PUBLIC SUBMISSION

As of: January 03, 2012
Received: January 01, 2012
Status: Pending_Post
Tracking No. 80f8c2b7
Comments Due: January 06, 2012
Submission Type: Web

Docket: NRC-2011-0269
Incorporation of Risk Management Concepts in Regulatory Programs

Comment On: NRC-2011-0269-0001
Incorporation of Risk Management Concepts in Regulatory Programs

Document: NRC-2011-0269-DRAFT-0001
Comment on FR Doc # 2011-30098

11/22/2011
76 FR 72220
1

Submitter Information

Name: N Prasad Kadambi
Address:
15015 Notley Road
Silver Spring, MD, 20905
Submitter's Representative: N. P. Kadambi
Organization: Kadambi Engineering Consultants

General Comment

Responses to questions in FRN with Docket No. NRC-2011-0269 have been provided in the attached file.

N. Prasad Kadambi

E-mail: npkadambi@verizon.net

Attachments

FRN Response_ File for Regulations.gov

SUNSI Review Complete
Template - ADM-013

E-RIDS = ADM-03
Add - C. Lui (CXL)

Docket No. NRC-2011-0269
Response to Questions by N. Prasad Kadambi

Incorporation of Risk Management Concepts in Regulatory Programs

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?

Experience shows that there is a lack of common understanding of many of the key terms related to using risk management techniques in nuclear regulation. The terms risk-informed, performance-based and defense-in-depth were formally defined by the Commission in the SRM to SECY-98-144 (White Paper on Risk-Informed and Performance-Based Regulation) for the benefit of NRC, industry and other stakeholders, but the Commission did not follow through by insisting on applying the definitions in subsequent activities. If the Commission had appropriately followed-through on the White Paper, various weaknesses with the definitions would have come to light and a process of continuous improvement in the terminology might have occurred. The definitions have more-or-less been reiterated in the NRC's Strategic Plans over the years, but most people involved with interactions with NRC staff do not even know that these definitions exist. The following address some of the elements of confusion in applying the terms and point to some key experiential evidence of how NRC's own deficiencies have contributed to the problem:

Risk-informed vs. Risk-based: The confusion that is generated by these two terms has detracted from the appropriate use of probabilistic methods in relation to deterministic methods. In the name of being properly risk-informed, probabilistic methods have gone off into a tangent of directing industry toward generating a "gold-plated PRA" instead of focusing on gaining system insights. Anecdotal information clearly points to a problem where risk applications have been stymied because numerical criteria have inappropriately and unnecessarily become the only focus of discussions in licensing and oversight.

Prescriptive vs. Performance-based: We need to recognize that a prescriptive approach makes regulation much more convenient. However, after a couple of decades of experience, the Commission and the staff reached the conclusion that although prescriptive approaches have a role, prescription alone is just the wrong way to pursue effective regulation. The Commission's processes seem to assume that conclusions such as these automatically guide future Commissioners and staff. The need to address enforcement of requirements has inevitably and appropriately drawn attention to the difficulties that attend a performance-based approach. A conventional wisdom has taken hold that requirements have to be prescriptive so as to assure proper inspection and enforcement. The Commission faced the need to deal with this issue in the 1990s and came out with a paper on "Safety and Compliance" (SRM to COMSAJ-97-008) dated August 25, 1997. It is clear that NRC staff is expected to focus on safety while it also enforces requirements. This is clearly relevant to performance-based approaches where the goal is optimal safety outcomes. Unfortunately, NRC practice frequently drifts into compliance with prescriptive requirements instead of safety outcomes. If NRC policy focuses on safety outcomes, performance-based regulatory approaches may garner greater support than apparently it currently enjoys. Without NRC leadership, this

holistic perspective on promulgation of regulations and enforcement of requirements will elude nuclear technology, much to the detriment of society at large.

