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Subject: PWR Owners Group
“PWR Owners Group Comments on the Nuclear Regulatory Commission (NRC) White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement,” [NRC-2013-0254]

To: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB)
Office of Administration, Mail Stop: 3WFN-06- 44M

Reference: 1.) ML13273A517, DRAFT “White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement”
2.) [NRC-2013-0254] Federal Register/ Vol. 79, No. 7 / Friday, January 10, 2014
3.) [NRC-2013-0254] Federal Register/ Vol. 78, No. 227 / Monday, November 25, 2013

Please find enclosed the Pressurized Water Reactor Owners Group’s (PWROG’s) comments on the Nuclear Regulatory Commission (NRC) White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement. These comments were prepared by the PWROG Risk Management Subcommittee (RMSC).

The staff’s request for comments appeared in the Federal Register Notice (FRN), Vol. 78, No. 227 (Monday, November 25, 2013). The public comment period was extended to February 28, 2014 in FRN, Vol. 79, No. 7, January 10, 2014.

If you have any questions, please do not hesitate to contact me at (205) 992-7037 or Mr. W. Anthony Nowinowski at (412) 374-6855.

Sincerely,

Jack Stringfellow, COO and Chairman
PWR Owners Group

DOYB
NRR

NJS:CMH:rfn

Enclosure (1) PWROG Comments on the White Paper on a Conceptual Example of a Proposed
Risk Management Regulatory Framework Policy Statement

cc: PWROG Management Committee
PWROG I&C Working Group
PWROG LSC Subcommittee
PWROG Risk Management Subcommittee
PWROG PMO

Mary Drouin, NRC
Jonathan Rowley, NRC
Jim Andrachek, Westinghouse

PWROG Comments on the White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement

The Pressurized Water Reactor Owners Group's (PWROG's) comments on the Nuclear Regulatory Commission (NRC) White Paper on a Conceptual Example of a Proposed Risk Management Regulatory Framework Policy Statement are provided below. These comments were developed by the PWROG Risk Management Subcommittee (RMSC).

The PWROG is only providing high-level comments, rather than addressing each of the suggested 26 questions provided in the original FRN.

1. The PWROG endorses the comments submitted by the Nuclear Energy Institute (NEI).
2. The White Paper proposes using the same (new) framework across the entire scope of the NRC's regulated areas, i.e., areas that include reactors, industrial, medical, waste, fuel cycle, and transportation. The development, testing, and implementation of such a regulatory framework would be a significant task for one area within the NRC. Accomplishing this across the entire agency in a coordinated, consistent manner would appear to be an extremely challenging task for the NRC that will require a long period of time, inter-agency coordination, and perhaps a dilution of methodological approaches to satisfy all of the agency's desires.
3. The White Paper uses a number of difficult-to-define terms, e.g., "**acceptably low**" (Summary, Section III/B), "**acceptable level of risk**" (Section I/A), "**appropriate**" (used in various contexts throughout the White Paper), "**acceptable reliability and availability of equipment and human actions**" (Section III/C), "**unacceptable releases**" (Section III/C), "**acceptable level of DID**" (Section III/C), "**acceptable design standards**" (Section III/C), "**acceptable safety margins**" (Section III/C), "**sufficient safety margins**" (Section I/B, Section III/D), "**sufficient DID**" (Section III/C), "**where practical**" (Section III/B), "**adequate DID**" (Section III/C), etc. As most of these terms are in Section III (Possible Statement of Risk Management Regulatory Framework Policy), the draft policy statement, and may be acceptable for a policy statement, the use of such (undefined) terms would make development, implementation, and enforcement of a regulatory framework difficult.

Another example is the sixth bullet under Section III/D.a, which states "**Sufficient safety margins are necessary in certain circumstances, and generally desirable in managing uncertainty in risk.**" This statement is an example of a difficult-to-define terms, and is too vague to have much value.

4. The defense-in-depth (DID) definition provided in this document is much too narrow. In Section I/B (and elsewhere), the concept of DID is reduced to "prevention/detection." However, the NUREG-2122 (Glossary of Risk Terms) provides the following:

Over time, various definitions have been used for defense-in-depth, including:

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- three barriers to contain radioactive material: fuel cladding, primary system boundary, and the containment
- the use of successive measures to prevent an accident or to mitigate the consequences of an accident
- the use of redundancy and diversity
- implementation of the single failure criterion

The definition in this draft Policy Statement captures only the concept of the second bullet. While “prevention/detection” is convenient because it is a simple way of treating DID, it does not include other significant potential elements of DID.

5. The end of Section II suggests that “PRA and other risk assessment tools and methods have matured ...” While a reasonable statement for internal events probabilistic risk assessments (PRAs), the continued need for the development of methods for fire PRAs (to reduce unwarranted conservatism) would contradict that statement. Serious efforts for other external hazard PRAs, Level 2 PRAs, Level 3 PRAs, and low power/shutdown PRAs do not have a sufficient amount of experience or exercising to claim “maturity” of the tools and methods. Those tools and methods are the ones that are utilized in the nuclear power industry – what about the other areas for which the NRC is responsible (as noted in Comment 1) – are all of those tools and methods considered “mature?” Have risk-related tools and methods been developed to evaluate all of the regulatory areas for which the NRC is responsible?

