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SUBJECT: Contract No. DE-AC07-05ID14517 – Next Generation Nuclear Plant Project Submittal – NRC Project No. 0748 – Response to NRC Request for Public Comment on the Incorporation of Risk Management Concepts in Regulatory Programs – Docket ID NRC-2011-0269

The purpose of this submittal is to respond to selected survey questions posed by the U.S. Nuclear Regulatory Commission (NRC) task force described in Federal Register Notice NRC-2011-0269, dated November 22, 2011. These responses are being provided by the Next Generation Nuclear Plant (NGNP) Project as a stakeholder in the overall effort to incorporate risk insights into the licensing process. These responses are consistent with the approach for establishing an updated regulatory framework that has previously been proposed by the NGNP Project. This proposed framework also directly supports NRC and industry initiatives regarding the development and implementation of a logical, systematic, and coherent regulatory framework for adequate protection that appropriately balances defense-in-depth and risk considerations.

The NGNP Project's response to survey Questions 1, 2, 5, and 8 are as described below.

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?***

The term "defense-in-depth" would most benefit from additional clarity, especially as it relates to incorporation of risk-management concepts into regulatory programs. To promote additional clarity on this topic, the NGNP Project has developed a defense-in-depth structure that is documented in the December 2009 report, *Next Generation Nuclear Plant Defense-in-Depth Approach* (INL/EXT-09-17139). (See response to Question 2 below for ADAMS Accession No.) A primary goal of this document is to advance the common understanding of defense-in-depth principles by incorporating risk-informed, performance-based design and regulatory framework philosophy early in the NGNP design and licensing process.

The proposed defense-in-depth framework addresses three major elements:

- *Plant capability defense-in-depth* reflects the decisions made by the designer in the selection of functions, structures, systems, and components (SSCs) for the design that ensure defense-in-depth in the physical plant.
- *Programmatic defense-in-depth* reflects the decisions made regarding the processes of manufacturing, constructing, operating, maintaining, testing, and inspecting the plant and the processes undertaken that ensure plant safety throughout the lifetime of the plant.

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- *Risk-informed evaluation of defense-in-depth* reflects the development and evaluation of strategies that manage the risks of accidents, including the strategies of accident prevention and mitigation. This aspect of defense-in-depth also provides the framework for performing deterministic and probabilistic safety evaluations, which help determine how well various Plant Capability Defense-in-Depth and Programmatic Defense-in-Depth strategies have been implemented.

While the first two elements of this proposed framework incorporate aspects related to traditional applications of defense-in-depth (including engineering judgment), it is the inclusion of the third element (*risk-informed evaluation of defense-in-depth*) that may provide further insights related to NRC task force efforts to develop a more risk-informed, performance-based regulatory approach.

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

Previous initiatives associated with licensing framework development for high temperature gas- cooled reactors (HTGRs) provide key insights regarding potentially acceptable and relevant approaches for applying risk management concepts through the implementation of risk-informed, performance-based initiatives. Past examples would include the licensing interactions associated with the Department of Energy's (DOE) Modular High-Temperature Gas-Cooled Reactor (MHTGR) and the Pebble Bed Modular Reactor (PBMR) project that was initiated by Exelon in the early 2000s.

The MHTGR design was submitted to the NRC for preapplication review in 1986 and the NRC staff's preliminary assessments were documented in NUREG-1338, "Draft Preapplication Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor," dated March 1989, and the subsequent revision dated June 1995. The MHTGR application included the concept of using a risk-informed approach for selecting events to be considered by the licensing process. While the MHTGR project was terminated prior to completion of the licensing activities, the draft NUREG provides many staff insights and caveats regarding development of a risk-informed licensing process.

Several documents were developed by Exelon and the NRC staff concerning Exelon's proposal for a risk-informed, performance-based licensing approach. These documents included the following, which were developed by Exelon and the NRC Staff to document the progress made prior to project closeout:

- Exelon Letter to USNRC, Subject: Revision of Exelon Generation Company's Proposed Licensing Approach for the Pebble Bed Modular Reactor in the United States dated March 15, 2002.

- NRC Letter to K. Borton, Manager of Licensing, Exelon Generation, Subject: NRC Staff's Preliminary Findings Regarding Exelon Generation's (Exelon's) Proposed Licensing Approach for the Pebble Bed Modular Reactor (PBMR), dated March 26, 2002.

- SECY-02-0139, "Plan for Resolving Policy Issues Related to Licensing Non-Light Water Reactor Designs," dated July 22, 2002.

Section 6.2 of the March 2002 Exelon letter summarizes the risk-informed approach that Exelon proposed for the PBMR, including consideration of defense-in-depth, the roles of accident prevention and

mitigation, and development of special treatments for safety-related SSCs considering plant-specific risk insights.

The NRC staff provided their preliminary assessment of Exelon's risk-informed, performance-based licensing approach in their March 26, 2002 letter cited above. Some of their conclusions can serve as lessons learned based on their assessment of the approach at that time. These conclusions included the following:

- The identification of top level regulatory criteria (TLRC) and development of a frequency-consequence curve may be considered acceptable criteria for the mitigation aspect of defense-in-depth, but from a regulatory aspect, it is important to have criteria for prevention as well.
- Plotting of TLRC is useful to illustrate bounding criteria and safety margins, but does not in itself constitute a complete licensing basis.
- The staff reaffirmed the acceptability of mechanistically-derived source terms if adequately justified (originally approved in the SRM for SECY-93-092).
- If the probabilistic risk assessment (PRA) is used to classify components as safety-related, there must be sufficient monitoring to ensure the validity of the SSC reliability and availability assumptions that are used in the engineering evaluations underlying the safety-related classifications.