Defense-in-Depth: Defense-in-depth constitutes a particularly thorny issue in relation to a holistic regulatory system. Its absence is most likely revealed during significant events when it may be too late. Its contribution during normal times is likely to be very difficult to quantify by a simple performance monitoring program. Hence, developing a common understanding of such a term is particularly challenging. The White Paper definition appears to address the most important aspects of defense-in-depth, but has not drawn much support. However, there is a consensus among technical experts that the adequacy of defense-in-depth is evidenced by designs that have sufficient redundancy, diversity and independence relative to key safety functions. It is quite possible that reviewing for the adequacy of defense-in-depth will require employing a strongly structuralist approach (as opposed to a rationalist approach). These are some of the key points that need to be considered for clarifying how to reach a practical understanding of what constitutes a sufficient level of defense-in-depth. Again, Commission leadership to take account of such philosophically challenging concepts and following through into regulatory practice is crucial if progress is to be achieved.

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

A somewhat successful risk-informed and performance-based regulatory initiative is the reactor oversight process (ROP). The key lesson to be learned from this experience is that time and effort invested in clearly defining an objectives hierarchy makes a huge contribution to optimizing safety regulation. If this structure had been available when the Commission was working on COMSAJ-97-008 regarding "Safety and Compliance", it is likely that "green" inspection findings would have been offered as examples that show that safety can be appropriately and adequately served even though compliance deficiencies may exist. It may also illustrate the point that regulatory efforts focused only on maintaining compliance (i.e. efforts to correct every "green" finding immediately) does not guarantee nor promote safety. By structuring safety objectives in a transparent way, the ROP has done more than anything in recent memory to foster confidence in regulatory oversight.

An unsuccessful initiative was the staff's attempt to develop a so-called technology neutral risk-informed and performance-based regulatory framework in NUREG-1860. The most technically sound critique of this work by Prof. Graham Wallis has been virtually ignored. Also ignored has been the fact that performance-based regulation is addressed in name only in NUREG-1860. The massive document contains no more than about 5-6 pages addressed to performance-based approaches, and even in that ignores the most salient developments from the research NRC sponsored on performance-based regulation. Although NUREG-1860 makes reference to NUREG/BR-0303, all the other documents that deal in more detail with structuring of objectives, finding appropriate performance indicators, defining safety margins, treatment of uncertainties, and using incentives appropriately to enhance safety focus have been ignored. This work is an example of how individual agendas can cast a shadow over the work at noble institutions such as the USNRC.

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

The answer to this question properly begins with defining what "deterministic regulatory actions" means. While the White Paper attempts a definition using language from the PRA policy statement, I feel that the answer should begin at a more fundamental level. One needs to probe why the philosophy of "determinism" found relevance in regulation of safety, and how the application of this philosophy has affected the regulatory mind set.

I posit that Rene Descartes' determinism was invoked because it is so much easier to practice than to deal with the difficulties of treating uncertainty posed by probabilistic approaches. Determinism has been a part of the foundation of conventional engineering practice for centuries. Descartes' "Rules for the Direction of the Mind" have become so entrenched that only rare and isolated challenges have occurred. Rule 2 of Descartes' "Rules" holds that we should only study objects about which we can obtain "certain and evident cognition." It is better not to study at all than to attempt a study when we can't tell what's right or wrong, true or false. All that is speculative or probable should be rejected and knowledge should be defined as what can be proven by reason beyond doubt. Given the state of knowledge in nuclear technology in the 1950s and 1960s, Rule 2 would have killed (as some still seek to do) this new industry. Deterministic regulatory actions came about as a defensive maneuver against the uncertainties of a new technology in the mid-20th Century.

The current deterministic regulatory approach that is exemplified prominently by the use of design basis events began with the postulation of "maximum credible accidents". There is no need to consider uncertainty if we confine ourselves to the domain of that which is credible and we build sufficient margins within extremely adverse postulated events. This approach created the stylized LOCA as the regulatory touchstone. If this approach is rigorously applied in the post-Fukushima era, every coastal site for a nuclear power plant would have to be designed to withstand a 50 foot tsunami. It appears that we will avoid sinking into that abyss, but the activities around finding the right regulatory approach to deal with extreme natural phenomena hazards shows that the concepts of risk management have become a necessity today and not just a nice ornamental feature to include in safety analyses.

The lesson to be learned from the basic success of the deterministic approach to safety is that the design basis event approach works well most of the time, and where we know that it works well, the regulatory process can be implemented in a relatively simple manner. Modern methods of safety analysis show quite well where it should not be expected to work very well. This is where probabilistic approaches need to be employed even though it becomes much more complicated as to how performance criteria for SSCs would have to be specified. Use of seismic margins analysis is an example of how a practical probabilistic method can help without necessarily invoking a "gold plated" PRA.

