regulations
- Dedication to the principals outlined in the (several) Presidential Directives on Plain Language and Improving Regulation
- Stakeholder input
- Response to stakeholder input
- Science

In reference to the bullets above, holism has to start with the NRC recognizing that adding more regulation should not be the goal of the organization and rule making should not occur in the isolation of the section in charge of the rule. The NRC is highly compartmentalized - one group in charge of a rule will acknowledge that another similar rule will have impact but choose to ignore that to meet their rule-making goals. Regulations tend to be "rule-oriented," legalistic, and overly specific -- instead of conceptual, outcome or goal oriented. This is publically presented as necessary for clarity and to prevent interpretation. Yet significant interpretation remains and is lost in the source documentation. There have been Presidential Directives on "Plain Language in Government Writing" and the recent Executive Order 13563 – "Improving Regulation and Regulatory Review" that the NRC needs to seriously consider. There is little evidence in recent regulation to show compliance to the principles in these Directives. Stakeholder input and serious response to stakeholder input have already been discussed above. And lastly and perhaps most difficult in government, rules should have basis in science, not politics.

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

Organizational inertia, lawyers, stakeholders, and politics. To have a real change, the same consistency of organizational direction and vision that has driven the NRC and the stakeholders to make this nation's power reactor industry the best in the world must be applied to the goal of a new regulatory framework.

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

Ten to fifteen years.

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

From the perspective of my RTR interests, ALARA, RTR relicensing and license amendments, guidance as opposed to regulation, consultation and advice in addition to rule-based inspection.

Again, thank you for allowing me the opportunity to participate in this open discussion. If you would like to discuss any of these comments please do not hesitate to contact me.

Sincerely,

Mark A. Trump
Associate Director for Operations

cc: K. Ünlü
TRTR