

DSI-12

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**To:** WND1.WNP2.SECY  
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**Subject:** Strategic Assessment - Issue Paper 12

Attached are my comments on Strategic Assessment Issue: Risk-informed Performance-based Regulation. The views are my own and were not submitted to my management for their review.

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## Strategic Assessment Issue 12 - Risk-Informed, Performance Based Regulation

1. What, if any, important considerations may have been omitted from the issue papers?

The paper notes fundamental differences in the application of risk regulation to reactor and material licensees, but further differences could and perhaps should be noted. "Risk" may mean different things to different people. A standard engineering definition is the expected value (in a stochastic sense) of the sum of the products of frequency and consequences. This definition can result in equal risk for a high frequency, (relatively) low consequence activity as for a high consequence, low frequency activity. (However, it is not clear that the public considers these risks to be equivalent.) Reactor risk is a very low frequency very high consequence accident. Because of the very low frequency of the high consequence accident, useful statistical data cannot be directly collected on the frequency of accidents. Instead, complex fault and event trees are used to model frequencies from more basic events for which a statistically more meaningful data base exists, and additional models are needed if consequences of core melt are to be quantified. Continuation of the risk-informed approach for these licensees means to continue to explore ways to utilize PRA insights in the regulation of reactors in order to focus regulatory and licensee resources on the greatest risks to the public, where the magnitude of the risks are quantified.

For material licensees, the accidents are much lower in consequence, but higher in frequency. Statistical data is collectable from events reported, rather than requiring analytical modelling. This data should be collected, analyzed and risk-informed regulatory decisions should be made for these licensees on the basis of such statistical accident data.

However, the material licensees that are conversion, enrichment, and fuel fabrication facilities are too few for statistically meaningful accident frequency data to be directly useable. PRA fault/event tree methods may also not be suitable for these facilities. Because of their diversity and competitiveness, generic modelling is difficult and of limited utility and the licensees appear reluctant to share information needed for assigning frequencies to basic events of a fault tree. But benefits from use of non-quantitative risk methods have been recognized both by industry (Petition for Rulemaking) and NRC staff. Further, the risk methodology involved is well documented in the chemical industry and requirements of both OSHA's Process Safety Management regulation and EPA's Risk Management Program regulation. Any overarching NRC risk policy should recognize the differences in quantitative (i.e., PRA) and non-quantitative risk approaches.

2. How accurate are the NRC's assumptions and projections for internal and external factors discussed in the issue papers?
  - A) Option 1 is stated as continuation of the current process. But Option 2, "More Rigorously Assess Relationship to Public Health and Safety," in some ways seems to me to better reflect the current process. The paper states

(page 21), "Underlying both [option 2] and the Continue Current Process option is the assumption that our regulations and current regulatory processes are adequate, and will continue to be adequate, to protect public health and safety. . . . Under Option 2, priority and scope in applying risk-informed, performance-based regulatory approaches would be primarily determined by the projected cost of the approach compared to benefit to the public health and safety." The procedure for performing a regulatory analysis under NRC Management Directive 6.3 Handbook and the criteria for rulemaking or other under the backfit rule, 10 CFR 50.109(a)(3) tend to ensure that priority and scope in rulemakings are risk-informed. Emphasis in rulemakings for some time has been on what have been referred to as performance-based regulations.

- B) The definitions of deterministic regulations and of performance-based regulations may be useful in defining some terms that perhaps have too many different meanings to different people, but some recognition perhaps should be given to some of the alternative meanings that these terms have had. On page 15 of the paper it is stated: "*Deterministic* approaches to regulation consider a set of challenges to safety and specify *how* those challenges should be mitigated." [emphasis added] Page 16 states "A *performance-based* regulatory approach requires at least four key elements:

1. *There are measurable parameters to monitor acceptable plant and licensee performance.* [emphasis added]
2. Objective performance criteria are established to assess performance.
3. There is licensee flexibility to determine how to meet established performance criteria.
4. Failure to meet a performance criterion must not result in unacceptable consequences."

Alternative definitions are that *prescriptive* regulations specify how the licensees are to achieve NRC's safety objectives, while *performance-based* regulations specify what the licensees are to accomplish but give flexibility as to how licensees are to do that.

3. Do the Commission's preliminary views associated with each issue paper respond to the current environment and challenges?

Issue paper 23 notes that regulatory excellence involves both regulatory effectiveness and regulatory efficiency. There can be no disagreement "that, in order to accomplish the principal mission of the NRC in an efficient and cost effective manner, it will in the future have to focus on those regulatory activities that pose the greatest risk to the public." The preliminary views section, however, also states that the staff should continue with its current efforts to obtain additional information about the appropriateness of a risk-informed, performance-based approach. There may be a tendency of staff to read the

Commission's preliminary views as direction to require quantitative risk estimates as justification for any regulatory activity.

Decisions on use of Risk-Informed, Performance Based Regulation could be made on the basis of individual situations depending upon whether that approach would improve regulatory effectiveness or efficiency, rather than on an overarching PRA approach applied to all regulatory activities, since for some activities, as noted above, PRA may not be the preferred tool.