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

A holistic risk management regulatory structure must first be formally defined so there can be societal consensus on its attributes. Along with the characteristics spelled out in this FRN for risk management concepts and approaches, the holistic part of the approach should include the idea of providing context for the analysis and the decision

making. The absence of context in the post-Fukushima analysis should be very disturbing to the technical community. Even though it has become abundantly clear that the health impacts of the nuclear incidents at Fukushima will be relatively minor, discussions of the earthquake and tsunami continue to ignore the tens of thousands of dead, and the huge devastation and suffering visited on the Japanese people by this unlikely natural event. The NRC should take the leadership in assuring that overall protection of public health and safety means that the radiological consequences of any accident are prioritized appropriately within the larger picture of the public health status in the area surrounding the plant. Miniscule quantities of radioactivity detected off-site should not draw vital resources away from activities that are likely to promote public health much more effectively.

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

As pointed out in response to Question 3 above, the traditional deterministic approaches work quite well over most of the safety domain subject to regulation. The experiences of the ROP and RTNSS have enabled the NRC to better define the boundaries where alternatives to the traditional approaches make more sense. The framework for a risk management regulatory structure should provide for a smooth transition where departure from the strict deterministic methods would, first, be permitted, and then may be required. In practice, such a framework may resemble quite closely the way things are done today.

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

The first challenge is to escape the "gold plated" PRA trap. We need to realize that everything we do relative to safety regulation is risk management. Using deterministic methods in a domain where its benefits are appropriate to seek is as much risk management as constructing a sophisticated PRA to help with safety regulation. There is a continuous spectrum of possibilities, with robust safety margins incorporated in designs using traditional methods occurring on one end, and on the other end we would find risk-informed decision making employing a "gold plated" PRA. Experience shows that there is likely to be diminishing returns from traditional methods as complexity of designs increase, and the knee-jerk reaction of just increasing safety margins becomes less and less cost effective. As PRA methods become the better tools to employ, the quality and sophistication of the PRA becomes more situation dependent, and a "one size fits all" approach should be avoided.

Beyond the methodological challenge of where and how to use a PRA appropriately, the key conceptual challenge lies in the incorporation of defense-in-depth. If one accepts a "structuralist" notion of defense-in-depth, determining the sufficiency of defense-in-depth is likely to always be a judgment call. Careful monitoring of operational events is probably going to provide the best indication of defense-in-depth sufficiency.

Beyond adequate safety margin and sufficient defense-in-depth, a holistic risk management regulatory structure would tackle the societal context in which regulation of radioactive materials is practiced. Currently, by any reasonable and objective safety assessment, much more is demanded of radioactive materials' regulation than other hazards. Even if we grant that this will always be the case, one can still look for a more

transparent articulation of the safety case so society is better able to gage what benefits accrue from the additional costs.

Some of the work sponsored by the NRC and published as NUREG/CR-6833, "Formal Methods of Decision Analysis Applied to Prioritization of Research and Other Topics" is likely to be useful in this endeavor. One of the techniques addressed in this work is to answer the question, "What are the potential likelihood and consequences of being either right or wrong about the decision criterion set in respect of any particular issue?" This is a more generalized formulation of risk management and a better approach than focusing on building better PRAs.

In this context, it is apparent that the Commission's Safety Goal Policy Statement, which attempted to address larger societal issues, is outdated. This does not mean that the technical arguments in the Policy Statement have been shown to be wrong. It just appears that the simplistic manner in which qualitative and quantitative objectives were laid out for radiological consequences are somewhat naïve in the current political climate.

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

An action plan that goes out to about five years appears reasonable and practical under present circumstances. The action plan should incorporate plenty of public interaction and ensure that it is international in scope.

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

The principles of a risk management regulatory approach should provide the central organizing framework for use of all radioactive materials. The regulatory approach should draw on lessons from all areas of application, including medical diagnostics and therapy. The framework should be implemented as a response to Commission direction that the staff and industry, working with international counterparts, develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach. The outcome should be defined to include providing options ranging from a complement to or alternative to the existing regulatory framework. It is entirely practical to pursue this work in a modularized fashion so that not all the work needs to be performed sequentially.