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10-Nov-2022

2022-XE-NRC-022

Project No. 99902071

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
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Submission of X Energy, LLC (X-energy) Xe-100 Licensing White Paper Probabilistic Risk Assessment Technical Adequacy Approach

The purpose of this letter is to submit the subject white paper to the U.S. Nuclear Regulatory Commission (NRC) on behalf of X Energy, LLC ("X-energy"). It is provided to obtain NRC feedback as indicated in the report, which will clarify expectations for future Xe-100 licensing applications. The specific review schedule will continue to be developed with X-energy's NRC project manager.

This report has been reviewed for proprietary and export-controlled information and has been determined to be available for unrestricted release.

This letter contains no commitments. If you have any questions or require additional information, please contact Drew Nigh at anigh@x-energy.com or Ingrid Nordby at inordby@x-energy.com.

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Xe-100 Licensing White Paper, "Probabilistic Risk Assessment Technical Adequacy Approach" (Non-Proprietary)

Xe-100 Licensing White Paper Probabilistic Risk Assessment Technical Adequacy Approach

Document ID Number	:	**005593**
Configuration Classification	:	**XE00-P-GL-GL-GL-GL-X**
Revision	:	**1**
Security Classification	:	**Unrestricted**
Status	:	**Approved**
Date Created	:	**4-Nov-2022**
Project	:	**XE-100**

E-SIGNATURES

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10 CFR 810 Export-Controlled Information Disclaimer

This document was reviewed by X-energy and determined to not contain information designated as export-controlled per Title 10 of the Code of Federal Regulations (CFR) Part 810 or 10 CFR 110.

Department of Energy Acknowledgement and Disclaimer

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CONFIGURATION CONTROL/DOCUMENT CHANGE HISTORY

Document Change History

Rev.	Date	Preparer	Page/Section Revised	Description
1	4-Nov-2022	D Nigh	Entirety	Initial Issue

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Abstract

This document discusses X-energy's approach to achieve PRA technical adequacy for a Construction Permit Application (CPA) in accordance with the regulations contained in 10 CFR Part 50 and RGs 1.233 and 1.247. Furthermore, this document describes the approach X-energy plans to take in future submittals for a 10 CFR 50 Operating License Application (OLA) and the standard design.

It provides a reproduction of the staff regulatory guidance in RG 1.247, Section C, with description of X-energy's intended approach to conformance, offering interpretation for how to apply this guidance to the Xe-100 design where necessary. The approach and methodologies described in this document are intended to initiate pre-application engagement with the NRC. X-energy is not seeking NRC approval for the Xe-100 approach to PRA technical adequacy—the purpose of this white paper is to obtain NRC feedback. Guidance for a CPA is not explicitly described in NRC regulatory guidance, so X-energy developed a project-specific approach based on RG 1.247, RG 1.233, other staff guidance, and NEI 21-07. The Xe-100 PRA will be developed to meet the current guidance in the applicable RGs and to meet the current requirements in 10 CFR 50 to support risk-informed licensing activities.

RG 1.247 describes one acceptable approach that the US Nuclear Regulatory Commission (NRC) staff has developed for determining whether a design-specific or plant-specific probabilistic risk assessment (PRA) used to support an application is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decision-making for non-light-water reactors (NLWRs). In this white paper, the term "application" refers to risk-informed applications that support the licensing basis for the Xe-100 licensing submittals, unless it appears in the context of the phrase "license application," which references to future X-energy license submittals.

By conforming to RG 1.247, X-energy aims to reduce the need for an in-depth review of the PRA by the NRC and allow them to focus their review on key assumptions and areas identified as being of concern and relevant to the application and the demonstration of PRA technical adequacy.

In addition, this white paper describes a proposed approach for evaluating the environmental risks of severe accidents, which is an application of the PRA in Environmental Reports (ERs) developed using RG 4.2. The approach leverages the NEI 18-04 approach to assess environmental risks for the Xe-100.

X-energy submits this document to foster a transparent, inclusive, and open relationship with the NRC. This document has been prepared to provide the proposed approach X-energy will use to establish PRA technical adequacy to obtain NRC feedback on the proposed approach to support Xe-100 plant licensing efforts.

Abbreviations/Acronyms

Abbreviations/Acronyms

Short Form	Phrase
ADAMS	Agencywide Documents Access and Management System
ANLWR	Advanced Non-Light-Water Reactor
ANS	American Nuclear Society
AR	Advanced Reactor
ASME	American Society of Mechanical Engineers
CC	Capability Category
CFR	Code of Federal Regulations
CP	Construction Permit
CPA	Construction Permit Application
DBEHL	Design Basis External Hazard Level
DBHL	Design Basis Hazard Level
DID	Defense-in-Depth
EOC	Error of Commission
ER	Environmental Report
HLR	High Level Requirement
LBE	Licensing Basis Event
LPSD	Low Power Shutdown
LTR	Licensing Topical Report
LWR	Light-Water Reactor
NEI	Nuclear Energy Institute
NLWR	Non-Light-Water Reactor
NRC	(US) Nuclear Regulatory Commission

Short Form	Phrase
OL	Operating License
POS	Plant Operating State
PRA	Probabilistic Risk Assessment
PSAR	Preliminary Safety Analysis Report
RG	Regulatory Guide
SAMA	Severe Accident Mitigation Alternative
SAMDA	Severe Accident Mitigation Design Alternative
SR	Safety-Related
SR	Supporting Requirement
SSC	Structures, Systems, and Components
TEDE	Total Effective Dose Equivalent
TICAP	Technology Inclusive Content of Applications
TI-RIPB	Technology Inclusive, Risk-Informed, Performance-Based
TMI	Three Mile Island

1. Introduction

1.1 Purpose

The purpose of this document is to:

- Describe how X-energy will implement the regulatory guidance in RG 1.247 to determine the appropriate site characteristics, PRA scope, level of detail, and degree of plant representation for a technically adequate PRA supporting the Xe-100 technology-inclusive, risk-informed, performance-based (TI-RIPB) licensing basis.
- Initiate an NRC review of X-energy's approach and methodologies for PRA technical adequacy to obtain NRC feedback for license submittals.
- Seek NRC feedback on the proposed approach to evaluating environmental risks associated with severe accidents to support development of Xe-100 Environmental Reports.

1.2 Scope

This document describes the approach and methods X-energy is using to develop the Xe-100 technical adequacy requirements for CPAs, OLAs, and the standard design. The approach attempts to demonstrate X-energy's conformance to the staff guidance in RG 1.247 to determine the appropriate site characteristics, scope, level of detail, risk metrics, and capability categories for a technically adequate PRA that informs the Xe-100 licensing basis.

Furthermore, this document proposes the Xe-100 approach to evaluating the environmental risks of severe accidents. Consistent with RG 4.2, the Xe-100 PRA will serve as a major input to severe accident analysis. RG 4.2 Appendix C notes that, "there may be significant differences in the analysis of accidents [for NLWRs]. An applicant for such a design should consult with the NRC staff … to discuss the information and analysis that should be provided in the ER to support the evaluation of the impacts of accidents."

1.3 Relationsip to Other Documents

PRA technical adequacy is an essential part of the NEI 18-04 process that X-energy committed to in the Risk-Informed Performance-Based Licensing Basis Topical Report [8]. Through the NEI 18-04 process, the PRA supports the following NRC engagements:

- Xe-100 Risk-Informed Performance-Based Licensing Basis LTR [8]
- Xe-100 Principal Design Criteria Development LTR
- Xe-100 White Paper Physical Protection System Approach [19]
- Expected future engagement: Xe-100 Physical Protection System Approach LTR
- Expected future engagement: Xe-100 Emergency Preparedness Approach

1.4 Document Layout

Section 2 discusses relevant regulatory requirements and guidance pertaining to PRA technical adequacy both generically and for specific applications. Section 3 presents an overview of X-energy's PRA technical adequacy approach for license applications. Section 4 presents the Xe-100 proposed approach to evaluating the environmental risks of severe accidents. Section 5 describes the conclusions of this white paper and presents NRC review objectives requested by X-energy. Section 6 lists references used.

2. Overview of Regulatory Requirements and Regulation Implementation Guidelines

2.1 Background

Originally, the regulations in 10 CFR 50 for licensing a nuclear power plant had no requirements for a probabilistic risk assessment (PRA). Following the Three Mile Island (TMI) accident, 10 CFR 50.34(f)(1)(i) was created requiring licensees and some applicants at that time to perform a PRA to improve reliability of core and containment heat removal systems.

In the decades since the introduction of PRA, the scope of risk-informed applications has significantly increased. In 1994, SECY-94-219 established an NRC PRA Implementation Plan on "increasing the use of PRA in regulatory matters to the extent practical given the state-of-the-art in PRA methods and data available," and followed in 1995 with a "Final Policy Statement on the Use of Probabilistic Risk Assessment [PRA] Methods in Nuclear Regulatory Activities," (60 FR 42622; ADAMS ML021980535) which states "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 defense-in-depth philosophy" [18].

In the 2008 NRC Policy Statement on the Regulation of Advanced Reactors, (73 FR 60612; ADAMS ML0827503701), NRC set expectations for advanced reactors: "… the Commission expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions."

NEI 18-04, endorsed by the NRC in RG 1.233, proposes a TI-RIPB approach with risk metrics more suitable for advanced NLWRs. NEI 18-04 provides a methodology for Licensing Basis Event (LBE) selection, SSC classification, and establishing adequacy of defense-in-depth. In addition, NEI 18-04 is intended "so license applicants can develop inputs that can be used to demonstrate compliance with applicable regulatory requirements, including but not limited to the following: [1]

- 10 Code of Federal Regulations (CFR) 50.34(a)"

Specifically, NEI 18-04 establishes a risk informed methodology supporting compliance with [3]:

- 10 CFR 50.34(a) (3) – Principal Design Criteria (PDC)
- 10 CFR 50.34(a) (4) – Analysis and Evaluation of SSCs
- 10 CFR 50.34(a) (7) – Quality Assurance Program

NEI 18-04 relies on a PRA for significant input and references consensus PRA standards for demonstrating PRA technical adequacy, defined in the NEI 18-04 glossary as:

> A set of attributes that define the technical suitability of a PRA capability to provide fit-for-purpose insights to risk-informed decision-making. It includes consideration of realism, completeness, transparency, PRA model-to-plant as-designed and as-built fidelity state, and identification and evaluation of uncertainties relative to risk levels. Strategies to achieve technical adequacy include conformance to consensus PRA standards, performance of PRA

[1] Note that these upper tier regulations contain requirements for reactor designers and license applicants to provide information that demonstrates compliance with other, more topic-specific regulations.

peer reviews, and structured processes for PRA model configuration control, maintenance and updates, and incorporation of new evidence that comprises the state of knowledge reflected in the PRA model development and its qualification.

The ASME/ANS NLWR PRA standard is endorsed in RG 1.247 with the NRC providing clarifications or exceptions on specific supporting requirements of the standard [1]. Together, RG 1.247 (for generic PRA technical adequacy) and RG 1.233 (for PRA technical adequacy for an NEI 18-04 licensing submittal application) provide the central NRC guidance on PRA technical adequacy for license applications.

NEI 21-07 provides more clarity and establishes expected content of applications for an applicant following the NEI 18-04 approach. Importantly, this document provides more clarity on how Principal Design Criteria (PDC) should be defined for NLWRs that follow the methodology NEI 18-04 and RG 1.233. X-energy expects to implement guidance from a future regulatory guide that endorses NEI 21-07, which is currently under development. The approach to PRA technical adequacy described in this paper will be revised as appropriate pending issuance of future regulatory guidance.

2.2 Applicable Code of Federal Regulations Requirements

X-energy performed a regulatory requirements analysis and identified the following requirements that necessitate the development of a PRA to support the Xe-100 licensing basis.

2.2.1 10 CFR 50.34(a)(1) - Contents of Applications; Technical Information.

X-energy will develop the Xe-100 licensing basis using the approach described in “Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development” [8]. This report describes how the risk-informed performance-based methodology developed in the US Licensing Modernization Project is being implemented by X-Energy for design, analysis, and licensing of the Xe-100 reactor. The approach facilitates compliance with 10 CFR 50.34(a)(1), which states:

> (a) Preliminary safety analysis report. Each application for a construction permit shall include a preliminary safety analysis report. The minimum information to be included shall consist of the following:
>
> (1) Stationary power reactor applicants for a construction permit who apply on or after January 10, 1997, shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.
>
> …
>
> (ii) A description and safety assessment of the site and a safety assessment of the facility. It is expected that reactors will reflect through their design, construction and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The following power reactor design characteristics and proposed operation will be taken into consideration by the Commission:
>
> (A) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;
>
> (B) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(C) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials;

(D) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE).

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE);

By implementing the NEI 18-04 approach as described in the “Xe-100 Risk-Informed Performance-Based Licensing Basis LTR” [8], X-energy will meet these regulations for the Xe-100. NEI 18-04 offers “guidance for advanced designs so license applicants can develop inputs that can be used to demonstrate compliance with applicable regulatory requirements, including … 10 Code of Federal Regulations (CFR) 50.34(a), [which] describes the content required in the Preliminary Safety Analysis Report for a Construction Permit application.” Specifically, the NEI 18-04 approach will allow for identification and selection of LBEs, safety classification of SSCs, and evaluation of DID adequacy.

2.2.2 10 CFR 50.34 (f) (1) (i) PRA to Improve Reliability of Core and Containment Heat Removal Systems

The only requirement in 10 CFR 50 for a PRA at the construction permit stage comes from 10 CFR 50.34(f)(1)(i) and it applies to “each applicant for a light-water-reactor construction permit or manufacturing license whose application was pending as of February 16, 1982”. The requirement states:

> Perform a plant/site specific probabilistic risk assessment, the aim of which is to seek such improvements in the reliability of core and containment heat removal systems as are significant and practical and do not impact excessively on the plant.

The Updated NRC Staff Draft White Paper Analysis of Applicability of NRC Regulations for Non-Light Water Reactors provides the following statement on the applicability of this regulation to NLWRs:

> Although not required for applications under 10 CFR Part 50, the Commission direction in the Staff Requirements Memorandum to SECY-15-0002 confirmed that its earlier directions for the 10 CFR Part 52 new power reactor applications be applied consistently to 10 CFR Part 50 new power reactor applications. In addition, the Commission approved revision of the regulations in 10 CFR Part 50 for new power reactor applications to more closely align with requirements in 10 CFR Part 52, incorporating the requirements identified by the staff in SECY-15-0002, including the TMI-related items under 10 CFR 50.34(f) and the PRA requirements under section 50.71(h).

Even though this requirement is applicable to light-water reactor designs, its intent will be implemented in the Xe-100 design using the approach described in the “Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development” [8].

Development of a PRA to support NEI 18-04 and RG 1.233 inherently requires modeling of systems that prevent or mitigate the release of radioactive material. For the Xe-100 design, this includes the modeling of core heat removal systems. The PRA will not only address the reliability of the core heat removal systems but will address the reliability of all safety significant SSCs and will also quantify the consequences of failure of core heat removal and all other safety significant SSCs. The Xe-100 employs a functional containment concept recognized in RG 1.233 and does not require or include a system for removing heat from the reactor building so the concept of a “containment heat removal system” does not apply. Application of the NEI 18-04 methodology includes a process of selecting reliability and capability targets and monitoring performance against these requirements. These targets inform the selection of special treatments to achieve them. Therefore, X-energy will meet the intent of this requirement despite no explicit requirement to follow the regulation for an advanced NLWR.

2.2.3 10 CFR 50.71 (h) Maintenance of Records – PRA

The additional Part 50 requirements for PRA only apply to holders of combined licenses:

> (h)(1) No later than the scheduled date for initial loading of fuel, each holder of a combined license under subpart C of 10 CFR part 52 shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.
>
> (2) Each holder of a combined license shall maintain and upgrade the PRA required by paragraph (h)(1) of this section. The upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade. The PRA must be upgraded every four years until the permanent cessation of operations under § 52.110(a) of this chapter.
>
> (3) Each holder of a combined license shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (h)(1) of this section to cover all modes and all initiating events.

While not required for a CPA, X-energy will meet the intent of these requirements for an OLA by developing a PRA in accordance with the ASME/ANS NLWR PRA standard. X-energy expects to update the PRA on a periodicity no greater than four years.

2.2.4 10 CFR 52.47(a) - Contents of Applications; Technical Information.

X-energy will develop the Xe-100 licensing basis using the approach described in the "Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development." This report describes how the risk-informed performance-based methodology developed in the US Licensing Modernization Project is being implemented for design, analysis, and licensing of the Xe-100 reactor. The approach facilitates compliance with 10 CFR 52.47(a), which states:

> The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC, and procurement specifications and construction and installation specifications by an applicant. The Commission will require, before design certification, that information normally contained in certain procurement specifications and construction and installation specifications be completed and available for audit if the information is necessary for the Commission to make its safety determination.
>
> (a) The application must contain a final safety analysis report (FSAR) that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and must include the following information:
>
> (1) The site parameters postulated for the design, and an analysis and evaluation of the design in terms of those site parameters;
>
> (2) A description and analysis of the structures, systems, and components (SSCs) of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which these requirements have been established, and the evaluations required to show that safety functions will be accomplished. It is expected that the standard plant will reflect through its design, construction, and operation an extremely low probability for accidents that could result in the release of significant quantities of radioactive fission products. The description shall be sufficient to permit understanding of the system designs and their relationship to the safety evaluations. Such items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent. The following power reactor design characteristics will be taken into consideration by the Commission:
>
> (i) Intended use of the reactor including the proposed maximum power level and the nature and inventory of contained radioactive materials;
>
> (ii) The extent to which generally accepted engineering standards are applied to the design of the reactor;

(iii) The extent to which the reactor incorporates unique, unusual or enhanced safety features having a significant bearing on the probability or consequences of accidental release of radioactive materials; and

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release from the core into the containment assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable containment leak rate and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE);

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem TEDE;

(3) The design of the facility including:

(i) The principal design criteria for the facility. Appendix A to 10 CFR part 50, general design criteria (GDC), establishes minimum requirements for the principal design criteria for water cooled nuclear power plants similar in design and location to plants for which construction permits have previously been issued by the Commission and provides guidance to applicants in establishing principal design criteria for other types of nuclear power units;

(ii) The design bases and the relation of the design bases to the principal design criteria;

(iii) Information relative to materials of construction, general arrangement, and approximate dimensions, sufficient to provide reasonable assurance that the design will conform to the design bases with an adequate margin for safety;

(4) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

(13) The list of electric equipment important to safety that is required by 10 CFR 50.49(d);

…

> (19) A description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Appendix B to 10 CFR part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to 10 CFR part 50 were satisfied;
>
> …
>
> (27) A description of the design-specific probabilistic risk assessment (PRA) and its results.

By implementing the NEI 18-04 approach as described in the "Xe-100 Risk-Informed Performance-Based Licensing Basis LTR" [8], X-energy will meet these regulations for the Xe-100. NEI 18-04 offers "guidance for advanced designs so license applicants can develop inputs that can be used to demonstrate compliance with applicable regulatory requirements, including … 10 CFR 52.47, [which] describes the required information for a FSAR associated with a Standard Design Certification application." Specifically, the NEI 18-04 approach will allow for identification and selection of LBEs, safety classification of SSCs, and evaluation of DID adequacy.

Regarding item (3)(i), the Principal Design Criteria for Xe-100 will be defined following the approach described in the Principal Design Criteria Licensing Topical Report [15].

2.2.5 10 CFR 51 Regulations Pertaining to Analyzing Severe Accident Risks in Environmental Reports

This section summarizes the parts of 10 CFR 51 that elicit consideration of severe accident risks as part of the initial Environmental Reports for advanced reactor applications.

10 CFR 51.45(b)(1), Environmental Report, states that "The environmental report shall contain a description of the proposed action… The impact of the proposed action on the environment. Impacts shall be discussed in proportion to their significance."

10 CFR 51.45(c) states that, "The environmental report must include an analysis that considers and balances the environmental effects of the proposed action, the environmental impacts of alternatives to the proposed action, and alternatives available for reducing or avoiding adverse environmental effects."

X-energy plans to develop and apply the PRA to evaluate the environmental risks of severe accidents as described in Section 4.

2.2.6 10 CFR 50, "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants"

10 CFR 50 "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" describes the policy the Commission intends to use to resolve safety issues related to reactor accidents more severe than design basis accidents. Its main focus is on the criteria and procedures the Commission intends to use to certify new designs for nuclear power plants. Per the policy:

> Severe nuclear accidents are those in which substantial damage is done to the reactor core whether or not there are serious offsite consequences. …

> One important source of new information is the experience of NRC and the nuclear industry with plant-specific probabilistic risk assessments. Each of these analyses, which provide detailed assessment of possible accident scenarios, has exposed relatively unique vulnerabilities to severe accidents. …
>
> The Commission believes that a new design for a nuclear power plant (as well as a proposed custom plant) can be shown to be acceptable for severe accident concerns if it meets the following criteria and procedural requirements:
>
> a. Demonstration of compliance with the procedural requirements and criteria of the current Commission regulations, including the Three Mile Island requirements for new plants as reflected in the CP Rule [10 CFR 50.34(f)]:
>
> b. Demonstration of technical resolution of all applicable Unresolved Safety Issues and the medium- and high-priority Generic Safety Issues, including a special focus on assuring the reliability of decay heat removal systems and the reliability of both AC and DC electrical supply systems;
>
> c. Completion of a Probabilistic Risk Assessment (PRA) and consideration of the severe accident vulnerabilities the PRA exposes along with the insights that it may add to the assurance of no undue risk to public health and safety; and
>
> d. Completion of a staff review of the design with a conclusion of safety acceptability using an approach that stresses deterministic engineering analysis and judgment complemented by PRA. …
>
> To obtain as much of this benefit as practicable for a custom design application, the Commission will require a CP application for a custom design to include design information that is sufficiently final and complete to permit completion of an adequate plant-specific PRA.

X-energy plans to develop and apply the PRA to evaluate the environmental risks of severe accidents as described in Section 4.

2.3 Regulation Implementation Guidelines

While guidance encourages the use of PRA, X-energy is utilizing PRA in a more comprehensive way to inform the design basis. Regulatory guidance provides the most detailed description of NRC expectations for technical adequacy for the application of PRA to an NEI 18-04 licensing application. The NRC can review the X-energy CPA to ensure compliance with 10 CFR 50.34 and 10 CFR 51.45 using the following:

- RG 1.233, Guidance for a Technology-Inclusive, Risk-Informed and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors [4].
- RG 1.247, Acceptability of Probabilistic Risk Assessment Results for Advanced Non-Light Water Reactor Risk-Informed Activities [1].

X-energy intends to apply the PRA in numerous ways by implementing the NEI 18-04 approach to inform design decisions and to develop the Xe-100 licensing basis. In addition, X-energy will use the PRA to identify LBEs derived from the NEI 18-04 process that are analyzed to support severe accident considerations as part of the Environmental Reports.

To determine the requirements for establishing PRA technical adequacy for risk-informing the Xe-100 licensing basis, X-energy's approach will consider:

- Trial use RG 1.247 Acceptability of PRA Results for NLWR Risk-Informed Activities [1]
- NRC input on NEI 20-09 [11]
- NRC input on ASME/ANS NLWR PRA standard [2]
- RG 1.233, Guidance for a Technology-Inclusive, Risk-Informed and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors [4]
- NRC input on NEI 18-04 [3]
- NRC input on NEI 21-07, Technology Inclusive Guidance for Non-Light Water Reactor Safety Analysis Report: For Applicants Utilizing NEI 18-04 Methodology [5]
- SECY-15-0002, Updating New Reactor Licensing Policies, Rules and Guidance [6]
- SECY-19-0084, New Reactor Licensing Rulemaking [7]
- Regulatory Guide 4.2, Preparation of Environmental Reports for Nuclear Power Stations [12]

2.3.1 RG 1.247 Acceptability of PRA Results for NLWR Risk-Informed Activities (for Trial Use)

RG 1.247 documents NRC endorsement of the ASME/ANS NLWR PRA standard with exceptions and clarifications [1]:

> This RG provides guidance, for trial use, on one way to determine the acceptability of a PRA that is used to support a risk-informed integrated decision-making process. More specifically, this RG provides guidance, for trial use, in the following four areas:
>
> - defining the acceptability of a PRA and its results used in support of an application;
> - the NRC's position on national consensus PRA standards, industry PRA peer review process documents, and other related industry documents;
> - demonstrating that the PRA and its results used in an application are acceptable; and
> - documentation to support a regulatory decision

X-energy expects the Xe-100 PRA to conform to the RG 1.247 guidance using the approach outlined in Section 3 of this document. This guidance varies based on design maturity and license application, so X-energy offers interpretation of the NRC expectations for PRA technical adequacy based on license application in Section 3.3.

RG 1.247 focuses PRA acceptability regarding national consensus standards, NRC staff positions, and PRA peer reviews. In accordance with RG 1.247, a peer review performed using the guidance in NEI 20-09 will support technical adequacy of the PRA for OLAs and the standard design. For a CPA, X-energy will perform a self-assessment of the PRA using the guidance in NEI 20-09 to establish PRA technical adequacy based on guidance in NEI 21-07.

RG 1.247 also mentions the relevance of PRA to assessing the risk of severe accidents:

> The Commission's severe accident policy statement articulates the Commission's determination that all new nuclear power plant designs can be shown to be acceptable for severe accident concerns, in part, by completing a PRA and considering the severe accident vulnerabilities the PRA exposes, along with the insights that it may add to the assurance of no undue risk to public health and safety.

The Xe-100 PRA will support addressing regulatory expectations related to severe accidents as described in Section 4.

2.3.2 RG 1.233 TI-RIPB Methodology to Inform the Licensing Basis

The "Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development" document summarizes how the Xe-100 approach adopts and, where necessary for effective implementation, interprets the NEI 18-04 guidance and addresses the Xe-100 approach to the NEI 18-04 clarifications noted in RG 1.233 [8]. X-energy requested the NRC staff review the approach described in this topical report to determine its acceptability in implementing the NEI 18-04 guidance for licensing basis event selection, classification of SSCs, ensuring the adequacy of defense-in-depth, and addressing clarifications provided in RG 1.233. NRC issued a Safety Evaluation Report on the X-energy Topical Report [9].

This section offers additional interpretation of RG 1.233 guidance as it pertains to PRA technical adequacy to support an NEI 18-04-based license application. The RG notes that:

> NEI 18-04 describes an expanded role for probabilistic risk assessment (PRA) for NLWRs beyond current 10 CFR Part 52 requirements or Commission policy for potential applications under 10 CFR Part 50. … The scope of the PRA, when completed, should cover internal and external hazards and provide an estimate of radiological consequences when the design is completed and site characteristics are defined. Designers seeking certifications or approvals prior to site selection may make assumptions related to site characteristics and external hazards, which would be confirmed or adjusted for licensing an advanced NLWR at a specific site. … PRA models are expected to be developed by the designer and refined as the design process progresses and the licensing-basis documents are developed.

X-energy interprets "completed" in the context of "design is completed" to mean the PRA and design for an OLA. The guidance allows assumptions around site characteristics and external hazards for approvals prior to site selection which aligns with the X-energy approach for CPA.

> NEI 18-04 describes a set of DBEHLs that will determine the design-basis seismic events and other external events that the SR SSCs will be required to withstand. When the DBEHLs are determined using NRC-approved methodologies, this approach is generally consistent with current practices and provides acceptable protection of SR SSCs. When supported by available methods, the PRA model is expected to address the full spectrum of internal events and external hazards that pose challenges to the capabilities of the plant, including external hazard levels exceeding the DBEHLs. The inclusion of external events within the BDBE category supports the overall risk-informed approach in NEI 18-04 and the DID assessments described in subsequent sections. The PRA results, including consideration of external hazards, will also validate a designer's initial selections of DBAs and SR SSCs protected against DBEHLs, and ensure no new DBAs are introduced by external hazards.

The Xe-100 CPA PRA will address the full spectrum of internal and external hazards to the extent practicable, however, the level of detail in their treatment will be limited due to lack of design and site information necessary to evaluate the prevention and mitigation of these hazards at a CPA stage. The PRA will cover a full scope of hazards with bounding qualitative and quantitative assessments using screening criteria in the PRA standard. Multiple modules and radionuclide sources will be assessed, albeit with conservative treatment considering the lack of design and site details at a CPA stage. Importantly, the Xe-100 CPA PRA will support identification of DBHLs (updated terminology for DBEHLs used in NEI 21-07) that provide reasonable confidence of a complete assessment of DBAs and definition of design criteria for SR SSCs.

For the standard design, the Xe-100 PRA will be developed for application to a range of sites and include justification of using a set of parameters to define an envelope of sites to assess the risk of external hazards and off-site radiological doses. For an OLA, the full scope of hazards for the given site will be modeled per the PRA standard. The ASME/ANS NLWR PRA Standard includes the following definition for bounding site:

> *Bounding Site*: a hypothetical site that is defined to bound the characteristics of a range of sites for use in the design of a standard plant. The site characteristics may be selected from site parameters from actual sites. For this bounding site, site-related parameters are defined using a set of scenarios that are chosen to provide appropriately high external hazard design parameter values and the most adverse meteorological conditions and population data for assessing off-site radiological impact.

2.3.3 NRC Input on NEI 21-07

NEI 21-07 describes an acceptable means of developing portions of the Safety Analysis Report content for advanced reactor applicants that utilize NEI 18-04, “Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development,” which was previously endorsed by the NRC in Regulatory Guide 1.233. Over the course of the last several years, the industry’s Advanced Reactor Regulatory Task Force has worked in close collaboration with the Southern-led Licensing Modernization Project to develop the guidance. There have been numerous meetings conducted with the NRC staff as well as several interactions with the Advisory Committee on Reactor Safeguards on the subject guidance. Lessons learned and associated insights from several tabletop exercises conducted with advanced reactor designers have also been shared with the staff, made publicly available and incorporated into the guidance. Revision 0 of NEI 21-07 was provided to the NRC following the culmination of a series of public meetings and workshops on the development of this guidance.

Revision 1 to NEI 21-07, which X-energy is implementing to develop its license applications, includes changes to address NRC’s feedback and comments on potential exceptions, clarifications, and additions (ML21274A032, ML21274A031, ML22013B183, and ML22012A274) regarding NEI 21-07, Revision 0 (ML21250A378). The discussions from the NRC staff’s public engagement with industry throughout the development of this guidance has been incorporated into the revision.

The development of NEI 21-07, Revision 1, and NRC endorsement via regulatory guide will create a more predictable licensing pathway for the Xe-100. X-energy looks forward to the issuance of regulatory guidance concerning NEI 21-07, which will further clarify regulatory expectations for the Xe-100 license applications.

NEI 21-07 states, "no PRA peer review should be required at the CP application stage." X-energy does not currently plan to seek design finality for the Xe-100 with a CPA and expects to maintain this approach assuming future regulatory guidance concerning NEI 21-07 maintains this position. Instead of a peer review, X-energy will perform a self-assessment of the Xe-100 PRA to establish PRA technical adequacy for a CPA as described in Section 3 of this document. Section 3.3.2 provides additional explanation about X-energy's proposed approach to achieving PRA technical adequacy using the NEI 20-09 process.

2.3.4 SECY-19-0084: New Reactor Licensing Rulemaking

SECY-19-0084 reinforced the NRC intent for rulemaking to include PRA requirements for new licenses under 10 CFR 50. The NRC indicated that the time frame for developing a PRA may be extended to four years after NRC endorsed guidance is available. X-energy intends to utilize the ASME/ANS NLWR PRA Standard and conform to trial use RG 1.247 for CPAs, OLAs, and the standard design.

2.3.5 SECY-15-0002: Updating New Reactor Licensing Policies, Rules, and Guidance

SECY-15-0002 notes that 10 CFR 50.34 (f)(1)(i) and 10 CFR 50.72(h) do not currently apply to new CP or OL applications but recommends that these requirements be applied to all new power reactor applications [6].

SECY-15-0002 clarifies NRC intent to update 10 CFR 50 to better align requirements for license applications under parts 50 and 52. The requirement proposed in SECY-15-0002 is:

> Develop a plant-specific probabilistic risk assessment, submit appropriate information describing that analysis as part of the construction permit and operating license submittals, and maintain and upgrade the probabilistic risk assessment throughout the duration of the operating license. …
>
> Provide a description of design features for prevention and mitigation of severe accidents.

The NEI 18-04 process meets these requirements. The enclosure provides additional detail:

> Therefore, the policy statement sets an expectation that construction permit applications include a preliminary risk analysis. …
>
> In order to address severe accidents for new Part 50 power reactor applications in a manner consistent with Part 52 design and licensing reviews, the NRC staff recommends that 10 CFR Part 50 be revised to provide requirements analogous to 10 CFR 52.47(a)(23) and 10 CFR 52.79(a)(38) to provide descriptions of severe accident design features. Construction permit applications should provide preliminary information in a manner similar to other preliminary safety analysis report (PSAR) content, while operating license applications should provide information sufficient to support a final licensing decision equivalent to a combined license.

X-energy intends to develop this "preliminary" information using a PRA, as described in Section 3.

2.3.6 Regulatory Guide 4.2 Preparation of Environmental Reports for Nuclear Power Stations

Although not required for applications under 10 CFR Part 50, the Commission direction in the Staff Requirements Memorandum to SECY-15-0002 confirmed that its earlier directions for the 10 CFR Part 52 new power reactor applications be applied consistently to 10 CFR Part 50 new power reactor applications. In addition, the Commission approved revision of the regulations in 10 CFR Part 50 for new power reactor applications to align with requirements in 10 CFR Part 52, incorporating the requirements identified by the staff in SECY-15-0002, including the TMI-related items under 10 CFR 50.34(f) and the PRA requirements under section 50.71(h).

The NRC requires, in Severe Reactor Accidents Regarding Future Designs and Existing Plants (50 FR 32138), the completion of a PRA for severe accidents for new reactor designs as specified in 10 CFR 52.47, Contents of Applications; Technical Information. The associated regulatory guide, Regulatory Guide 4.2, Preparation of Environmental Reports for Nuclear Power Stations, specifically states:

> Enclosure 1 of SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future Reactor Applications," discusses unique challenges to assessing risks and SAMAs/SAMDAs (Ref. A7). The 10 CFR Part 52 requirements to provide a description of a design-specific probabilistic risk assessment (PRA) do not apply to new reactor license applications submitted under 10 CFR 50, such as a CP, as of the time of this revision. However, the Staff Requirements Memorandum for SECY-15-0002 (Ref. A8) sets an expectation that licensing under 10 CFR Part 50 be performed consistently with 10 CFR Part 52, including how risk and severe accidents are addressed. Therefore, a CP application should provide information derived from the preliminary design to address these topics. A CP application should provide the best available information to assess SAMAs/SAMDAs. The applicant of an OL referencing the CP is required in the OL application to provide new and significant information, including any such information related to SAMAs/SAMDAs. Therefore, the staff recommends that any prospective applicant for a CP engage with the staff during pre-application activities in accordance with 10 CFR 51.40 regarding the extent to which it plans to address SAMAs/SAMDAs at the CP and OL stages.

X-energy seeks NRC feedback on a proposed approach for identifying and analyzing LBEs for the Environmental Reports, which aims to meet the intent of the RG 4.2 guidance related to severe accidents. Section 4 provides the proposed approach.

Per RG 4.2, Section 5.11.2, "Severe Accidents:"

> The applicant should evaluate the mean environmental (i.e., individual, population, economic, and contaminated land area) probability-weighted consequences, or risks, of severe accidents involving radioactive material within a 50 mi radius of the site. Severe accidents involve multiple failures of equipment or function and, therefore, the likelihood of occurrence is lower for severe accidents than for DBAs; however the consequences of such accidents may be higher. The risks for specific severe accident types are defined as the product of the probability of that type of accident occurring multiplied by the estimated consequences for that type of accident. Severe accident types (or major release categories), source terms, and associated probabilities (i.e., core damage frequencies) are reactor-specific and determined from the design (i.e., Level 1 and Level 2) probabilistic risk assessment (PRA).

The Level 1 and Level 2 PRAs should be consistent with NRC staff's safety review guidance for PRAs (see SRP Chapter 19 of NUREG-0800). The site-specific environmental risks of severe accidents (i.e., