Gallagher, Carol

Subject: FW: Comments from STP
Attachments: Comments to Apostolakis FRN.docx

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From: Grantom, Carl [mailto:crgrantom@STPEGS.COM]
Sent: Thursday, January 19, 2012 3:45 PM
To: INFOCOLLECTS Resource
Cc: Lui, Christiana
Subject: Comments - Reference: Federal Register Notice (NRC-2011-0269) on Incorporating Risk Concepts into the Regulatory Programsto Apostolakis FRN.docx

Please find attached comments relative to FRN [NRC-2011-0269].

If you have any questions, please feel free to contact me.

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SUNSI Review Complete
Template = ADM-013

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

NUCLEAR REGULATORY COMMISSION
Federal Register Notice [NRC–2011–0269]
Incorporation of Risk Management Concepts in Regulatory Programs

The task force is seeking stakeholder input on the following questions to assist in its work. The task force will use the comments received to inform its deliberations, and its report will address the key issues raised in the comments which are relevant to task force activities. However, the task force does not plan to prepare a detailed response to individual comments or prepare an analysis of comments.

The comments offered in this document are structured for each question contained in the subject Federal Register Notice.

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?

Comment: No, there is not a common understanding and usage of the terms risk-informed, performance-based, and defense-in-depth within the NRC, industry and other stakeholders. All three terms, in the opinion of this commenter, are unclear. Across NRC, industry, and other stakeholder organizations if there is an understanding it is a high level understanding that risk informed means some element of risk analysis is incorporated and that performance-based means that some elements of operating experience is include. What are missing are the criteria, scope, level of detail, applicability, and regulatory process that transforms an initiative from being non-risk informed to "risk-informed" or "performance-based". The degree to which something (i.e., regulatory action or rule) is not risk informed/performance based and then becomes risk informed/performance based is not defined in any regulatory mechanism to the extent needed for consistent and practical organizational application (i.e., no criteria).

There needs to be clearer definitions of how to determine the degree to which something should be risk informed with a clear technical basis supported and guided by associated processes/procedures/approvals for accomplishing it. The terms are not broadly or consistently applied in the regulatory structure as most of the "risk-informed" efforts to date have been associated with the reactor side of the scope with little to none in other regulatory areas such as physical security, materials, etc. There should be no exclusion of risk informed application to any regulatory requirement or jurisdictional area without proper technical justification and, such justification should, de facto, include risk information in the determination.

A regulatory process requiring the incorporation of risk analysis (both quantitative and qualitative) through a systematic approach (ensures a consistent, technically acceptable analysis is performed) should be developed and deployed in the regulatory processes with supervisor/managerial oversight. This systematic approach should contain generally accepted features of comprehensive risk informed processes (e.g., analysis, modeling, operating experience, decision criteria, periodic feedback, and oversight). These same elements should also be included for regulatory/industry programs or initiatives that are characterized as "performance-based".

The process for risk-informed applications is described at a high level in RG 1.174 but is not detailed enough to allow effective incorporation and implementation by organizations. Additionally, the process and oversight for incorporating risk insights into regulatory programs does not appear to be consistent across NRC organizations. Regulatory risk implementing procedures and processes applicable to all NRC organizations should be developed requiring the use of risk information with appropriate due diligence mechanisms to ensure that the proper level and scope of risk information/analyses has been appropriately applied.

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

Comment: Lessons learned from previous risk-informed and performance-based initiatives are characterized as process and governance related. Without upper level and executive management involvement with well defined, oversight provisions and documented expectations, risk-informed and performance-based initiatives are less likely to be effective or successful. Risk informed performance indicators are essential and should be defined as a part of the project/initiative development. Organizational philosophical differences and biases exist in both NRC and industry organizations which indicate that the intent of risk-informed and performance-based programs is not well understood or consistently understood.

Risk-informed and performance based programs are sometimes viewed as relaxations of regulatory requirements instead of programs that optimize safety. In this commenter's opinion there is a legacy issue with the NRC in that, deterministic analyses and methods used to support regulatory requirements are viewed to be more comprehensive (i.e., better) than risk informed (i.e., licensees get less regulated and can do what they want). This is not a true or accurate reflection of the risk informed regulatory process. This commenter points out that under many deterministic regulations or other deterministic regulatory solutions there are no compensatory measures required, no mandatory considerations for defense-in-depth, no mandatory considerations regarding safety margins, no consideration of uncertainties, no requirements for feedback or lessons learned. Commercial nuclear operating history has demonstrated that using strictly deterministic methods to establish regulatory programs and rules for the nuclear industry does not necessarily protect against events that may occur during the operating life of a nuclear power plant that can lead to significant events (i.e., Fukushima). Design basis events are rare since they are, for the most part "designed away". The design basis concept does perform an important role is designing, fabricating, and erecting robust components and equipment; however, it does not account for "operational basis events" (events reasonably expected to occur during plant lifetime) where procedures, processes, and human/organizational actions are required. In this commenter's opinion risk informed regulation is more robust and effective than deterministic regulation since it includes considerations of both and also factors in safety margin, defense-in-depth, and