In SECY-03-0047, "Policy Issues Related to Licensing Non-Light Water Reactor Designs," dated March 28, 2003, the staff provided recommendations for Commission consideration on policy issues fundamental to licensing non-light water reactor designs. The related SRM, dated June 26, 2003, documented the approval for the following risk-informed, performance-based licensing approach topics:

- Development of a policy statement on defense-in-depth to include the associated objectives, scope, and high level principles and guidelines. The policy statement was directed to be technology neutral and risk-informed.
- Allow the use of a probabilistic approach in the identification of events to be considered in the design, provided there is sufficient understanding of plant and fuel performance and deterministic engineering judgment is used to bound uncertainties.
- Allow a probabilistic approach for SSC safety classification.
- Replace single failure criterion with a probabilistic (reliability) criterion.
- Retain the Commission's guidance, allowing the use of scenario-specific source terms, provided there is sufficient understanding and assurance of plant and fuel performance and deterministic engineering judgment is used to bound uncertainties.

The NGNP Project is currently engaged in a series of interactions with the NRC staff concerning a number of topics related to development of a risk-informed, performance-based licensing approach for HTGRs. The table below lists the topics and corresponding documents that capture the technical discussions that have taken place to date. The staff is currently developing a series of assessment reports

that will present the staff's current evaluations of the specific objectives contained in the white papers listed below.

HTGR Topic	NGNP White Paper	ADAMS #	RAI Correspondence	ADAMS #
Defense in Depth	INL/EXT-09-17139, *Next Generation Nuclear Plant Defense-in-Depth Approach*, December 2009	ML093480191	NRC RAI Letter #1 NRC RAI Letter #2	ML102020580 ML112140366
			NGNP RAI Response #1 NGNP RAI Response #2	ML102590481 ML11290A188
Event Selection	INL/EXT-10-19521, *Next Generation Nuclear Plant Licensing Basis Event Selection White Paper*, September 2010	ML102630246	NRC RAI Letter	ML112140366
			NGNP RAI Response	ML11290A188
SSC Safety Classification	INL/EXT-10-19509, *Next Generation Nuclear Plant Structures, Systems, and Components Safety Classification White Paper*, September 2010	ML102660144	NRC RAI Letter	ML112140366
			NGNP RAI Response	ML11290A188
Use of PRA	INL/EXT-11-21270, *Next Generation Nuclear Plant Probabilistic Risk Assessment White Paper*, September 2011	ML11265A082	None	N/A
			None	N/A

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

A blend of risk-informed and deterministic approaches is needed. For some elements of the blended regulatory approach, the probabilistic risk assessment insights would naturally lend themselves to providing the base upon which to infuse the deterministic criteria. An example of this is for the selection of Licensing Basis Events (LBE). For other elements of the regulatory structure, such as safety classification of SSCs, the risk insights would best inform the conventional deterministic practices. Further, there may be licensing elements such as regulatory special treatment that would be risk informed, such as the ongoing ASME development of a Reliability Integrity Management program for passive components.

Deterministic approaches are reliant on judgments to deal with uncertainties that frequently need to be revised to address unexpected issues identified in reactor incidents and accidents such as those at Three Mile Island and Fukushima. An integrated method of blending risk-informed and deterministic elements has been outlined in the documents described in our response to Question 2 above.

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

Transitioning to a risk managed regulatory approach would promote increased focus on the areas that are critical (risk significant) to protecting public health and safety, and include establishing the following fundamental elements

- ***What*** must be met: Top Level Regulatory Criteria (TLRC)
- ***When*** must TLRC be met: LBEs

- ***How*** must TLRC be met: Safety Functions, General/Principal Design Criteria, Safety Classification
- ***How well*** must TLRC be met: Deterministic DBAs, Regulatory Special Treatment, Defense-in-Depth

The selection of LBEs is viewed as a prime area that would benefit from application of risk insights. The LBEs used in the licensing process are derived from plant design by comparison to the risk requirements of the TLRC to support the plant safety analysis and to derive design specific performance requirements for SSCs. LBEs include the wide spectrum of events for which the plant is conservatively designed (e.g., Anticipated Operational Occurrences, Design Basis Events, and Accidents), and for low frequency events it has an expected capability to prevent and mitigate (e.g., Beyond Design Basis Events).

PRA provides a rigorous process to assess both the frequency and consequence of LBEs. This process:

- Considers the comprehensive performance of the facility design by applying a systematic process to ensure all sequences are captured and properly assessed.
- Provides a rational approach for identifying, understanding, and addressing uncertainties.

Initial LBEs are identified early in the design process. Once the initial LBEs are identified, the design can be refined to reduce the frequency or consequence of a given LBE. This suggests an iterative design process where more design and analysis detail is available at each phase of design development.

The NGNP Project white papers summarized in the response to survey Question 2 above, describe the fundamental elements of this technology-neutral approach. We believe these papers can also serve as a pilot for a risk management regulatory approach.

If you have questions or require additional information regarding our responses to the survey questions above, please contact me at (208) 526-6063 or James Kinsey, Director, NGNP Regulatory Affairs at (208) 569-6751.

Sincerely,

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