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FOR: The Commissioners

FROM: William Travers
Executive Director for Operations

SUBJECT: LICENSING APPROACH FOR EXELON'S PEBBLE BED MODULAR REACTOR

PURPOSE:

To inform the Commission of the staff's preliminary assessment of the Exelon Generation's (Exelon's) proposed licensing approach for the pebble bed modular reactor (PBMR).

BACKGROUND:

The PBMR is a modular high-temperature gas-cooled reactor design. Exelon wants to license the design in the United States. Each PBMR module contains its own reactor and power conversion system and produces approximately 116 MWe. Exelon defines a "PBMR facility" as up to 10 small reactors, or modules, operated from one control room.

The Nuclear Regulatory Commission (NRC) has previously licensed high-temperature gas-cooled reactors, Fort St. Vrain being the last. The staff's licensing review of Fort St. Vrain focused on an assessment of the applicability and intent of the general design criteria in Appendix A to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50).

In addition to the experience with Fort St. Vrain, the staff conducted a partial licensing review of the Modular High-Temperature Gas-Cooled Reactor (MHTGR) in the late 1980s and early 1990s. The MHTGR is a small, modular, graphite-moderated, helium-cooled reactor plant design similar to but with a lower power density than that of the Fort St. Vrain plant. The licensing approach proposed by the Department of Energy (DOE) for the MHTGR is similar to that proposed by Exelon for the PBMR. In its review of the MHTGR, the NRC staff compared DOE's approach with the NRC regulatory approach, which is to apply regulations, regulatory

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guides (RGs), general design criteria (GDC), and endorsed codes and standards. The staff also evaluated the designer's probabilistic risk assessment (PRA), and use of defense-in-depth. Defense-in-depth contributes to light water reactor (LWR) safety, and the staff wanted to be sure that the MHTGR design used the defense-in-depth principles. The staff concluded that DOE's approach was a systematic and useful approach for designing a nuclear power plant; however, it was not an adequate substitute for the NRC's regulatory approach to the safety and licensing review. Specifically, the staff identified that many regulatory criteria and much standard review plan guidance were applicable to the MHTGR, and these criteria must be applied to ensure that the MHTGR achieves a level of safety at least equivalent to current-generation LWRs. The results of the MHTGR review were documented in NUREG-1338, "Pre-application Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor; Draft Copy of the Final Report," published in 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 June 1988, the 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 applicants so that regulatory requirements for advanced reactors can be identified early 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.

In addition, there are four key NRC documents that represent the staff's efforts to develop and implement concepts of risk-informed and performance-based approaches to regulation and support a risk-informed framework for licensing of nuclear power plants. These documents are: (1) SECY-00-198, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," (2) RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," (3) the Commission policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities," and (4) the Commission has issued a white paper on "Risk-Informed and Performance-Based Regulation."

In a letter dated December 5, 2000, citing the NRC's "Statement of Policy for Regulation of Advanced Nuclear Power Plants," Exelon expressed interest in conducting pre-application activities with the staff. The staff began its pre-application review in a meeting with Exelon on April 30, 2001. During the 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, and September 19, 2001, to discuss the proposed licensing approach. In these meetings, the NRC staff provided opportunity for other stakeholders to comment on the proposed licensing approach. In a 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 to incorporate the information exchanged during the public meetings. Exelon submitted this revision by letter dated August 31, 2001. This letter is the basis for the staff's preliminary assessment. The current documentation for the Exelon licensing approach does not include an PRA. However, Exelon has stated that it will prepare a PRA that meets appropriate quality standards, such as those proposed by the American Society of Mechanical Engineers and the American Nuclear Society, and will include it in the submittals which will constitute the basis for licensing. A detailed PRA is required for a complete application of the risk-informed regulatory approach.

DISCUSSION:

In principle, the goal of the safety review that NRC conducts relative to any proposed reactor design is to determine whether a sufficient basis has been developed for the staff to reach a finding of adequate protection of the public health and safety. The main factors that the staff considers in evaluating the information on a design are conformance with the NRC's regulations and the methods to treat the various types of uncertainties, to estimate the safety margins, and to apply the principles of defense-in-depth. If the methods applied to analyze and evaluate these factors are sufficiently rigorous and robust, the assessment itself can provide a sound basis for reaching a favorable or unfavorable conclusion regarding adequate protection. For LWRs, the results of analyses and research are buttressed by a long and well-studied operational record to provide the basis for the adequate protection finding. A new design cannot offer or rely on operating data; hence, the staff is faced with the challenge of effectively applying or modifying existing criteria for evaluating treatment of uncertainties, estimating safety margins and assuring defense-in-depth. The staff will use the insights gained during the development of risk-informed regulatory approaches to effectively apply or modify existing criteria.

The staff has approached the review of pre-application submittals from Exelon with the objective of meeting the Commission's direction to engage in early interactions with potential applicants and consider review criteria or novel regulatory approaches that may be proposed by them. Hence, at this stage, the staff has conducted a high-level review which does not consider all the levels of detail Exelon has addressed in periodic meetings with the staff. The staff is conscious of maintaining its regulatory independence during these interactions. The staff will primarily rely on its depth and breadth of experience with (1) reviewing non-LWRs using the existing regulations and regulatory practice, and (2) applying risk-informed, performance-based approaches to regulation, and will supplement this experience with information received from Exelon.

To a considerable extent, Exelon has used past work on non-LWRs, most notably the work on the MHTGR, to develop its licensing approach.

Exelon's licensing approach has three guiding principles:

1. To conform with the current regulations while recognizing that the current regulatory requirements are based on LWR technology. Hence, rulemaking is not expected to be necessary. The licensing approach is focused on the safety regulations in 10 CFR 50. Certain regulatory objectives are not amenable to probabilistic treatment in the present regulatory environment. These include administration, process, occupational exposure minimization, environmental impacts other than radiological, and security and safeguards. These objectives will be met in the conventional manner consistent with existing practice.

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. Where regulations do not apply directly, alternative regulatory criteria will be considered to achieve the intent of the regulations.

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) similar to the process employed for the MHTGR.

In reviewing Exelon's proposed licensing approach, the staff has taken into account the previous staff review of the MHTGR, the risk-informed framework provided to the Commission in SECY-00-198, RG 1.174, the Commission policy statement on PRA, and the Commission's White Paper on risk-informed and performance-based regulation. The staff will use the Option 3 framework to develop appropriate risk metrics and guidelines for applying them. The attributes relative to evaluating treatment of uncertainties, estimating safety margins and assuring defense-in-depth that have been articulated in RG 1.174 and the White Paper will be employed to assess the various prevention and mitigation aspects of the PBMR design. The regulatory criteria for monitoring the performance of unique features of the PBMR design will be developed based on the principles of the White Paper.

Exelon plans to use the staff's preliminary assessment of the proposed licensing approach as part of the basis for a feasibility study that will assist them in the commercial decision on whether to proceed with licensing in the U.S. The commercial prospects for Exelon's proposal are not relevant to the NRC's responsibilities; hence, staff's views of the licensing approach were not influenced by the commercial factors that will be considered in the feasibility study.

The staff's assessment of Exelon's licensing approach is attached.

CONCLUSIONS:

The staff has concluded that the licensing approach proposed by Exelon, if adequately implemented, has the potential to be a reasonable process for assuring that the Commission's regulations are met and for identifying PBMR-specific regulatory requirements. The process does not appear to present any unsurmountable obstacles that could preclude a finding relative to adequate protection at the licensing stage. Part of the basis for this conclusion is the similarity between the approach proposed by Exelon and the one the staff reviewed for the MHTGR. The MHTGR pre-application safety evaluation report (published in 1995) raised some licensability issues, such as fuel design, containment leak-tightness, fission product transport codes, and reactor cavity cooling system design, that may apply to the PBMR and should be addressed as more detailed design information becomes available.

The staff also concluded that the licensing approach has the potential to provide a sufficient basis for confidence that safety issues are raised and satisfactorily addressed during the licensing of the PBMR. However, several elements of the Exelon proposal have potential policy implications. These potential policy implications (discussed in the attachment) will be as follows:

- The use of quantified probabilistic criteria to select events to be considered in the design and in emergency planning (EP) may be an extension of risk-informed regulation beyond current practice. The issues of treatment of uncertainties, margins of safety, and defense-in-depth need to be assessed and any policy matters identified.

- The use of Exelon's proposed acceptance criteria, in conjunction with the events to be considered in the design, and how the criteria relate to decisions on the role of a containment in the design and EP, need further assessment for policy implications.

The staff's assessment is preliminary. The staff will continue to solicit stakeholder feedback and finalize its assessment later in the pre-application review. The staff intends to give the Commission a paper on technical policy issues regarding the PBMR in December.

Exelon has requested continued interactions with the staff regarding the proposed licensing approach for the PBMR. The staff will continue to exercise caution in these interactions to ensure that regulator independence is maintained.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Advisory Committee on Reactor Safeguards was briefed on October 4, 2001.

William D. Travers
Executive Director
for Operations

Attachment: Staff Preliminary Assessment of Exelon's Proposed Licensing Approach

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DISTRIBUTION: See attached.

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Staff Preliminary Assessment of Exelon's Proposed Licensing Approach

ATTACHMENT

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INTRODUCTION

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 applicants so that regulatory requirements for advanced reactors can be identified early 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.

In a letter dated December 5, 2000, citing the NRC's "Statement of Policy for Regulation of Advanced Nuclear Power Plants," Exelon expressed interest in conducting pre-application activities with the staff. The NRC staff began its pre-application review in a meeting with Exelon Generation (Exelon) on April 30, 2001. During the 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, and September 19, 2001, to discuss the proposed licensing approach. In these meetings, the staff provided time for other stakeholders to comment on the proposed licensing approach. In a 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.

Exelon plans to use the staff's preliminary assessment of the proposed licensing approach as part of the basis for a feasibility study that will assist them in the commercial decision on whether to proceed with licensing in the United States. The commercial prospects for Exelon's proposal are not relevant to the NRC's responsibilities; hence, staff's views of the licensing approach were not influenced by the commercial factors that will be considered in the feasibility study.

This report presents the staff's assessment of the approach. In the sections below, the staff first summarizes key information about Exelon's proposal and then presents the staff's comments and reaction to the proposal. The staff also discusses other documents and information that were considered as part of the assessment. In its assessment, the staff has focused upon the merits of the approach as a process. Conclusions with respect to what specific requirements would result for the pebble bed modular reactor (PBMR) as such conclusions could not be made in the absence of more detailed design information.

PAST NRC EXPERIENCE WITH HIGH-TEMPERATURE GAS-COOLED REACTORS

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 this last case to see how the agency has dealt with the issue of applicable regulations, particularly the General Design Criteria (GDC), for insights on how the process might be done for the PBMR.

Fort St. Vrain was an 842-MWt high-temperature gas-cooled reactor, received its construction permit in 1968, an operating license in 1973, and then 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 all 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 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 safety evaluation (SE) report included a section on the use of the principles of defense-in-depth and fission product barriers in this design, describing the confinement building noting that the fuel particles were coated with ceramic and that the primary coolant reactor vessel liner, the walls of the primary coolant reactor vessel, and the primary and secondary enclosures of the penetrations formed the primary coolant system envelope and provided the containment function. The conclusion was 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) but most were not.

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

The licensing approach proposed by Exelon for the PBMR is similar to that proposed by the Department of Energy (DOE) for the Modular High-Temperature Gas-Cooled Reactor (MHTGR). 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 initial phase of the pre-application review lasted from 1986 through 1989 and is documented in draft NUREG-1338, "Draft Pre-application Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor," issued in 1989. The final phase of the review was conducted from 1990 through 1996 by the Office of Nuclear Reactor Regulation and is documented in draft NUREG-1338, "Pre-application Safety Evaluation Report for the Modular High-Temperature Gas-Cooled Reactor (MHTGR); Draft Copy of the Final Report," published in 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 conformance to 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) – a review of the plant against the Standard Review Plan (SRP) sections in NUREG-0800, the regulations in 10 CFR Parts 50 and 100, including the GDCs in 10 CFR Part 50, Appendix A, regulatory guides (RGs), and staff-endorsed industry codes and standards. The staff also evaluated the designer's probabilistic risk assessment, and use of defense-in-depth and safety margins. Defense-in-depth and safety margins contribute to LWR safety and the staff wanted to be sure that the MHTGR design used the defense-in-depth and safety margin principles. 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

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 that DOE's approach was a systematic and useful approach for designing a nuclear power plant, but that the approach correlated safety and regulation too closely with probabilistic methodology and focused too narrowly on 10 CFR Part 100 dose guidelines, removing 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 was a useful tool in evaluating a design, but did not consider it to be developed to the point where it could be used as the primary measure of reactor safety or acceptability.

EXELON'S PROPOSED LICENSING APPROACH AND STAFF ASSESSMENT

In a letter dated August 31, 2001, Exelon set forth its proposed licensing approach for evaluating the PBMR and requested the staff to use this document alone as the basis for an assessment. Exelon's specific objectives which are discussed in more detail below for developing the PBMR licensing approach 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 top-level regulatory criteria (TLRC) (what must be satisfied)

- Establish an agreed-upon risk-informed method for selecting licensing basis events (when the TLRC must be met)

- Establish a design-specific method to select and determine special treatment of safety-related systems, structures, and components (how and how well the criteria are met).

Exelon intends to utilize current regulations to guide the ongoing design process, and is not seeking any new rulemaking as part of its combined operating license application. Exelon's 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 mid-80s for the MHTGR and modified to reflect the advances that have been made since then 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 based on objectives of limiting public exposures during normal operation and preventing and mitigating accidents. Certain regulatory objectives are not amenable to probabilistic treatment in the present regulatory environment. These include administration, process, occupational exposure minimization, environmental impacts other than radiological, and security and safeguards. These objectives will be met in the conventional manner consistent with existing practice.

Exelon has requested continued interaction with the staff regarding the proposed licensing approach for the PBMR. The staff will continue to exercise caution throughout these interactions to ensure that regulator independence is maintained.

Screening of Regulations

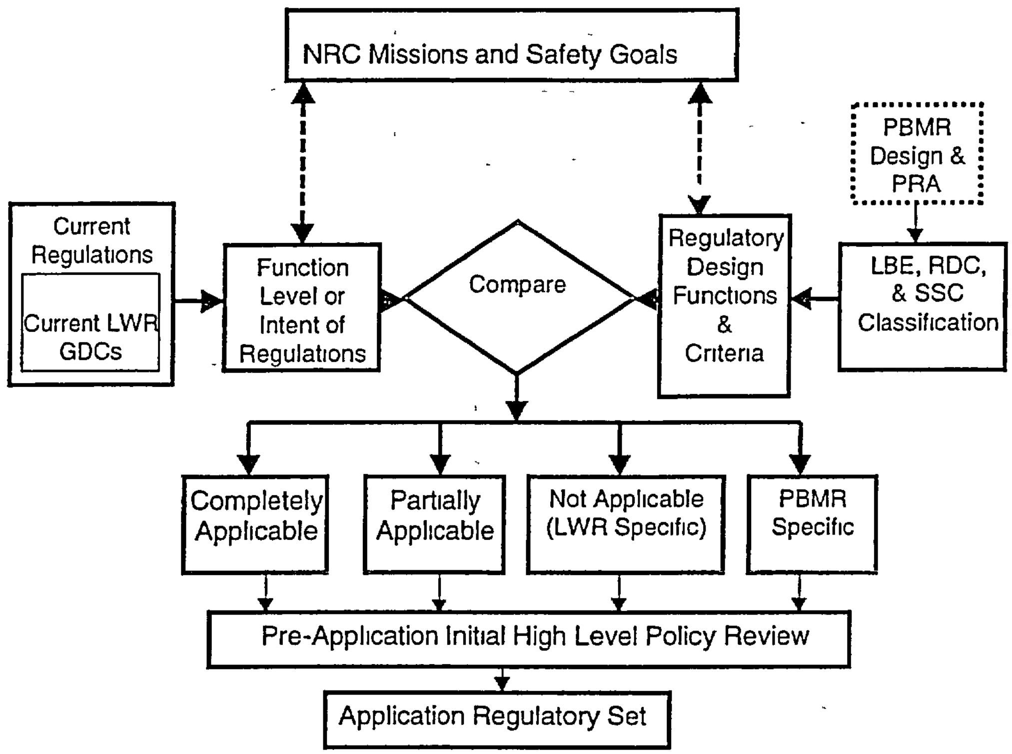
Exelon Proposal

Given the very limited regulatory experience with gas 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 requirements will have to be crafted out of the existing regulations, regulatory guides and standard review plans to guide the applicant in preparing its license applications and NRC in reviewing them. This situation is recognized in the Introduction to Appendix A to 10 CFR Part 50 and 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. In the policy statement, the Commission encourages applicants to interact very early with the NRC staff and to propose ways to better guide the development of the application and the review of the advanced design. That is the objective of the regulatory screening process that Exelon is conducting, using an expert elicitation panel.

A top-down, safety-focused method to create a specific set of requirements using a combination of deterministic and risk-informed techniques to decide specific requirements for the design has been developed. The requirements for the design would then be compared with the existing body of regulations. It has been recognized by Exelon and NRC that some of the current design-related regulations are fully applicable to any design, some are not applicable to gas reactors, and many may be partially applicable. There may also be some features of the PBMR design that cannot be addressed by any current regulatory document, thus requiring new guidance documents to be developed or other agreements reached between Exelon and the NRC during the pre-application period. The process proposed by Exelon of addressing deterministic and risk-informed objectives is represented in Figure 1. The process yielded several products that will help shape future activities. For example, the process provided a preliminary view on the applicability of each of the regulations in 10 CFR Part 50 plus a partial set of other rules that could be used to shape the application and review requirements for the PBMR design.

In determining the applicability of the regulations to the PBMR, the expert panel considered two questions: (1) Does the regulation literally apply to gas-cooled reactors? (2) If not (e.g., if the regulation on its face applies only to LWRs), is the regulation useful as guidance for the PBMR. If either of these questions was answered yes, the regulation was designated as applicable to the PBMR (or partially applicable in cases in which the regulations have multiple parts, some applicable and some not). In those cases in which a regulation was applicable or partially applicable, the expert panel also determined whether the regulation was applicable as a legal requirement or as guidance (i.e., an LWR regulation that will be applied as guidance to the PBMR).

Figure 1



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, appropriate PBMR-specific requirements will be developed and applied.

Staff Assessment

The staff has not reviewed the preliminary list of regulations in any detail because of the need to have the design and design analysis information available to reach agreement. NRC does agree that issues on how to interpret certain rule wording (e.g., reactor coolant pressure (RCP) boundary, loss-of-coolant accident, containment) with respect to use for PBMR will be significant as the review proceeds. The staff will use as a starting point the MHTGR safety evaluation (which considered GDC and other requirements and guidance) in its review. The ultimate determination of applicability of regulations will be made by the staff.

The staff recognizes that a potential weakness of this process is that the regulatory issues addressed are only those that have been confronted as part of the development of LWR regulations. This is why the information from the boxes on the top right of the figure, on regulatory design functions and criteria, is needed to bring forth PBMR-specific issues.

The staff does find that the classification in terms of regulations which apply, partially apply, do not apply or requirements which are PBMR specific is sufficiently encompassing to permit an effective screening of regulations. The process also permits considerations to be developed that may serve as bases for appropriate exemption requests. The staff intends to pursue a screening of regulations independently. However, in the interests of efficiency, it should be possible to reduce the efforts expended by accepting at face value a finding on the part of Exelon that a given regulation applies. The focus then would be on how the regulatory requirements are complied with. Identification of PBMR specific requirements will have to await much more design information than is currently available, and perhaps a completed PRA.

Top-Level Regulatory Criteria

Exelon Proposal

The TLRC identified by Exelon are plotted on Figure 2. These are stated to be updates of TLRC presented by DOE in support of the MHTGR in 1989. The TLRC are characterized as a set of criteria which is a fundamental and quantitative basis that is both consistent and unambiguous for judging the current acceptability of potential radionuclide releases such that protection of the public health and safety and the environment is adequately maintained. These criterion specify numerical limits on radiological releases (either directly as dose limits or as risk metrics). 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 to individuals and the environment. The TLRC are based upon existing NRC and Environmental Protection Agency regulations, safety goals, and guidance. In addition, Exelon has based the TLRC on being independent of reactor type and site, as well as having the characteristic of being well defined and quantifiable in terms of risk metrics.

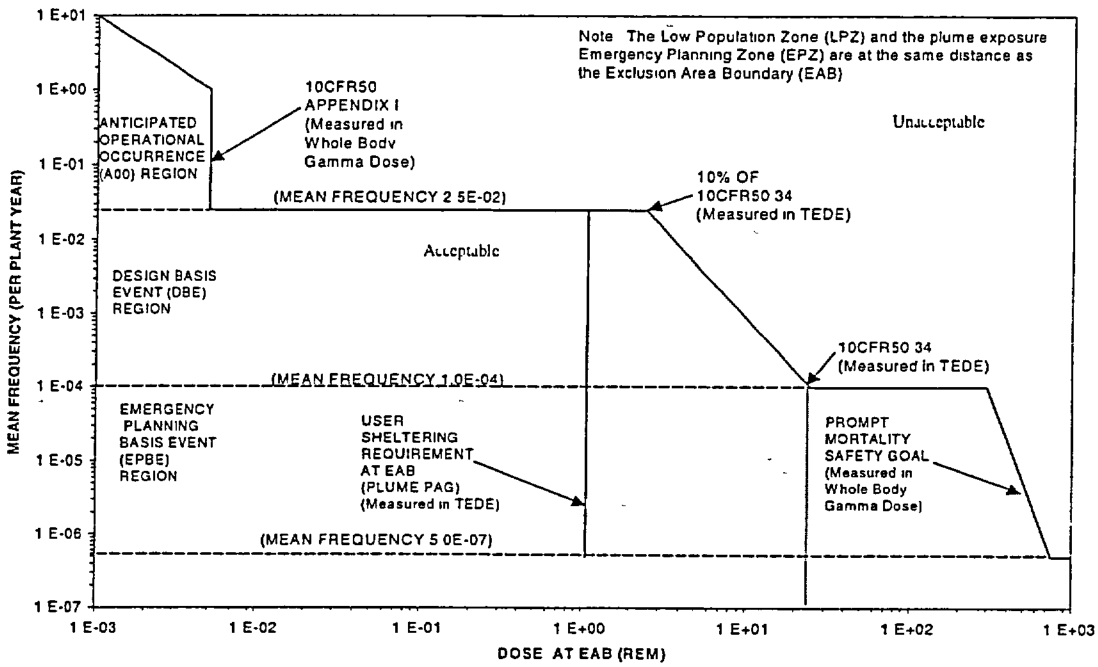
The consequence limits in the TLRC can be transformed into risk criteria, because the event sequences against which they are applied have understood frequency ranges. For example, (1) the limits in 10 CFR Part 50, Appendix I, 10 CFR Part 20, and 40 CFR 190 all pertain to normal operations and anticipated operational occurrences; (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 are plotted on Figure 2 and show the bounding values with frequency ranges, as proposed by Exelon, over which they would apply.

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)
- 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

Figure 2



independently. Thus, in the case of the PBMR, the total impact of installing multiple modules (up to 10) will be evaluated similar to 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 licensing approach considers the cumulative risk posed by the 10 modules, rather than considering each module separately.

Staff Assessment

The licensing approach as it relates to applicability of the regulations is focused on the safety regulations in 10 CFR Part 50 as it currently exists. The plotting of the TLRC is consistent with past principles but poses technical challenges such as the appropriate frequency ranges applicable to each of the regions. The staff expects that when such technical questions arise, it will also include policy implications which may require Commission input before such questions are resolved. Some of these technical and policy issues have been indicated in this assessment, but these may not be all that would have to be dealt with as the review proceeds. Also, the staff expects that continued interaction with Exelon will help clarify some issues. For example, the TLRC use one of the quantitative health objectives (QHO) from the Commission's safety goal policy (the risk of prompt fatality); however, the other QHO on latent cancer risk is not addressed.

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 recognized so as to make the applicant accountable for validating them.

With regard to the application of the TLRC, the current regulations include a frequency reference for the definition of AOOs but a similar reference does not exist 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. Some of the considerations are cumulative effects (for the families of events and for multiple modules) as well as the frequency ranges considered in other advanced reactor reviews.

While not a regulatory requirement, the staff will assess the information contained in the EPRI (Electric Power Research Institute Utility) Requirements Document for Passive ALWRs 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 which incorporate sufficient generality that comparison with existing plants would be possible. However, difficulties could arise when non-quantitative aspects of defense-in-depth and avoidance of "risk-based" decisions become significant considerations.

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. Exelon, in a September 5, 2001, letter agrees 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, such as the safety-related design conditions (SRDCs) and regulatory design criteria (RDC), that are applied to the safety-related equipment to meet the licensing basis events (or other special regulatory objectives such as anticipated transients without scram (ATWS) or station black-out (SBO)), not just being within the plot of the TLRC. The PRA confirms risk insights for a design, and can be used for other purposes as noted, but the licensing is still on a "deterministic" basis.

Selection of Licensing Basis Events

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 as the best available safety analysis method that shows how the dependencies and interactions among systems, structures, components (SSCs), human operators, and the internal and external plant hazards that may perturb the operation of the plant can 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. The PRA will be used to select families of events (based upon expected frequencies and consequences) which will become the licensing basis events for the PBMR. The families will consist of events of similar characteristics (initiator, end states).

Families of events may have significant uncertainties in the estimate of their frequencies. The consideration of these uncertainties is necessary to ensure 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

AOOs are 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, 10 CFR Part 50, Appendix I is the applicable criterion as it specifies the numerical guidance to assure that releases of radioactive material to unrestricted areas during normal reactor operations, including AOOs, are maintained ALARA.

Design Basis Event Region

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 10^{-4} per plant year is being 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, 10 CFR 50.34(a)(1) provides the quantitative dose guidance for accidental releases for siting a nuclear power plant to ensure that the surrounding population is adequately protected.

Emergency Planning (EP) Basis Event Region

The emergency planning basis event (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 acceptable, 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 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, 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 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.

Events below the EPBE region are 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. The PBMR would be expected to have 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

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 representative design decisions.

Assurance is needed that the events used to define the licensing basis constitute a reasonably complete set. SECY-01-0100, "Policy Issues Related to Safeguards, Insurance, and Emergency Preparedness Regulations at Decommissioning Nuclear Power Plants Storing Fuel in Spent Fuel Pools," issued on June 4, 2001, states that "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 was, in part, due to the difficulty in 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 staff also believes the PRA should also include accidents involving spent fuel stored on site (analogous to spent fuel pool accidents in LWRs).

During the MHTGR pre-application review, in the staff requirements memorandum (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 the 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 candidate LBEs that will be considered for application within the framework of the TLRC will first be established from a deterministic standpoint and will then be assessed and compared to the TLRC using risk insights. The staff believes this is consistent with the previous Commission guidance. The staff has also indicated to Exelon and Exelon has agreed that the licensing approach must accommodate for the assessment of licensing basis events proposed by the staff. 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.

During the MHTGR pre-application review, 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. Identification of an appropriate source term is inherent to the licensing approach in that LBEs cannot be compared to the TLRC without an estimation of the source term. The staff intends to adhere to the previous Commission guidance.

Determination of Safety-Related Structures, Systems, and Components (SSCs)

Exelon Proposal

The selection of the LBEs requires that the radionuclide retention functions that keep the events in the AOO and DBE 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 RDC.

The required safety functions to meet the TLRC will be identified. The functions are to be those needed for both public and personnel TLRC. 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 such that LBEs meet the TLRC are to be met using only safety-related equipment.

The 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 kept in the acceptable range.

Consequence Mitigation: The first step is to classify one or more structures, systems, or components (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. Note that this step does not result in any equipment being classified as safety-related if the EPBE would be acceptable in the higher DBE region. This step has the effect on the chart of preventing high-consequence events from moving up (in frequency) into the DBE region.

Regulatory Design Criteria: 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. 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 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 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, it is expected 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.

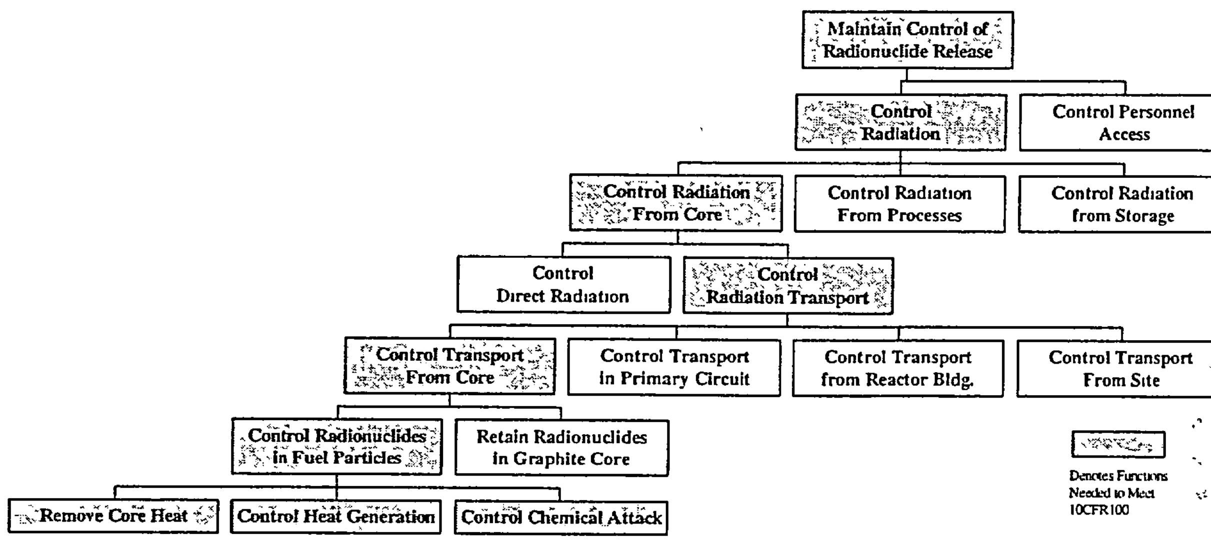
Staff Assessment

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, not just being within the plot of the TLRC. The PRA confirms risk insights for a design, and can be used for other purposes as noted, but the licensing safety analysis is still on a "deterministic" basis.

In the licensing approach, Exelon proposed 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 approach proposed by Exelon is a novel approach that has not yet been considered by the staff in its risk-informed activities. Because Exelon's approach proposes to use frequencies and dose-consequences rather than core damage frequency (CDF) and large early release frequency (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. The staff will continue to pursue this approach with Exelon in its pre-application review.

The licensing approach discusses required safety functions and used a figure (shown below as Figure 3) to illustrate. 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.

Figure 3: Radionuclide Retention Functions for the MHTGR



During the MHTGR 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 be using current LWR criteria to the extent practicable.

During the MHTGR pre-application review, 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, regarding regulatory treatment of non-safety systems, the Commission approved the process proposed by the staff 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 to evaluate the overall safety characteristics of the PBMR plant. Systematically enumerating a sufficiently complete set of accident scenarios and assessing the frequencies and consequences of the scenarios individually and in the aggregate can be used to predict the overall risk profile. 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 clearly documented and scrutable.

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 licensing basis events
- 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
- To provide insight on the available defense-in-depth in the design

Exelon also discussed the scope and major elements of the PBMR PRA. 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 of consequences to public safety, public health, and the environment by quantifying the frequency of different consequence magnitudes. The scope of the PBMR PRA needed to support Exelon's 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 LWR 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 encompasses the functions of a full scope Level 1-2-3 PRA.

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 this can be accomplished without the need for separate models for each mode of operation.

The modular aspect of the PBMR creates the potential for anywhere from 1 to as many as 10 reactors 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 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 from conceptual design, completion of 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, to compare specific percentiles of the uncertainty distributions against the criteria, and to compute the probability that specific criteria are met.

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

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 characteristics of LWRs that are 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, it is not appropriate to fit a PBMR PRA into the mold of the Level 1-2-3 framework. Instead an integrated PRA that develops sequences from initiating events all the way to source terms and consequences is developed.

- As noted above, it is not necessary to perform a completely different set of PRA models for full power vs. 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 extend 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.

With these adjustments, Exelon believes it is reasonable to apply the applicable LWR PRA standards and peer review processes to assessing 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 Level 1-2-3 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). However, the staff believes that further development of standards is necessary because the current ASME standard does not address Level 3 PRAs, focusing on LERF analysis for Level 2 PRAs. Although the ASME standard provides requirements for treating uncertainties, the lack of operation 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.

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 believes 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. In addition, Exelon has not proposed bounding events as was done during the MHTGR pre-application review, although Exelon has indicated the intention to examine events below the EPBE range to assure that residual risk is negligible.

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 decision-making. In August 1995, the NRC adopted a policy statement regarding the expanded use of PRA. One of the major aspects 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 complements 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.

In NRC 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 staff defined an acceptable approach to analyzing and evaluating proposed licensing basis changes. This approach supports the NRC's desire to base its decisions on the results of traditional engineering evaluations, supported by insights (derived from the use of PRA methods) about the risk significance of the proposed changes. Decisions concerning proposed changes are expected to be reached 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 regulatory guide, 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 and show that these principles are met. Each of these principles should be considered in a risk-informed, integrated decisionmaking 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.

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

The staff has determined that, while developed for use in evaluating changes to a licensing basis, these principles are applicable with some adjustment.

The staff will also consider the concepts incorporated in the Commission's White Paper on "Risk-Informed and Performance-Based Regulation" including application of performance-based approaches where appropriate as well as the attributes of defense-in-depth provided in the paper, viz:

"Defense-in-depth is 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."

In addition, in SECY-00-198, "Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," 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's 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 Jackson, dated May 19, 1999.

(2) 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
- 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
- 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 is avoided on programmatic activities to compensate for weaknesses in plant design
- independence of barriers is not degraded
- the defense-in-depth objectives of the current GDC in Appendix A to 10 CFR Part 50 are maintained

(2) The framework considers both design basis as well as core-melt accidents.

(3) The framework considers uncertainties.

(4) 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] That is, the framework is constructed in such a way that 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). The framework uses quantitative guidelines, based on the safety goals and the subsidiary objectives of 1 x 10^{-4} per reactor year for CDF and 1 x 10^{-5} per reactor-year for LERF, 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.

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

POTENTIAL POLICY ISSUES

Several elements of the Exelon proposal involve approaches that have potential policy implications. These potential policy implications are:

The use of quantified probabilistic criteria to select events to be considered in the design and in EP may be an extension of risk-informed regulation beyond current practice. The issues of defense-in-depth, treatment of uncertainties, and margin of safety to be achieved need to be assessed and any policy matters identified.

The use of Exelon's proposed acceptance criteria, in conjunction with the events to be considered in the design, and how the criteria relate to decisions on the role of a containment in the design and EP, need further assessment for policy implications.

[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