feedback. Focusing on postulated worst case conditions as done in deterministic approaches does not, de facto, improve safety margin or defense-in-depth and further does not require any further consideration of significance or effectiveness of a new or revised regulation. When used in combination in a balanced and systematic way deterministic and probabilistic offer the opportunity to achieve both safety and effectiveness.

Another feedback item for this question is the related to the activities associated with developing and pursuing a risk informed regulatory initiative. In deterministic regulatory approaches the issue or concern may be different, but the process is the same. In risk informed approaches the issue or concern may be different, and the process is never the same. Each risk informed initiative seems to present a new opportunity to "reinvent the wheel" and this is not only with NRC but also with industry as well. Additionally, the degree to which deterministic criteria is used with or without risk criteria is not reviewed from a due diligence perspective. Use of deterministic criteria again gets preferred consideration without justification due to the opinion that the worst possible case will be bounding and cover all uncertainty. This has produces a high potential for misappropriation of regulatory and industry resources. The opinions of regulatory and industry reviewers many times took precedence over viable risk informed approaches without appropriate technical basis RG 1.174 is used but the understanding of the process to produce a RG 1.174 submittal seems to be new and different each time with a new set of players that have to be trained on risk informed approaches indicating that risk informed approaches are not socialized within the NRC.. Each risk informed application

10CFR50.65 can be pointed to as a success but the scope of the rule was not risk informed (required all safety related equipment to be included). In this commenter's opinion this is an example of the lack of criteria for risk-informed programs and initiatives relative to scope and level of detail.

Risk Managed Technical Specifications represents a successful risk informed initiative. It has elements of deterministic criteria with the 30-day backstop but allows for a quantitative configuration risk management program to be used to calculate "risk informed allowed outage times". A key lesson learned from this risk informed initiative is the "disconnect" between safety functions identified by the deterministic approach versus safety functions identified in the risk approach. In the deterministic approach assumptions are made relative to design basis accidents including postulated radiological dose. Based on the postulated dose from a design basis accident, equipment needed to provide a safe environment for control room operators under the postulated radiological condition was appropriately designed and installed as safety related equipment and included in Technical Specifications. Level 1 PRAs use core damage frequency as a surrogate for the safety goals and therefore dose is not a modeled function since, by definition, a core damaging event has already occurred and the radiological release is subsequently determined from Level 2 PRAs. Since Technical Specifications were developed on a system-by-system basis the importance of systems relative to the

safety functions that they support was based solely on judgment and not on a technical basis using criteria based on a defined figure-of-merit (i.e., CDF, LERF).

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

Comment: Deterministic methods have as a fundamental underlying principle that all uncertainty is accommodated by conservative, bounding approaches. Since TMI on through to Fukushima the assumption that worst case deterministic criteria will subsume all other scenarios has not resulted in the elimination of severe accidents or prevented recurrence of significant reactor safety events.Although many deterministic regulationsare appropriate and effective, some have resulted in onerous and administratively heavy processes that licensees must implement and NRC must regulate and enforce (e.g., physical security, fatigue rule). Many times reglatory issues and associated deterministic requirements are seenby owner/operators as the price of nuclear power plant operations. Individually, they may not seem too burdensome; however, taken in aggregate with all the attendant administrative processes, procecdures, inspections,, and subsequent process changes administrative regulations that are not directly associated with nuclear safety functions can be quite burdensome and result in compliance driven organizations. Additional resources may or may not be available which can lead to imbalances when station needs and conditions are high.. Additional organizational effects as a result of the overall level of effort and resource expenditures to comply with the regulation, these regulations can significantly divert utility resources from the administrative level up through the supervisory management level to account for deviations, interpretations, or other special contingencies requiring higher organizational levels of approval.

That being said, risk informed regulations have also had additional administrative burdens placed on them that has reduced their effectiveness; however, risk informed regulations with performance measures have the opportunity to be more easily streamlined and made more effective due to the requirements for feedback and lessons learned. Such contingencies are built into the risk informed approach and provide for an approved process mechanism that incorporates efficiencies while focusing attention and resources to issues/items of more significance. Currently, many risk informed regulations have deterministic riders that can be well intentioned and good, but some are restrictive and serve to complicate the risk informed process rather than improving the effectiveness (e.g., MSPI, 50.46a). It is important for any regulation be it deterministic or risk informed, to return data, information, operational experience, etc. that serves to improve the effectiveness of the intended requirement and not be "cast in stone" such that adjustments require burdensome regulatory processes to be employed (exemption, rule making, NOEDs, etc.). In fact, regulatory processes should be self adjusting based on events and should have risk significance included as a basis for regulatory self-adjustment.

Again, depending on the risk significance and the "legacy" significance of the issue there are ranges of effectiveness. The deterministic methods for regulations, thus far, has achieved a level of performance relative to the number of events determined to have regulator significance (a proposed performance indicator for purposes of this discussion). Likewise, risk informed, performance-based programs have also achieved a level of performance on a corrsponding basis. Of interest is the difference in the regulatory significance between the two approaches. This exercise if attempted it could illuminate strengths and weaknesses of each approach.

Since the majority of nuclear regulations are deterministic then the current performance level as indicated by number of significant events can be reasonably assumed to be an effectiveness measure for deterministic regulatory approaches. The key issue is how "significant" is defined. The current Reactor Oversight Program (Significance Determination Program) for reactor issues is, in the opinion of this commenter, a more objective way to establish significance since it is correlated more directly to nuclear safety functions. Using this as a means to determine significance would seem a reasonable approach to establish whether or not a certain regulation is effective at identifying, prioritizing, and precluding future significant events.

The previous discussion is offered in part because increasing regulatory burdens from recently enacted regulations (e.g., work hour rule) and proposed regulations (e.g., cyber security) do not allow for a risk treatment in the development of problem statements for the issue and do not allow for risk methods to be used for determining significance criteria for regulatory responses (e.g., increased monitoring, required regulatory actions, enforcement). Other significant regulatory requiremements such as those associated with physical security, materials, fuel cycle, etc. do not have appropriate risk informed significance criteria established which results in ever increasing burdens without reconciliation with respect to real nuclear safety significance.

The change that needs to occur in the regulatory process is that both deterministic and risk-informed approaches should be required to be used together in a blended, systematic manner to produce the best regulatory structure to support 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?

Comment: An appropriate vision for a holistic, risk informed, performance-based regulatory structure would be a risk informed regulatory process that can be applied generically across functional areas such as reactors, materials, waste, fuel cycle, and security. The vision expressed below is high level but its basis is rooted in classic risk analysis. (i.e., what can go wrong, how likely is it, and what are the consequences). This concept applied at an organizational level both horizontally and vertically can be powerful and can be adjustable as new information is presented. Organizational policies, processes, and procedures can be used in all organizational structures that

could be "rolled up" into overarching goals, objectives, and performance measures of the organization (e.g., NRC, Industry, etc.). Cross-functional issues could be identified, monitored, or corrected (e.g., risk benefit in one area may have a detrimental risk benefit in another). This vision would have to originate at the Commission level and be accepted by NRC executive levels. Pilot testing in each organizational area would allow for needed feedback and corrections. In a truly risk informed regulatory structure, a licensee could commit to that process for regulation and the NRC would have a special "rule" or mechanism to regulate based on the risk informed, performance based approach. All current requirements would be measured, monitored, regulated, enforced based on accepted risk criteria (some of which would be quantitative and some would be qualitative) that would become the new licensing basis. Since it is risk informed, there would be some regulations that might remain deterministic (e.g., fabrication, construction, erection) and some would be probabilistic (e.g., operational events, testing/maintenance, inspection, etc.).

In order to apply a risk informed process generically across such diverse functional areas, a high level risk assessment and evaluation process must be developed. Such a process would include identification of initiators/hazards, risk analysis (quantitative)/risk assessment (qualitative) of those initiators/hazards (includes assessment of the state-of-the-art, likelihood of the initiators/hazards, and the consequences of the initiators/hazards). This would be the first step in the risk informed, performance based regulatory process. All NRC organizations would be required to comply with the generic approach to identify initiators/hazards and establish a "risk statement" or position, which could be either quantitative or qualitative or a combination of both. Next, would be the requirement to develop risk informed decision criteria risk. These criteria could be tied to Safety Goal criteria, for example, or other accepted "goals" that may exist for the area in question (i.e., reactors, materials, waste, fuel cycle, and security). Next steps would be to establish accepted prevention/mitigation strategies, risk management strategies, and feedback/lessons learned (to improve based on experience).

Key characteristics for a holistic risk management regulatory structure are the capability of evaluating rare events or events that have not been observed in a dynamic and systematic process. This evaluation would need to incorporate a process for determining the proper figure-of-merit or risk metric appropriate for an enterprise or holistic risk management structure. An example is a risk metric for public health and safety which is supported to a significant degree by Level 3 PRAs. However, it is well known that other risk metrics will be necessary for other regulatory areas sufficient to cover the nuclear fuel cycle. One example could be associated with environmental aspects such as radioactive effluent releases (e.g., tritium). The risk metrics should address societal risk, environmental, physical security, personnel safety, and operational events.

Risk and Uncertainty will need to be a key factor that is included in all areas associated with the regulatory decision-making such as rule development, enforcement, and prioritization. Risk Thresholds or other risk criteria will need to be established in order to determine at what level of risk are regulatory requirements not required?

The case for transitioning needs to be defined. Reasons for transitioning to a risk informed structure include focusing resources on items/issues that are the most regulatory risk significant in an era when new plants will be built and additional licenses are added. Each functional area within the scope of the Task Force (i.e., reactors, materials, waste, fuel cycle, and transportation) should be evaluated. This evaluation would include the following:

1. *Identification of hazards that should be regulated*
2. *The likelihood that these hazards could occur*
3. *The consequences if the hazards occur*
4. *Identification of risk metrics and associated performance measures*
5. *Risk Assessments that would be needed to characterize the risks and associated contributors (either quantitative or qualitative)*
6. *Identification of mitigation and/or prevention strategies that would be required and regulated*
7. *Monitoring and Measurement strategies (e.g., Dashboards, Performance Indicators, etc.)*
8. *Periodic Feedback & Lessons Learned (Oversight Boards)*

The above evaluation would be performed across the current regulations and regulatory scope of documents such as Inspection Guides, Regulatory Guides, Proposed Rules, Enforcement Guides, etc. Specially trained risk management teams could perform these evaluations and provide the recommended regulatory structure for a risk informed alternative in the areas of reactors, materials, waste, fuel cycle, and transportation. NRC Staff would need new regulatory implementation guidance and procedures. This guidance would contain the criteria for reviewing/approving initial licenses, license amendments, and issues occurring during the facility's life cycle. This effort would seem to be even more important with the advent of new plants on the horizon.

Some items that have bee previously attempted by NRC and which could provide some information would be the technology neutral framework that was developed several years ago.
Get a pilot plant to work with NRC to develop the framework and associated processes. (Need to expand more here)

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

Comment: Traditional deterministic approaches appear to not have similar considerations and restrictions as risk informed approaches. This results in some having the opinion that risk informed approaches are too expensive and their outcomes are uncertain, whereas, deterministic approaches are less costly and their outcomes are more certain. In the opinion of this commenter, this is because less robust methods are applied in the traditional deterministic approaches. For example, the following is a

comment relative to DG-1226:

With regard to the following statement:

"Instead, in this regulatory guide, the NRC has chosen a more restrictive policy that would permit only small increases in risk and only when it is reasonably assured, among other things, that sufficient defense-in-depth and sufficient margins are maintained. This policy is adopted because of uncertainties and to account for the fact that safety issues continue to emerge regarding design, construction, and operational matters notwithstanding the maturity of the nuclear power industry. These factors suggest that nuclear power reactors should operate routinely only at a prudent margin above adequate protection."

This basis statement for the approach used in this DG is not an adequate technical basis for structuring a position that would, *"...permit only small increases in risk and only when it is reasonably assured, among other things, that sufficient defense-in-depth and sufficient margins are maintained."*

This reviewer bases this comment on the following"
The NRC does not define what "uncertainties" are of concern. Several NUREGs and other guidance documents have been published on addressing probabilistic uncertainties which have provided good guidance for addressing this issue. This reviewer is not aware of similar documents addressing "deterministic uncertainties". Thus, the NRC's basis that this DG's policy is adopted because of uncertainties is not defined and not objective. Additionally, the NRC states that safety issues continue to emerge regarding design, construction, and operational matters. With the risk informed Reactor Oversight Process being in effect over a number of years it would seem the NRC has significant data to be able to assess the risk significance of safety issues associated with design, construction, and operational matters such that this DG should be advancing the methods and criteria and not defaulting to a minimalist approach. This review contends that this DG should be structured to provide guidance on evaluating risk contributors and associated compensatory measures for risk informed, performance based applications consistent with the safety goal subsidiary objectives.

The above example illustrates the point that uncertainties are not systematically considered in traditional deterministic approaches but are a fundamental part of risk informed approaches. Examples of this kind are repeated globally across all regulatory sectors and, as Fukushima has demonstrated, reduces or eliminates discussions, considerations, analyses, etc. with regard to the spectrum of outcomes relative to a selected issue by only considering "worst case" conditions (which is basically an

opinion) without regard for likely conditions or conditions "beyond design basis".

Additionally, one recommendation for integrating traditional deterministic approaches into a risk management regulatory structure would be to risk inform Chapter 15 of the licensee's safety analysis reports. Proposals to this effect have occurred in the past but were not received well as risk approaches were not permitted. In particular, the PWROG proposed in 2003 in WCAP-16084-NP to risk inform safety analyses for non-LOCA events by incorporating insights from PRAs into revised regulatory guidance for transient classes (i.e., Moderate, Infrequent, Limiting). This approach combined with a commensurate safety analysis treatment strategy for safety functions and associated equipment could be a significant mechanism to improve safety analyses and, thus, overall safety.

For LOCA events, the recent risk informed pilot activities associated GSI-191 has resulted in significant technological improvements in the way deterministic analyses and probabilistic analyses can be used in conjunction with each other to produce robust and dynamic analyses for nuclear safety issues. These analyses represent opportunities to re-evaluate not only a closure path for GSI-191, but also an opportunity to establish an updated evaluation methodology for satisfying 10CFR50.46, ECCS Acceptance Criteria. If regulatory approval were to be achieved for the risk informed approach to GSI-191 to be an alternate evaluation method, no exemption to 10CFR50.46 would be necessary since the risk informed GSI-191 approach robustly satisfies the existing rule language in 10CFR50.46 and other associated regulatory guidance (e.g., RG 1.157).

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

Comment: Need to have an institutional process that incorporates risk analysis processes for evaluating issues and problems. Included in this is PRA but not necessarily so for every possible issue. If PRA is applicable, then, yes, it should be used. If not, then risk analysis should be performed. What is important is that the process captures the issue, identifies the major contributors to risk, and assesses the uncertainties is a systematic process.

Challenges will be that in some cases the technology may not exist to evaluate the risk, the costs associated with it, and the communication of it. This could best be done through an Operational Risk Management Institute led through academia and sponsored by NRC and industry.

The commitment relative to the time scale, budget, and resources necessary to accomplish full implementation of a risk informed regulatory structure. For example, an annual budget of $5 to $10 million would be needed over several years and around 50 FTEs. Thus, it would be an effort for NRC, industry, and vendors together or an institute to develop the structure.

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

Comment: Depending upon how aggressive the planning, development, and the funding associated with this effort, the following is offered:
2 to 3 years to get a draft transition plan for a risk informed framework for each regulatory sector developed including organizational impacts;
2 to 3 years to commence fully funded pilot risk informed regulatory initiative;
3 years to achieve a fully approved regulatory action plan for incorporating risk concepts into the regulatory structure of all NRC sectors;
5 to 7 years for a robust risk informed regulatory framework to be fully developed and approved; and
7 to 10 years to fully implement across all regulatory sectors.

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

Comment: Improved safety from an enterprise risk perspective. Better operational flexibility and decision-making, much improved regulatory decision-making (other federal agencies would subsequently emulate the risk informed structure), societal benefit (public health & safety), societal quality-of-life (non-polluting, safe, reliable, and abundant nuclear power), worker safety, worker quality-of-life.

Specific areas that, in this commenter's opinion, would benefit from a transition to a risk management regulatory approach are:

- *Reactor Programs – all equipment issues and programs within the scope of reactor regulation*
- *Emergency Response Programs – risk management and analysis should be incorporated into emergency response in terms of drill scenarios, emergency response organizational makeup, streamlining requirements, and improving effectiveness*
- *Physical Security – all security programs should be risk informed*
- *Seismic requirements – inspections and seismic requirements should be based on the geographic seismic hazard and not globally applied*
- *External Event requirements – provisions, capabilities, and emergency response activities should all be informed by risk analyses and risk management and structured for the specific geographic external event hazards.*
- *Emergency Response – all of it should be risk informed*
- *Cyber Security – scope and level of response/requirements should be risk informed*
- *Materials – material requirements and inspection programs should be risk informed*
- *Dedication processes, Equipment Reliability programs, and 10CFR50.69 –*

should be further risk informed to allow improved focus on safety significant equipment, offset obsolescence issues (allow flexibility), and base regulatory requirements on performance and not solely on compliance with prescriptive "Appendix B-Type" requirements.

Should you have any questions related to the information above, please contact C. R. Grantom at crgrantom@stpegs.com or at (979) 429-0779.