Further, this “maturity” is cited as a reason to withdraw the current PRA policy statement. Even if there is maturity of the tools and methods, what is the “cause-and-effect” relationship that would suggest that it is appropriate or timely to withdraw the current PRA Policy Statement? The 1995 PRA Policy Statement has clearly not accomplished all of its intended goals (as of 2014). The draft White Paper repeats most of the objectives of the 1995 Policy Statement, indicating there is still value in those original objectives. Considering the scope and time required to implement what is suggested in the White Paper, it is premature to consider withdrawing the existing PRA Policy Statement.

6. Section III.A

- a. Item 1 appropriately invokes the use of the risk triplet across all regulatory fields. If the NRC determines the likelihood and consequence quantitatively across all of the agency’s responsibilities, it could be considerably more challenging than is acknowledged in the White Paper, and will likely require the development of completely new methodologies, e.g., the risk-informed approach to GSI-191, which has been a long-term activity, as would be expected for a first-of-a-kind effort.
- b. Item 3 discusses performing “analysis using risk evaluation techniques.” All such approaches are being considered – however, it is not clear how easily or effectively these approaches can be applied in regulatory areas (other than to reactors) for the first time. This may involve the need for the NRC and the industry to invest in a “science project.” Again, consider the industry and the NRC effort to develop and approve, respectively, a risk-informed approach to GSI-191.

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- c. Item 4 proposes deliberation using integrated decision making “by evaluating options, considering uncertainties and acceptability criteria, considering external factors, and determining appropriate risk-informed and performance-based defense-in-depth protection.” How is such an “appropriate ... defense-in-depth protection” determined? Using what scale or metric? And how much defense-in-depth is “enough?” This decision process could be so overwhelming that no decisions would ever be made.
 - d. Section III.A goes on to say “use of risk information which is of sufficient technical quality for its intended use, and which accurately and completely describes [sic] the limitations of the methodologies/risk assessment tools ...” Even with the mature internal events PRA, the issue of technical adequacy for a particular application has required much discussion between the industry and the NRC (and even within the industry) – there will continue to be issues as the PRA scope increases to include fire, seismic, flood, high winds, low power/shutdown, etc. A regulatory framework that is established across all of the agency’s different responsibilities will require a substantial effort to determine the criteria for “technical adequacy,” without even considering the effort required by the licensee to achieve it. There are tools (e.g., PRA Standards) to assist with PRAs, but what about other methodological approaches, e.g., integrated safety analyses (ISAs)? How will the criteria be determined? How will the criteria be assessed?
 - e. To accomplish what is described in comment “4.d” (above), licensees will be required to “develop and maintain licensee-specific PRAs or other related risk analyses ...” The nuclear power industry currently does this with internal events PRAs. The White Paper suggests the list includes ISA, acceptable qualitative methods, etc. Are such tools (other than PRAs) to be used by the NRC? Will the NRC need to develop more standardized plant analysis risk (SPAR) models or SPAR-like models for risk analyses that use tools other than PRAs? If PRAs are to be required, the issues identified above related to PRA technical adequacy need to be resolved to the point where the PRAs are accepted by the NRC for all regulatory applications, rather than the current process of relying on the NRC SPAR models.
7. The third bullet in Section III/B (“Risk evaluations in support of regulatory decisions should be as *realistic* as practical and appropriate to the extent necessary to support the regulatory application.” [emphasis added]) is the only location in this draft Policy Statement that addresses the issue of realistic risk assessments. This should be a major element of effective risk-informed decision-making. If conservative biases are allowed to enter the assessment of risk, then the risk management process may not be effective, because the “true” risk may not be appropriately represented. Risk insights may be masked by undue conservatism. This draft Policy Statement should state more strongly that, “Risk evaluations in support of regulatory decisions should be based on realistic, best-estimates of risk, without excessive conservative bias. This ensures that different hazards are treated consistently. Conservative margin should be factored into risk management actions rather than the risk evaluation.”

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8. The White Paper should explicitly cite and use the philosophical underpinnings of Regulatory Guide (RG) 1.174, yet the RG is never mentioned.
9. Section B suggests that risk assessment tools should be “used to identify and address **new** safety and risk significant information.” This was the purpose of Generic Letter (GL) 88-20 for nuclear power reactors – why is it necessary to do this again? GL 88-20 was a “snapshot” in time, and licensee should not ignore any new insights (good or bad) that are derived from revised or reworked PRAs. Including such a requirement in the regulatory framework would not promote regulatory stability. For NRC regulatory areas other than nuclear power reactors, an activity equivalent to GL 88-20 might be appropriate.
10. Section C (For Prevention Criteria/first bullet) suggests establishing “goals on component, system, human reliability, and accident or damage prevention.” Does the NRC expect to regulate the industry against such goals? The mitigating system performance index (MSPI), which is supposed to be a “performance index” now has an impact on how a licensee operates the plant – the text in Section C suggests vastly increasing the scope of the MSPI or an MSPI-like index. Establishing goals at the component, system or individual operator action level has the potential to focus efforts on less risk significant activities. This has already been seen in some areas of the MSPI, where licensees are required to monitor the unavailability of trains that have no impact on the performance index.