March 26, 2002

Mr. Kevin F. Borton
Manager, Licensing
Exelon Generation
200 Exelon Way
Kennett Square, PA 19348

SUBJECT: NRC STAFF'S PRELIMINARY FINDINGS REGARDING EXELON GENERATION'S (EXELON'S) PROPOSED LICENSING APPROACH FOR THE PEBBLE BED MODULAR REACTOR (PBMR)

Dear Mr. Borton:

This letter provides the staff's preliminary assessment of the Exelon's proposed licensing approach for the PBMR. This review was predicated on the series of events outlined below. By letter dated December 5, 2000, Exelon expressed interest in conducting pre-application activities with the NRC staff for the potential licensing of the PBMR. During an April 30, 2001, meeting, Exelon discussed a licensing approach that they believe merits consideration by the staff because of the unique features of a gas-cooled reactor design. By letter dated June 1, 2001, Exelon submitted its initial proposed licensing approach. By letter dated August 16, 2001, the staff provided comments to Exelon on the proposed licensing approach and requested that Exelon submit a revision to incorporate information exchanged during numerous public meetings. Exelon submitted this revision by letter dated August 31, 2001, and it is the basis for the staff's enclosed preliminary assessment. Subsequent to the preparation of the staff's assessment, Exelon submitted revisions to the proposed licensing approach dated January 31, 2002 and March 15, 2002. The staff is in the process of reviewing these later submittals.

Exelon's licensing approach expands on the licensing approach proposed by the Department of Energy (DOE) for the Modular High-Temperature Gas-Cooled Reactor (MHTGR). It has three guiding principles: (1) to conform with the current regulations while recognizing that many of the current regulatory requirements are based on light-water reactor technology; (2) to use a decision-making process that determines the applicability of existing regulations; and (3) to use a risk-informed process to supplement existing regulations.

The enclosed report presents the staff's preliminary assessment of Exelon's proposed licensing approach. The staff summarizes the main considerations contributing to it's preliminary assessment, provides information about Exelon's proposal, and presents the staff's comments and reaction to the proposal.

In its assessment, the staff has focused upon the merits of the approach as a potential process for ensuring compliance with existing regulations and identifying PBMR-specific regulatory requirements.

The staff has concluded that the licensing approach proposed by Exelon, if adequately implemented, is a reasonable process for ensuring that the Commission's regulations are met and for identifying PBMR-specific regulatory requirements. However, it is recognized that implementation of Exelon's proposed licensing approach or any other approach requires additional design and probabilistic risk assessment (PRA) information that Exelon has not yet provided. A detailed PRA is required for implementation of Exelon's proposed risk-informed regulatory approach and the staff will continue to assess the issues of treatment of uncertainties, margins of safety, and defense-in-depth. Furthermore, the degree to which the staff may be able to rely on PRA information for the PBMR will be a consideration due to the more limited operating experience for such designs. The staff will continue to assess Exelon's proposal during the remainder of the PBMR pre-application review.

If you have any questions concerning this report, please contact Prasad Kadambi at 301-415-5896 or Stephen Koenick at 301-415-1239.

Sincerely,

/RA/

Farouk Eltawila, Director
Division of Systems Analysis and Regulatory Effectiveness
Office of Nuclear Regulatory Research

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Staff Preliminary Assessment of Exelon's Proposed Licensing Approach

Enclosure

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INTRODUCTION AND SUMMARY

In June 1988, the Nuclear Regulatory Commission (NRC) issued NUREG-1226, "Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants." This policy statement encourages the earliest possible interaction between the agency and prospective applicants to facilitate early identification of regulatory requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety characteristics of advanced reactor designs. The policy statement also encourages advanced reactor designers, in their design submittals, to propose specific review criteria or novel regulatory approaches which NRC might apply to their designs.

By letter dated December 5, 2000, citing the NRC's "Statement of Policy for Regulation of Advanced Nuclear Power Plants," Exelon Generation (Exelon) expressed interest in conducting pre-application activities with the staff. The Commission authorized pre-application review activities in its June 6, 2001, Staff Requirements Memorandum (SRM) to SECY-01-0070, "Plan for Pre-Application Activities on the Pebble Bed Modular Reactor (PBMR)." During an April 30, 2001, meeting, Exelon discussed a licensing approach that Exelon believes merits special consideration by the staff because of the unique features of a gas-cooled reactor design. By letter dated June 1, 2001, Exelon submitted its initial proposed licensing approach. The staff held public meetings with Exelon on June 12, July 17, August 9, August 15, September 19, and October 25, 2001, to discuss the proposed licensing approach. In these meetings, the staff provided time for other stakeholders to comment on the proposed licensing approach. By letter dated August 16, 2001, the staff provided comments to Exelon on the proposed licensing approach and requested that Exelon submit a revised version of its proposed licensing approach. Exelon submitted this revision by letter dated August 31, 2001, and this revision is the basis for the staff's preliminary assessment. Subsequent to the preparation of the staff's assessment, Exelon submitted revisions to the proposed licensing approach dated January 31, 2002 and March 15, 2002. The staff is in the process of reviewing these later submittals.

This report presents the staff's preliminary assessment of Exelon's proposed licensing approach. In the sections below, the staff summarizes the main considerations which contributed to the staff's preliminary assessment, provides information about Exelon's proposal, and presents the staff's comments and reaction to the proposal. In its assessment, the staff has focused upon the merits of the approach as a potential process for ensuring compliance with existing regulations and identifying PBMR-specific regulatory requirements.

The staff concluded that the licensing approach proposed by Exelon, if adequately implemented, is a reasonable process for ensuring that the Commission's regulations are met and for identifying PBMR-specific regulatory requirements. However, it is recognized that implementation of Exelon's proposed licensing approach or any other approach requires additional design and probabilistic risk assessment (PRA) information that Exelon has not yet provided. A detailed PRA is required for implementation of Exelon's proposed risk-informed regulatory approach and the staff will continue to assess the issues of treatment of uncertainties, margins of safety, and defense-in-depth. Furthermore, the degree to which the staff may be able to rely on PRA information for the PBMR will be a consideration due to the more limited operating experience for such designs. The staff will continue to assess Exelon's proposal during the remainder of the PBMR pre-application review.

CONSIDERATIONS FOR THE STAFF'S PRELIMINARY ASSESSMENT

The primary objective of the staff's review is to determine whether Exelon's proposed licensing approach, if implemented, would satisfy NRC requirements and provide for adequate protection of the public health and safety. As noted above, the staff's preliminary assessment of Exelon's proposed licensing approach has focused on the merits of the approach as a potential process for ensuring compliance with existing NRC regulations and identifying PBMR-specific regulatory requirements. Despite this aim, the staff's assessment has nonetheless been informed by an array of considerations that provide a broader framework or context for the assessment. Some of the salient considerations (and various regulatory documents reflecting such considerations) are identified and discussed below. These include the NRC staff's experiences with the Fort St. Vrain and Modular High-Temperature Gas-Cooled Reactor (MHTGR) advanced reactor designs and the overarching policy or performance goals articulated by the Commission in the NRC Strategic Plan.

Licensing of Fort St. Vrain

The NRC (Atomic Energy Commission at the time) has previously licensed high-temperature gas-cooled reactors, Fort St. Vrain being the last. The staff reviewed the records for the Fort St. Vrain case to see how the agency has applied the regulations to a gas-cooled reactor design, particularly with respect to the General Design Criteria (GDC), in order to gain insights into how the process might be done for the PBMR.

Fort St. Vrain, an 842-MWt high-temperature gas-cooled reactor, received its construction permit in 1968, its operating license in 1973, and ceased operation in 1989. The NRC, in its review of the construction permit application, requested that the applicant describe how the design met the intent of the applicable criteria in the proposed version of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix A, General Design Criteria for Nuclear Power Plant Construction Permits (as published July 11, 1967). The June 21, 1968, safety evaluation (SE) report for the construction permit noted that the applicant had met the intent of all applicable criteria, but the report did not present the basis for this conclusion in detail. The SE report included a section on the use of the principles of defense-in-depth and fission product barriers in this design. The report described the confinement building, noting that the fuel particles were coated with ceramic. It also noted that the primary coolant reactor vessel liner, the walls of the primary coolant reactor vessel, and the primary and secondary enclosures of the penetrations collectively formed the primary coolant system envelope and provided the containment function. The report concluded that the design provided sufficient barriers and defense-in-depth. In the SE for the operating license, dated January 20, 1972, some of the GDC were discussed explicitly (e.g., GDC 17 for the onsite and offsite power systems); most were not discussed.

Pre-Application Review of the Modular High-Temperature Gas-Cooled Reactor

The licensing approach proposed by Exelon for the PBMR is similar to that proposed by the Department of Energy (DOE) for the MHTGR in that it proposes the comparison of selected events to the top-level regulatory criteria (TLRC) as an acceptance criteria for the design. In 1986, DOE submitted its conceptual design of the MHTGR for the purpose of staff review. The MHTGR is a small, modular, graphite-moderated, helium-cooled reactor plant. The purpose of the staff's review was to provide guidance early in the design process on the regulatory acceptability of the MHTGR design. The result of the pre-application review is documented in draft NUREG-1338, "Pre-Application Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor," dated December 1995, and submitted to the Commission in SECY-95-299 on December 19, 1995. This document was made available to the public and transmitted to DOE on February 26, 1996.

In the MHTGR pre-application review, the staff evaluated the proposed MHTGR design and licensing approach for conformity with the Commission's advanced reactor policy statement, safety and policy issues, research and development plans, and proposed new licensing criteria. The review approach was, in general, the same approach used by the staff for licensing light water reactors (LWRs). It entailed a review of the plant against the regulations in 10 CFR Parts 50 and 100, including the GDCs in 10 CFR Part 50, Appendix A; the guidance contained in the Standard Review Plan (SRP) sections in NUREG-0800; regulatory guides (RGs); and staff-endorsed industry codes and standards. The staff also evaluated the designer's probabilistic risk assessment (PRA), and use of defense-in-depth and safety margins. The staff provided assessments in two major areas:

1. significant safety issues, or licensability issues, that may present obstacles to licensing the design, such as fuel design, containment leak-tightness, fission product transport codes, and reactor cavity cooling system design; and

2. advanced reactor policy issues that are applicable to the MHTGR design, such as the use of risk information for selection and evaluation of accidents, classification of equipment as safety-related, identification of an appropriate source term, and regulatory treatment of non-safety-related systems.

The staff concluded DOE's approach was a systematic and useful approach for designing a nuclear power plant, but the approach correlated safety and regulation too closely with probabilistic methodology and focused too narrowly on 10 CFR Part 100 dose guidelines. The staff believed that DOE's approach removed from regulatory review items important to defense-in-depth, safety margin, and provisions to keep dose as low as reasonably achievable (ALARA). The staff recognized that PRA could be a useful tool in evaluating a design, but did not consider it to be sufficiently developed to be used as the primary measure of reactor safety or acceptability.

NRC Strategic Plan

The staff's approach for reviewing Exelon's proposal is informed by the Commission's performance goals as stated in the NRC's Strategic Plan for the nuclear reactor safety arena. The performance goals are to: (1) maintain safety, protection of the environment, and the common defense and security; (2) increase public confidence; (3) make NRC activities and decisions more effective, efficient, and realistic; and (4) reduce unnecessary regulatory burden on stakeholders. The staff will apply the regulatory practices that have contributed to the successful operating history observed in current reactors, including the strategies associated with the performance goals. However, the staff notes that the Commission's performance measures stated in the Strategic Plan are not directly applicable to a new reactor design. Full development of such measures for the PBMR or other advanced reactors, may not be possible until sufficient operating experience is available. The elements of the staff's approach that correspond to the individual performance goals are provided in the Appendix.

EXELON'S PROPOSED LICENSING APPROACH AND THE STAFF'S PRELIMINARY ASSESSMENT

In a letter dated August 31, 2001, Exelon set forth its proposed licensing approach for evaluating the PBMR and requested that the staff use this document as the basis for an assessment. Exelon's licensing approach has three guiding principles.

1. To conform with the current regulations while recognizing that some of the current regulatory requirements are based on LWR technology;

2. To use a decision-making process that systematically classifies existing regulations as regulations that apply to the PBMR; regulations that partially apply to the PBMR; regulations that do not apply to the PBMR; and PBMR-specific requirements that could be imposed by license conditions; and

3. To use a risk-informed process to define those events for which the plant is to be designed, their acceptance criteria, and a classification process whereby design requirements are specified for structures, systems and components (SSCs). Current risk metrics (i.e., quantitative standards or measures) of core damage frequency (CDF) and large early release frequency (LERF) may need to be supplemented or replaced by additional metrics more amenable to gas-cooled reactor accident performance. Certain regulatory objectives are not currently amenable to probabilistic treatment. These include administration, process, occupational exposure minimization, environmental impacts other than radiological, and security and safeguards. These objectives will be met consistent with existing practice.

Exelon's specific objectives for developing the PBMR licensing approach, which are discussed in more detail below, are as follows:

- Establish a process to determine which regulatory requirements and guidance are applicable and to what extent they need to be supplemented for the PBMR;

- Establish agreed-upon quantitative TLRC (which Exelon characterizes as what must be satisfied);

- Establish an agreed-upon risk-informed method for selecting licensing basis events (LBEs) (which Exelon characterizes as when the TLRC must be met); and

- Establish a design-specific method to select and determine special treatment of safety-related SSCs (which Exelon characterizes as how and how well the criteria are met).

Exelon intends to utilize current regulations to guide the ongoing design process and has taken the position that rulemaking is not necessary for the staff to license the PBMR. According to Exelon, its approach incorporates risk-informed elements and insights and also is consistent with the existing applicable NRC regulations that have been developed on a largely deterministic basis for LWRs. Exelon further states that the approach is based on methods developed in the late-80s for the MHTGR and modified to reflect subsequent advances in risk-informed regulation. In a letter dated August 16, 2001, the staff informed Exelon that the staff's review of the proposed licensing approach would focus on the acceptability of the approach and not the acceptability of the PBMR design.

A top-down risk-informed performance-based licensing approach for the PBMR has been developed by Exelon based on objectives of limiting public exposures during normal operation and preventing and mitigating accidents. Certain regulatory objectives are not amenable to probabilistic treatment. These include occupational exposure minimization, non-radiological environmental impacts, and security and safeguards. These objectives will be met consistent with existing practice. Any requirements resulting from the staff's reassessment of security and safeguards provisions as a result of the events of September 11, 2001, will be applied to the PBMR.

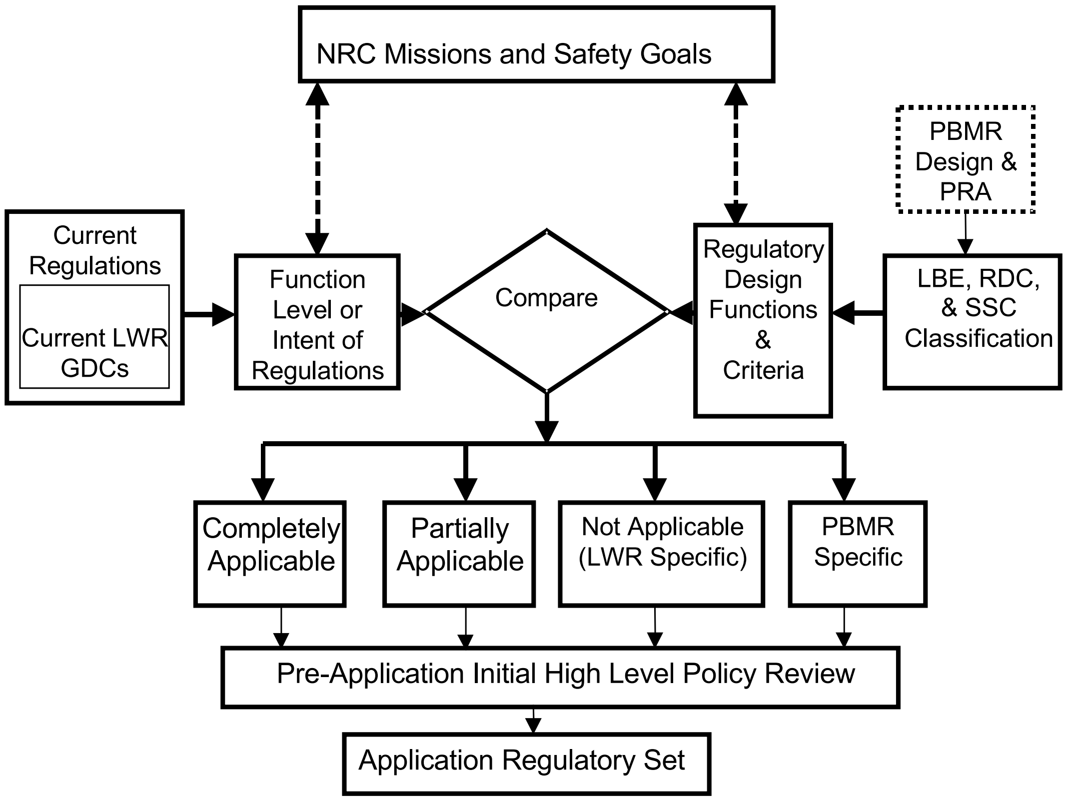
<u>Screening of Regulations</u>

Exelon Proposal

Given the very limited regulatory experience with gas-cooled reactor technology in the U.S., there is not an existing body of regulations directly suited to the PBMR design. Consequently, for a license application to be prepared, a different set of requirements will have to be developed from the existing regulations, RGs, and SRPs to guide the applicant in preparing its license applications and the NRC in reviewing them. This situation is recognized in the Introduction to Appendix A to 10 CFR Part 50 and the NRC's policy statement on advanced reactors. Appendix A states that the GDC were developed for LWRs and are intended to provide guidance in establishing the principal design criteria for other types of reactors.

Exelon has proposed a process, which is represented in Figure 1, to develop a set of specific requirements for the PBMR design. There are three major parts to this effort, one being a top-down, safety-focused method, which combines deterministic and risk-informed techniques to determine necessary acceptance criteria and functional requirements (shown by boxes on the right-side of the figure) for the PBMR. These requirements will be derived from the other steps within the licensing approach discussed below. The second part is an applicability screening of existing regulations (shown on the left-side of the figure). The final step is a comparative analysis using the results of the first two steps to determine which regulations are (1) completely applicable, (2) partially applicable, or (3) not applicable. Exelon conducted this process on a trial basis using an expert panel.

Figure 1



In determining the applicability of the regulations to the PBMR, the expert panel considered two questions: (1) Does the regulation apply directly, by its terms, to gas-cooled reactors; and (2) if not (e.g., if the regulation applies only to LWRs), could the regulation nonetheless serve as useful guidance for the PBMR? If the panel answered yes to either of these questions with respect to a given regulation, then that regulation was designated as "applicable" to the PBMR. That is, the regulation was deemed either: (1) applicable as a current NRC requirement; or (2) applicable in the sense that it might provide guidance in the development of future PBMR-specific requirements. In those instances in which a regulation was deemed applicable as a current NRC requirement, the regulation was further categorized as completely applicable or partially applicable (partially applicable in that the regulation contained multiple parts, some of which were clearly not applicable to the proposed PBMR). The process yielded insights that will help shape future interactions with the NRC. For example, the process provided Exelon's preliminary view on the applicability of each of the regulations in 10 CFR Part 50, as well as other existing regulations, that could be used to shape the application and review requirements for the PBMR design.

To develop the overall set of regulatory requirements for design, the applicable regulations from this screening process will be compared with the set of safety-related design conditions established to satisfy the regulatory design criteria arising from the licensing basis event analyses. Where existing applicable regulations exist, these will be used. Where a required function is not addressed by regulation with associated defense-in-depth protection, appropriate PBMR-specific requirements will be developed and applied.

Staff Assessment

As stated in the August 15, 2001, letter to Exelon, the staff's assessment will not focus on the preliminary list of regulations provided by Exelon because of the need for additional design and design analysis information necessary to complete such an assessment. The staff agrees with Exelon that issues pertaining to the interpretation of certain regulatory language (e.g., how traditional LWR terms like reactor coolant pressure (RCP) boundary, loss-of-coolant accident (LOCA), and containment are applied to the PBMR) may become significant as sufficient design information becomes available. The staff will perform an independent assessment of the applicability of the regulations. The staff will use the MHTGR safety evaluation as a starting point (which considered GDC and other requirements and guidance) in its review. The staff will continue to interact with Exelon with the purpose of sharing its views on the applicability of NRC regulations; however, the ultimate determination of applicability of regulations will be made by the staff.

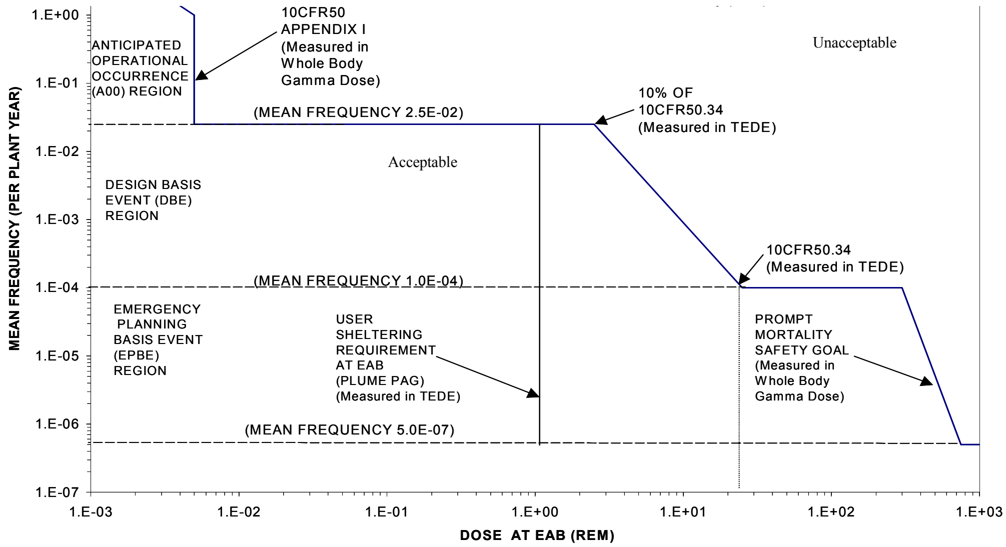
The staff recognizes that this process only addresses the regulatory issues that have been identified as part of the development of LWR regulations. This is why the information represented by the boxes on the top right of Figure 1 concerning regulatory design functions and criteria is needed to fully elicit and identify PBMR-specific issues.

The staff finds that Exelon's proposed classification scheme (which purports to classify existing NRC regulations as completely applicable, partially applicable, or not applicable and identify necessary PBMR-specific requirements) is sufficiently comprehensive to permit an effective screening of regulations. The process also permits the development of considerations that may serve as a basis for appropriate exemption requests. In any event, the staff intends to pursue an independent screening of the regulations. However, in the interest of efficiency, if Exelon concludes that a given regulation is applicable, then the NRC may want to consider accepting such a finding at face value and instead focus its efforts on determining how Exelon will comply with such a regulation. The staff notes that any final identification and delineation of PBMR-specific requirements would require considerably more design information than is currently available, and may also require a completed PRA.

Top-Level Regulatory Criteria

Exelon Proposal

Exelon characterizes the TLRC as a set of criteria that provides a fundamental quantitative basis for consistently and unambiguously evaluating the current acceptability of potential radionuclide releases, such that protection of the public health and safety and the environment is adequately maintained. The criteria specify numerical limits on radiological releases (either directly as dose limits or as risk metrics). According to Exelon, the quantitative regulatory criteria are established to bound and ensure an acceptable level of health and safety as measured by the risks of radiological consequences. Exelon has purportedly selected TLRC that are independent of reactor type and site and use well-defined and quantifiable risk metrics. The TLRC identified by Exelon, which are described as updates of TLRC presented by DOE in support of the MHTGR in 1989, are plotted in Figure 2.



<u>Figure 2</u>

Exelon has identified a number of current regulations and regulatory guidance documents as sources of top-level criteria. Exelon maintains that the consequence limits contained in these various sources can be transformed into risk criteria, because the event sequences against which they are applied have understood frequency ranges. For example, (1) the design objectives in 10 CFR Part 50, Appendix I, 10 CFR Part 20, and 40 CFR Part 190 all pertain to normal operations and anticipated operational occurrences (AOOs); (2) 10 CFR Part 100 and 10 CFR 50.34 pertain to design basis events; and (3) the reactor safety goals and protective action guides generally pertain to severe accidents. The TLRC plotted in Figure 2 show the bounding values with frequency ranges over which they would apply, as proposed by Exelon.

In Figure 2, the frequency regions consist of a spectrum of releases covering a frequency range from normal operation to very low probability off-normal events. The spectrum of potential accidental radioactive releases from a plant is divided into the following three regions:

- anticipated operational occurrences (AOO);
- design basis events (DBE); and
- emergency planning basis events (EPBE).

In the evaluation of the PBMR, the consequence criteria are numerically taken to be independent of a reactor plant, i.e., the criteria apply to a plant regardless of the number of reactors or modules. However, the criteria are for the licensing application for a new plant, which may or may not be on a site with existing, previously licensed reactors/plants. The existence of multiple modules would increase the frequency of single-module scenarios and create the potential for scenarios involving multiple modules concurrently. By contrast, in the case of LWRs, safety goals and other relevant criteria have been applied to each reactor unit independently. Thus, in the case of the PBMR, Exelon proposes to evaluate the total impact of installing multiple modules (up to10) in a manner akin to the evaluation of the equivalent impact of adding a single large LWR in the same location. In other words, in determining whether a 10-module PBMR facility satisfies the TLRC, the proposed licensing approach would consider the cumulative risk posed by the 10 modules, rather than considering each module separately.

Staff Assessment

Exelon's proposed licensing approach, as it relates to applicability of NRC regulations, focuses on the safety regulations contained in the current 10 CFR Part 50. Exelon's plotting of the TLRC is consistent with past principles, but poses technical challenges, such as determining the appropriate frequency ranges applicable to each of the regions. The current regulations include a frequency reference for the definition of AOOs, but do not contain a similar reference for DBEs. Exelon has chosen 1×10^{-4} per plant year as the lower frequency for a DBE. The staff will continue to assess the appropriateness of this value and its consistency with current practice and the criteria contained in SECY-00-198 which discusses RIP 50 Option 3, taking into account such considerations as cumulative effects (for the families of events and for multiple modules) and the frequency ranges considered in other advanced reactor reviews. In the event that such technical questions arise, they might have concomitant policy implications which could require Commission guidance before such questions can be resolved. Some of these technical and policy issues have been identified in this assessment, but more could arise as the staff's pre-application review proceeds. For example, the TLRC use one of the quantitative health objectives (QHO) from the Commission's safety goal policy (i.e., the risk of prompt fatality); however, the other QHO on latent cancer risk is not addressed. The staff expects continued interactions with Exelon to help clarify some issues.

In the absence of design details that are required for a final PRA, the applicant must make assumptions regarding the design and performance of various systems (in consideration of the right-hand side of Figure 1); these assumptions need to be explicitly identified so as to make the applicant accountable for validating them.

While not a regulatory requirement, the staff will assess the information contained in the EPRI (Electric Power Research Institute) Utility Requirements Document for Passive LWRS, which stipulates that the frequency of exceeding a dose of 25 rem (at 0.5 mile) be less than 1×10^{-6} per plant year.

In concept, the staff considers the TLRC to be an attempt on the part of Exelon to propose objective criteria which are amenable to quantitative evaluation and applicable to all types of reactors. However, difficulties could arise when non-quantitative aspects of defense-in-depth and avoidance of "risk-based" decisions become significant considerations.

It is the staff's view that the TLRC approach does not provide a mechanism for consideration of defense-in-depth. The TLRC may be considered to be acceptance criteria for the mitigation aspect of defense-in-depth, but from a regulatory standpoint, it is very important to have criteria for prevention as well. In addition to the TLRC, Exelon should consider the use of deterministic licensing criteria, such as a peak pebble temperature, degraded pebble geometric configurations, or flow bypass caused by unexpected flow channelization. In a September 5, 2001, letter, Exelon agreed with this comment, but has not yet offered specific deterministic criteria.

The staff notes that plotting of TLRC is useful to illustrate bounding criteria and safety margins. However, the licensing basis is the set of requirements that are applied to the safety-related equipment to meet the LBEs (or other special regulatory objectives such as anticipated transients without scram (ATWS) or station black-out (SBO)); simply falling within the plot of the TLRC does not in itself constitute a complete licensing basis. Moreover, while the PRA confirms risk insights for a design, and can be used for other purposes as noted above, licensing activities will be a mix of “deterministic” analysis supplemented with risk insights. The lack of operational data for some of the unique PBMR SSCs makes complete reliance on PRA difficult.

Selection of LBEs

Exelon Proposal

Exelon proposes to use a PRA to provide a logical and structured method to evaluate the overall safety characteristics of the PBMR plant. This will be accomplished by systematically enumerating a sufficiently complete set of accident scenarios and by assessing the frequencies and consequences of the scenarios individually and in the aggregate to predict the overall risk profile. A PRA is seen by Exelon as the best available safety analysis method for showing how the dependencies and interactions among SSCs, human operators, and the internal and external plant hazards that may perturb operation of the plant and produce an accident. The quantification of both frequencies and consequences must address uncertainties because it is understood that the calculation of risk is affected by uncertainties associated with the potential occurrence of rare events. These quantifications provide an objective means of comparing the likelihood and consequences of different scenarios and of comparing the assessed level of safety against the TLRC. Exelon seeks to use the PRA to select families of events (based upon expected frequencies and consequences) which will become the LBEs for the PBMR. The families will consist of events of similar characteristics (initiator, end states).

Exelon notes that families of events may have significant uncertainties in the estimate of their frequencies. The consideration of these uncertainties is necessary to assure that all events will be assessed against the appropriate criteria. An additional factor is placed on the mean frequency to assure that event families falling just above or below a region are evaluated in the most stringent manner.

Anticipated Operational Occurrences Region

Exelon identifies AOOs as those conditions of normal operation which are expected to occur one or more times during the life of the plant. Using a licensing basis design lifetime of 40 years yields a lower boundary for the AOO region of 2.5×10^{-2} per plant year. For this region, Exelon views 10 CFR Part 50, Appendix I as providing the applicable criterion, as it specifies the numerical guides on design objectives for assuring that releases of radioactive material to unrestricted areas during normal reactor operations, including AOOs, are maintained ALARA.

Design Basis Event Region

Exelon states that the DBE region encompasses releases that are not expected to occur during the lifetime of one nuclear power plant but for which the plant is designed to successfully mitigate. The frequency range covers events that are expected to occur during the lifetime of a population (several hundred) of nuclear power plants; and therefore a lower limit of 1×10^{-4} per plant year has been proposed by Exelon. Estimates of LWR core damage accidents which exceed the design basis have been in the range of 1×10^{-5} to greater than 1×10^{-4}. For this region, Exelon views 10 CFR 50.34(a)(1) as providing the quantitative dose criteria to be considered for accidental releases from a nuclear power plant facility and site, so as to ensure that the surrounding population is adequately protected.

Emergency Planning (EP) Basis Event Region

Exelon states that the EPBE region considers improbable events that are not expected to occur during the lifetime of several hundred nuclear power plants. This is to assure that the risk to the public from low-probability events is within the appropriate TLRC, and that adequate emergency planning is developed to protect the public from undesirable exposure to radiation from improbable events. The frequency cutoff implicit in the acute fatality risk goal in NUREG-0880 is taken by Exelon as the lower frequency boundary of the EPBE region. NUREG-0880 notes that the individual mortality risk of prompt fatality in the United States is about 5×10^{-4} per year for all accidental causes of death. The prompt mortality risk design objective limits the increase in an individual's annual risk of accidental death to 0.1% of 5×10^{-4}, or an incremental increase of no more than 5×10^{-7} per year. If the frequency of a scenario or set of scenarios is at or below this value, Exelon claims that it can be assured that the individual risk contributions from these scenarios would still be within the safety goal independent of the magnitude of consequences. Therefore, this value is used as the lower frequency bound for the EPBE region.

All EPBEs would be expected to result in offsite doses. The EPBE and DBE mean doses are compared to the protective action guidelines contained in 40 CFR Part 190 and the EPBE mean doses together with those of the DBEs and the AOOs are summed over their entire frequency distribution and compared to the safety goal quantitative health objective.

Exelon further proposes that events below the EPBE region also be examined to assure that the residual risk is negligible with respect to the latent mortality safety goal and to provide general assurance that there is no "cliff" in which a high consequence event goes unnoticed. This includes events involving more than one module and still lower frequency events beyond the licensing basis that would be examined to assure low residual risk.

Staff Assessment

To complete its review the staff will have to determine whether the events used to define the licensing basis constitute a reasonably complete set. The rationale for EP is based upon a spectrum of consequences from accidents (including severe accidents, even though they may be unlikely), tempered by probability consideration. This rationale was chosen over others (i.e., risk, probability and cost/benefit) because consequences could be used to help identify adequate planning standards and establish bounds for planning efforts. The reason for not choosing risk, probability, or cost/benefit is, in part, due to the difficulty associated with defining the appropriate levels of these criteria. Thus, the staff will need to carefully consider whether the EPBEs developed through Exelon's process constitute a sufficiently complete and appropriate spectrum of events for EP purposes. The use of quantified probabilistic criteria to select events to be considered in the design and in EP has potential policy implications. The staff further believes that the PRA should include accidents involving spent fuel stored on site (analogous to spent fuel pool accidents in LWRs).

On a more general note, in the SRM for SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements,” issued April 8, 1993, regarding accident selection and evaluation — the Commission approved the staff recommendation that events and sequences be selected deterministically and use conservative assumptions, and be supplemented with insights from the PRA for the specific design. In Exelon’s August 31, 2001, document containing its proposed licensing approach, Exelon appears to be using probabilistic criteria to select AOOs, DBEs, and EPBEs. However, from verbal interactions with Exelon, the staff believes that the candidate LBEs which will be considered for application within the framework of the TLRC will first be established deterministically, and will then be assessed and compared to the TLRC using risk insights. To the extent Exelon adheres to such an approach, the staff believes it would be consistent with previous Commission guidance. The staff notes that Exelon’s submittal of January 31, 2002, describes some LBEs postulated to occur with the reactor operating at full power. The staff is in the process of reviewing this submittal.

However, as discussed in greater detail below with respect to the determination of safety-related SSCs and Exelon’s proposed use of a risk-informed framework, Exelon's approach proposes to use frequencies and dose-consequences rather than CDF and LERF as risk metrics. As such, it is not directly comparable with the risk-informed options currently being developed by the staff for risk-informing Part 50 regulations. Exelon has openly acknowledged this fact, noting that no end states comparable to core damage and large early releases exist for the PBMR. Nonetheless, Exelon has chosen 1×10^{-4} per plant year as the lower frequency for a DBE and has further noted that, in order to judge consistency of its proposed lower frequency for the DBE region with the NRC’s current licensing practice, it has had to infer the frequency which is beyond the design basis region. The staff notes that it will continue to assess the appropriateness of 1×10^{-4} per plant year as Exelon’s lower frequency for a DBE as well as its consistency with current NRC practice and the criteria contained in SECY-00-198, which discusses RIP 50 Option 3. Additionally, the staff expects that as more design information becomes available, the role of a containment in the design will need to be carefully addressed using deterministic and risk insights.

Exelon states “it is expected that the process for selecting LBEs and developing the associated regulatory design criteria will lead to design decisions to employ an appropriate level of system redundancy, independence, diversity, and appropriate defenses against common cause failures and human errors. . . Hence applying the above considerations for ensuring defense-in-depth is consistent with the proposed licensing approach and anticipated PBMR design requirements.” The staff therefore believes that there cannot be complete validation of the licensing approach until there is validation of the appropriateness of relevant design decisions.

Identification of an appropriate source term is inherent to the type of licensing approach proposed by Exelon in that LBEs cannot be compared to the TLRC without an estimation of the source term. In the SRM for SECY-93-092 regarding source term, the Commission approved the staff's position that the source terms for advanced reactors should be based upon a mechanistic analysis if the performance of the reactor and fuel under normal and off-normal conditions is sufficiently well understood to permit a mechanistic analysis, and the transport of fission products can be adequately modeled for all barriers and pathways to the environs. The staff intends to adhere to the previous Commission guidance, and will accept mechanistically-derived source terms if adequately justified.

Determination of Safety-Related Structures, Systems, and Components

Exelon Proposal

The selection of the LBEs requires that the radionuclide retention functions that keep the events in the AOO, DBE, and EPBE regions are identified from the PRA. Even if the event does not have a release, it becomes a basis in the regulatory review for showing compliance with the associated TLRC. Identification of the required safety functions is the first step in equipment classification and the development of the corresponding regulatory design criteria (RDC).

According to Exelon, the safety functions required to meet the TLRC will be identified. The design is expected to include functions for radionuclide retention within the fuel particles, graphite core, primary circuit, reactor building, and site. The necessary functions for LBEs to meet the TLRC are to be accomplished using only safety-related equipment.

Exelon's proposed method for selecting safety-related equipment to be relied on for meeting the required safety functions consists of two steps: (1) to assure that DBE consequences meet 10 CFR 50.34 doses and (2) to assure that the frequencies of high-consequence EPBEs are within the TLRC.

Consequence Mitigation

Under Exelon's proposed approach, the first step is to classify one or more SSCs that are available and sufficient to perform the required safety functions to assure that all DBEs meet the DBE dose criteria. On the plot of the TLRC, this step keeps events to the left of the DBE dose criteria line. These SSCs would be designated as safety-related.

High-Consequence Event Prevention

The second step is to classify one or more SSC that are available and sufficient to perform the required safety functions to assure that all EPBEs with doses greater than 10 CFR 50.34 remain below the design basis frequency region. This step has the effect, as illustrated in Figure 2, of preventing high-consequence events from moving up (in frequency) into the DBE region.

Regulatory Design Criteria (RDC)

RDC are statements written at a functional level to describe the requirements for SSCs needed during DBEs to assure compliance with 10 CFR 50.34. The RDC are similar in nature and purpose to the GDC in Appendix A to Part 50, and will address PBMR safety functions that are not addressed in the GDC. The RDC have a one-to-one correspondence to the required safety functions.

The RDC are qualitative, functional statements for the SSCs classified as safety-related. Under Exelon's proposed approach, quantitative requirements are developed by requiring that the safety-related SSCs by themselves be sufficient for each of the DBEs to meet the DBE dose criteria (or to keep the EPBE events at a low frequency). A nonmechanistic reevaluation of the DBE with only the safety-related SSCs available leads to the safety-related design conditions (SRDCs). The SRDCs are used to develop the temperatures, stresses, heat loads, etc., that the SSCs must meet for each of the DBE. The design, fabrication, and operational requirements for the safety-related SSCs are directly linked to the DBEs on a case-by-case basis.

Exelon proposes that an appropriate set of regulatory design requirements for treatment of safety-related SSC be developed for each DBE on a case-by-case basis and that risk-informed special treatment then be applied to the corresponding SSCs.

Currently, Exelon does not expect that there will be a need for special treatment of SSCs solely for the purpose of preventing or mitigating EPBEs. For example, for the MHTGR, the design functions that ensured that EPBEs remained within acceptable limits were the same functions that were needed for the DBEs. Since an appropriate level of special treatment is applied to ensure the reliability and availability of the equipment required to perform these design functions for purposes of protecting against DBEs, additional treatment would not be needed for these functions with respect to EPBEs. A similar result is expected for the PBMR.

Additionally, Exelon expects that some non-safety-related SSCs will perform a defense-in-depth function or provide safety margin. These SSCs will be evaluated on a case-by-case basis to determine whether enhanced treatment (i.e., treatment in excess of normal industrial practices) is warranted. In some cases, such as fire protection systems and radwaste systems, some enhanced treatment may be warranted. For active systems that are normally operating, no additional treatment may be warranted.

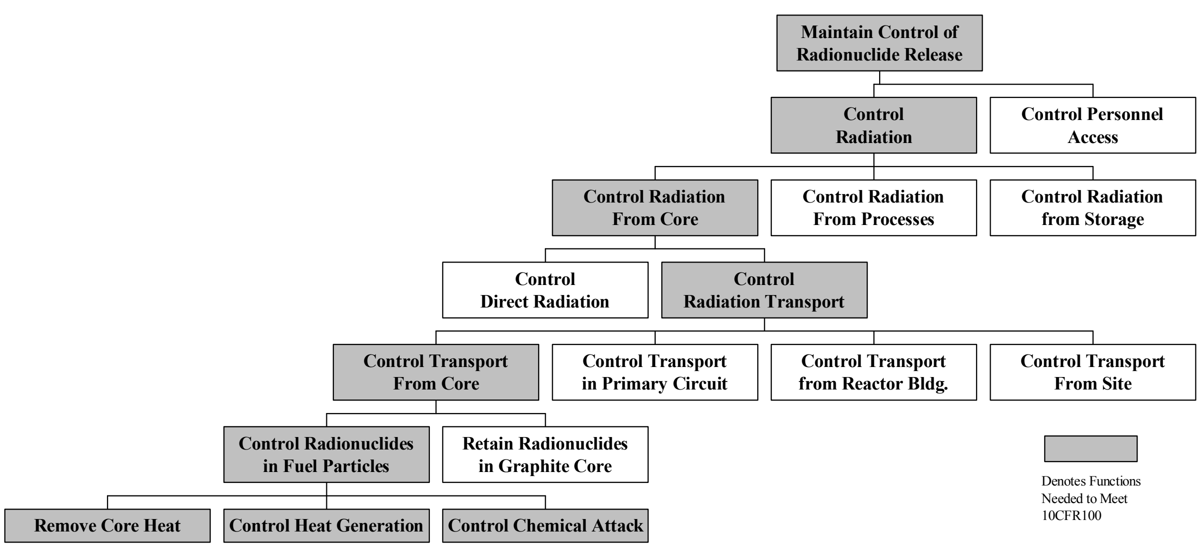
Staff Assessment

The licensing basis is the set of requirements, such as SRDCs and RDC, that are applied to the safety-related equipment to meet the LBEs; simply falling within the plot of the TLRC does not in itself constitute an acceptable licensing basis. Moreover, although the PRA confirms risk insights for a design, and can be used for other purposes, the licensing safety analysis will be performed on the basis of a combination of "deterministic" analysis supplemented with risk insights.

In its licensing approach, Exelon proposes that an appropriate set of regulatory design requirements for treatment of safety-related SSCs be developed for each DBE on a case-by-case basis, and that risk-informed special treatment then be applied to the corresponding SSCs. The staff recognizes that Exelon provided additional information on this matter on March 15, 2002. The staff is in the process of reviewing this submittal. The approach proposed by Exelon is a novel approach that has not been previously considered by the staff in its risk-informed activities. Because Exelon's approach proposes to use frequencies and dose-consequences rather than CDF and LERF as risk metrics, it is not directly comparable with the risk-informed options currently being developed by the staff for risk-informing Part 50 regulations. The special treatment requirements for classified SSCs will be developed based on the required function for each DBE. The approach proposed by Exelon has the potential to impose special treatment requirements on equipment at the component level. Establishing requirements at the component level would present difficulties in documenting the design criteria for each component and establishing a consistent application of special treatment requirements on a system level. Also, while Exelon has stated that it does not anticipate the need for special treatment of SSCs solely for the purpose of preventing or mitigating EPBEs, the staff emphasizes that SSCs relied on to avoid exceeding TLRC, or to keep the frequencies of similar event sequences within the acceptable range (e.g., within the AOO, DBE, or EPBE range) should be classified as safety-related. The staff also expects that the treatment applied to safety-related SSCs should consider the limiting environment under which the SSCs must be available to perform their safety-related design function. In addition, Exelon's discussion of monitoring the performance of SSCs does not specifically address the monitoring of safety-related SSCs to identify unexpected equipment performance or to ensure that the regulatory design requirements are being met. Because Exelon proposes to use PRA 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 evaluation (i.e., PRA) underlying Exelon's safety-related classifications. The staff notes that the term "safety-related" may not be directly applicable to the PBMR concept, and that a more appropriate term may have to be developed. The staff will continue to pursue these issues with Exelon during the staff's pre-application review.

Exelon's proposed licensing approach discusses required safety functions and uses a figure (shown below as Figure 3) to illustrate how safety functions could be met.

Figure 3
Radionuclide Retention Functions for the MHTGR



While the staff understands that this is not a PBMR-specific figure, the figure seems to imply that the function can be met without controlling radionuclide transport from the reactor building and from the site, which appears to contradict the defense-in-depth philosophy. The role of a containment in the PBMR design will be specifically addressed and is expected to be presented to the Commission as a policy issue. The staff believes that system redundancy, defense-in-depth, and maintenance of safety margins should be incorporated into the process for categorizing SSCs as safety-related. The staff will continue to discuss these concerns with Exelon in its pre-application review.

In the SRM for SECY-93-092 regarding safety classification, the Commission approved the position that the staff should apply the current LWR criteria (RCP boundary protection, safe shutdown, and prevention and mitigation of accidents) to the advanced reactors at the pre-application review stage. As noted in the discussion on screening of regulations, the staff will use current LWR criteria to the extent practicable.

Additionally, in the SRM for SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems in Passive Plant Designs," issued March 28, 1994, the Commission approved the staff's proposed process for maintaining appropriate regulatory oversight of non-safety-related active systems in the passive advanced reactor designs. The staff intends to adhere to the previous Commission guidance.

<u>Use of the Risk-Informed Framework</u>

Exelon Proposal

Exelon's rationale for using PRA is that the PRA provides a logical and structured method for evaluating the overall safety characteristics of the PBMR plant. Exelon maintains that, by systematically enumerating a sufficiently complete set of accident scenarios and assessing the frequencies and consequences of the scenarios individually and in the aggregate, it can predict the overall risk profile for the PBMR. The quantification of both frequencies and consequences must address uncertainties because the calculation of risk is affected by uncertainties associated with the potential occurrence of rare events.

Exelon noted that all key assumptions that are used to develop success criteria, to develop and apply probability and consequence models, and to select elements for incorporation into the models should be explicable, defensible, and clearly documented.

In order to determine the scope and necessary characteristics of the PRA that will be required for the development of licensing bases for the PBMR, Exelon noted the following objectives of the PBMR PRA:

- To confirm that the top-level regulatory criteria, including the safety goal quantitative health objectives for individual and societal risks, are met at a U.S. site or sites;

- To support the identification of LBEs;

- To provide a primary technical basis for the development of RDC for the plant;

- To support the determination of safety classification and special treatment requirements of SSCs;

- To support the identification of EP specifications, including the location of the site boundary;

- To support the development of technical specifications; and

- To provide insight on the available defense-in-depth in the design.

Exelon also discussed the scope and major elements of the PBMR PRA, noting first the scope and major elements of the LWR PRA for purposes of comparison. For LWRs, a Level 1 PRA is used to characterize the CDF; Level 2 is used to describe the aspects of the scenarios involving releases of radioactive material from the containment, including the frequencies of different release states and estimates of the source terms for the releases; and Level 3 is used to characterize the aspects of the scenarios involving transport of radioactive material from the site and determine the radiological consequences by quantifying the frequency of different consequence magnitudes. According to Exelon, the scope of the PBMR PRA needed to support its risk-informed approach to PBMR licensing will be as comprehensive and complete as a full-scope, all-modes Level 3 PRA covering a full set of internal and external events.

Exelon stated that since there is no counterpart for the LWR core damage end-state, the splitting up of event sequences involving releases into Level 1 and Level 2 segments does not apply to the PBMR. The elements of the PBMR PRA are integrated around a single-event sequence model framework that starts with initiating events and ends in PBMR-specific end states for which radionuclide source terms and offsite consequences are calculated. The integral PBMR PRA provides equivalent information as a full scope Level 1-2-3 PRA regarding radiological consequences.

Exelon discussed another distinction in the PBMR PRA elements related to the treatment of initial operating states such as full-power, low-power and shutdown modes. In contrast to LWRs, the different configurations of the PBMR do not have so many different applications of the safety functions, and therefore, lend themselves to a single integrated PRA that accounts for all operating and shutdown states. Furthermore, the online refueling aspect and specifications for maintenance on the large rotating machinery (i.e., the turbo units and power turbine generator) mean that the fraction of time the plant is shutdown is expected to be an order of magnitude less than a current LWR. Hence, for each PBMR PRA element it is necessary to address applicable sequences in all modes of operation, and Exelon suggests that this can be accomplished without the need for separate models for each mode of operation.

Exelon notes that the modular aspect of the PBMR creates the potential for anywhere from 1 to 10 reactor modules co-located at the same site. The PRA needs to account for the risk of multiple modules. The existence of multiple modules increases the likelihood of scenarios that impact a single module independently, and creates the potential for scenarios that may dependently involve two or more modules.

As emphasized in the current LWR PRA standards, the PBMR PRA must be capable of a thorough treatment of dependent failures, including the comprehensive treatment of common-cause initiating events, functional dependencies, human dependencies, physical dependencies, and common-cause failures impacting redundant and diverse components and systems. Exelon has stated that, in general, the applicability of the PBMR PRA will be consistent with the American Society of Mechanical Engineers (ASME) PRA standard for PRA Capability Category III. A full quantification of uncertainties is required. The quantification must reflect the iterative nature of the PRA as the PBMR evolves through the stages of conceptual design, construction, and eventual commissioning. Quantification of uncertainties provides the capability to determine the mean frequencies and consequences of each accident family to be compared against the TLRC and to compute the probability that specific criteria are met.

In order to support the evaluation of RDC, the PRA will reportedly be capable of evaluating the cause and effect relationships between design characteristics and risk as well as allow for a structured evaluation of sensitivities to examine the risk impact of adding and removing selected design characteristics.

Exelon acknowledges that recent LWR PRA quality efforts have been aimed at improving PRA quality. These initiatives include an industry PRA peer review program and efforts to develop PRA standards by the ASME and the American Nuclear Society (ANS). The concepts and principles that are being developed in these initiatives address both fundamental aspects of PRA technology and certain aspects that are rooted in LWR characteristics not shared by the PBMR. While the fundamental aspects are applicable, Exelon stated that the following aspects of these initiatives will be modified to apply to a PBMR PRA:

- The current quality initiatives are focused on PRA that are used to calculate CDF and LERF. If one replaces CDF and LERF with the PBMR task of providing estimates of each characteristic PBMR accident family, which is defined by appropriate combinations of PBMR-specific initiating events and end-states, then the associated high-level and supporting requirements can be viewed as directly applicable to the PBMR.

- As noted above, Exelon maintains that it is not appropriate to fit a PBMR PRA into the mold of the Level 1-2-3 framework. Instead, Exelon suggests that an integrated PRA which develops sequences from initiating events all the way to source terms and consequences should be developed.

- As noted above, it is not necessary to perform a completely different set of PRA models for full power versus low power and shutdown, because the PBMR lends itself to an integrated treatment of accident sequences that cover all operating and shutdown modes.

- For the current LWR applications the staff utilized surrogate risk metrics such as CDF and LERF rather than generally extending the PRA to Level 3. These risk surrogates may not be suitable for the PBMR, where Exelon has indicated that the initial PBMR applications will include offsite dose consequences to demonstrate the safety case and to meet licensing framework objectives.

- In view of the applications envisioned for the PBMR PRA, a full-scope treatment of internal and external events is anticipated by Exelon.

With these adjustments, Exelon believes it is reasonable to apply the applicable LWR PRA standards and peer review processes in its assessment of PBMR PRA quality until such time as PBMR-specific standards and peer review processes are developed. The applications envisioned for the PBMR are assumed to use ASME PRA Capability Category III. These standards will define the scope, level of detail, and capability levels needed to support the risk-informed approach to licensing the PBMR.

Staff Assessment

The staff supports Exelon's plan to develop a full-scope, detailed PRA including internal events and external events (e.g., fires, earthquakes, floods, high winds) and to follow the fundamental applicable aspects of industry PRA standards (i.e., ASME, ANS). While such a PRA may not fit into the mold of the Level 1-2-3 framework, it can provide equivalent information regarding radiological consequences. However, the staff believes that further development of standards is necessary because the current ASME standard focuses on LERF analysis for Level 2 PRAs and does not address Level 3 PRAs. Although the ASME standard provides requirements for treating uncertainties, the lack of operating experience (e.g., initiating event frequencies, component reliability, phenomenology, fuel performance) to factor into the PBMR PRA will lead to relatively large uncertainties in the PRA results. The staff will take up with standards developing organizations the need for PBMR PRA standards.

Exelon has stated that CDF and LERF are not the most applicable risk metrics for the PBMR and that alternative metrics, such as accident family consequences and frequencies, should be used. The staff notes that relying solely on a consequence-based risk metric does not necessarily provide a balance between event prevention and event mitigation. The staff will determine appropriate risk metrics for the PBMR and expects to seek consideration of this issue on a policy level by the Commission. In addition, Exelon has not proposed bounding events as was done during the MHTGR pre-application review, although Exelon has indicated an intention to examine events with frequencies below the EPBE range to assure that residual risk is negligible.

The staff has noted, under the defense-in-depth discussion in the Appendix, that some elements of defense-in-depth are dependent upon risk insights while other elements are independent of risk insights. Given the preliminary nature of the PBMR PRA providing the risk insights, the staff will be placing considerable emphasis on those elements independent of risk insights.

The staff will continue to build on the lessons learned regarding the use of risk information in a regulatory context. During the last several years, both the NRC and the nuclear industry have recognized that PRA has greatly evolved, to the point that it can be used increasingly as a tool in regulatory decisionmaking. In August 1995, the NRC adopted a policy statement regarding the expanded use of PRA. One major aspect of the policy is that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that compliments the NRC's deterministic approach and supports the NRC's traditional philosophy of evaluating treatment of uncertainties, estimating safety margins and assuring defense-in-depth.

POTENTIAL POLICY ISSUES

The staff has identified several elements of Exelon's proposed licensing approach as having potential policy implications. The staff intends to seek Commission guidance on these issues once we receive the requested information from Exelon. The potential policy issues include:

- The use of quantified probabilistic criteria to select events to be considered in the design and in EP;

- The use of quantified probabilistic criteria to select SSCs and its effect on defense-in-depth, including the issue of containment versus confinement; and

- The applicability of CDF and LERF as risk metrics for the PBMR.

The staff will continue to assess Exelon's proposal during the PBMR pre-application review.

Appendix

Application of NRC's Performance Goals

Maintain Safety, Protection of the Environment, and the Common Defense and Security

The staff used the guidance in the Commission's advanced reactor policy statement to interpret this performance goal. The policy statement expresses an expectation that, as a minimum, advanced reactors will be required to provide the same degree of protection to the public that is required for current generation LWRs. The policy statement also states an expectation that advanced reactors will provide enhanced margins of safety and/or utilize simplified, inherent, passive, or other innovative means to accomplish their safety functions.

The staff activities which support this performance goal are: (1) application of all current regulations which are found to be applicable; (2) development of appropriate supplemental PBMR design-specific regulatory requirements; (3) accounting for uncertainties by providing sufficient safety margins; and (4) application of the defense-in-depth principles. The staff expects that accounting for uncertainties, including confidence levels and some inevitably qualitative factors, may be a significant technical challenge for the PBMR. Since minimal operational experience applicable to the PBMR design is available, the staff expects that a robust performance monitoring program will be necessary.

Defense-in-depth is an important aspect of the staff's review. As with LWRs, the most significant aspect of this concept is the appropriate balance between prevention and mitigation of radiological releases in accident scenarios. In the Commission White Paper on Risk-Informed and Performance-Based Regulation provided in the March 1, 1999, SRM to SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation," the principle of defense-in-depth is described as:

> "...an element of the NRC's Safety Philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges."

More detailed guidance was approved by the Commission in the Staff Requirements Memorandum (SRM) to SECY-00-198, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) [RIP 50 Option 3] and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," (September 2000), in which the staff incorporated the attributes contained in an earlier document, RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (July 1998). The following features of defense-in-depth were articulated:

The defense-in-depth approach includes elements that are dependent upon risk insights and elements that are employed independent of risk insights. Risk insights are used to set guidelines that:

- limit the frequency of accident-initiating events;
- limit the probability of core damage, given accident initiation;
- limit radionuclide releases during core damage accidents; and
- limit public health effects caused by core damage accidents.

Safety function success probabilities (commensurate with accident frequencies, consequences, and uncertainties) are achieved via appropriate:

- redundancy, independence, and diversity;
- defenses against common-cause failure mechanisms;
- defenses against human errors; and
- safety margins.

The following defense-in-depth elements are employed independent of risk insights:

- prevention and mitigation are maintained;
- reasonable balance is provided among prevention, containment, and consequence mitigation;
- over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided;
- independence of barriers is not degraded; and
- the defense-in-depth objectives of the current GDC in Appendix A to 10 CFR Part 50 are maintained.

<u>Increase Public Confidence</u>

The Commission's advanced reactor policy encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory requirements for advanced reactors, and to provide all interested parties, including the public, with a timely, independent assessment of the safety characteristics of advanced reactor designs. The staff has facilitated public participation by ensuring that the regulatory process for the pre-application review of the PBMR has been accessible to all stakeholders. The staff has provided opportunities for public comment and discussion during all meetings with Exelon. Additionally, the staff will ensure that Commission guidance from recent public-confidence-building initiatives (such as using feedback forms and the Internet) will be followed.

The main activities that support this performance goal are those that emphasize the independence of the staff in conducting its review. For example, the staff will pursue its own screening of regulations to determine which LWR requirements apply to the PBMR or warrant the development of analogous requirements for the PBMR. The staff will present its findings in public meetings with Exelon. The staff will continue to exercise caution throughout these interactions to ensure that the NRC's independence as a regulator is maintained.

Make NRC Activities and Decisions more Effective, Efficient, and Realistic

A central element of this performance goal is the use of risk-informed and performance-based regulatory approaches. A major aspect of using such approaches is to apply the guidance in RG 1.174 which defined an acceptable approach to analyzing and evaluating proposed licensing basis changes. The staff's decisions concerning proposed changes are made in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors as well as quantitative analyses and information. In the RG, the staff articulated a set of key principles that are expected to be met. Some of these principles were written in terms typically used in traditional engineering decisions (e.g., defense-in-depth, safety margin). Nonetheless, it should be understood that risk analysis techniques can be, and NRC encourages them to be, used to help ensure that these principles are met. Each of these principles should be considered in a risk-informed, integrated decision-making process. These principles are:

- The proposed change meets the current regulations unless it is explicitly related to a requested exemption or rule change, i.e., a "specific exemption" under 10 CFR 50.12 or a "petition for rulemaking" under 10 CFR 2.802;

- The proposed change is consistent with the defense-in-depth philosophy;

- The proposed change maintains sufficient safety margins;

- When proposed changes result in an increase in CDF or risk, the increases should be small and consistent with the intent of the Commission's safety goal policy statement; and

- The impact of the proposed change should be monitored using performance measurement strategies.

The staff has determined that, while these principles were developed for use in evaluating changes to a licensing basis, they appear to be applicable to the PBMR.

The staff will also consider the concepts incorporated in the Commission White Paper on Risk-Informed and Performance-Based Regulation for application of performance-based approaches, where appropriate, including application of the high-level guidelines for performance-based activities. These guidelines were provided to the Commission in SECY-00-0191, “High-Level Guidelines for Performance-Based Activities” (September 2000).

In addition, in SECY-00-198, the staff has developed a framework for evaluating risk-informed regulations with five key features as follows:

(1) The framework utilizes a risk-informed, defense-in-depth approach to accomplish the goal of protecting public health and safety. This defense-in-depth approach builds on: (a) the principles in RG 1.174; (b) the Commission White Paper on Risk-Informed and Performance-Based Regulation, dated March 11, 1999; (c) the reactor oversight cornerstones; and (d) the Advisory Committee on Reactor Safeguards (ACRS) recommendations on defense-in-depth, as discussed in the ACRS letter to former Chairman Shirley A. Jackson, dated May 19, 1999;

(2) The defense-in-depth approach includes elements as described above under the first performance goal;

(3) The framework considers both design basis as well as core-damage accidents;

(4) The framework considers uncertainties; and

(5) The framework considers the Commission's safety goal policy.

It should be noted that the intent of SECY-00-198 was to address possible rule changes for LWRs (e.g., risk-informed alternatives to 10 CFR Part 50), whereas Exelon's licensing approach is to work within the current set of regulations without new rulemaking. Nevertheless, with modification of the risk metrics to better reflect the PBMR design attributes, the key features of the framework of SECY-00-198 are applicable to Exelon's PBMR licensing approach.

Reduce Unnecessary Regulatory Burden on Stakeholders

The Commission's safety goal policy provides guidance on when regulatory burden could be considered unnecessary. Consistent with the Commission's direction in its June 19, 1990, SRM, the staff is using the safety goals to define how safe is safe enough.[1] Risk-informed alternatives to 10 CFR Part 50 will be developed consistent with this direction (using the subsidiary objectives of the safety goals as guidelines). For LWRs, quantitative guidelines, based on the safety goals and the subsidiary objectives of 1×10^{-4} per reactor year for CDF and 1×10^{-5} per reactor-year for large early release frequency (LERF), have been developed to assist the staff in determining the appropriate balance between prevention and mitigation and whether or not to recommend a risk-informed alternative to the current requirements. Similar guidelines will be considered for high-temperature gas-cooled reactors.

[1] The safety goals are not limits, but goals. The Commission believes the staff should strive for a risk level consistent with the safety goals in developing or revising regulations. In developing and applying such new requirements to existing plants, the backfit rule (10 CFR 50.109) should apply. Thus, the safety goals provide guidance on how far to go when proposing safety enhancements."

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SUBJECT: NRC STAFF'S PRELIMINARY FINDINGS REGARDING EXELON GENERATION'S (EXELON'S) PROPOSED LICENSING APPROACH FOR THE PEBBLE BED MODULAR REACTOR (PBMR)

ORIGINATOR: **S. Koenick/P. Kadambi**

SECRETARY: **C. Nagel**

DATE: **March 27, 2002**

●●● ROUTING LIST ●●●

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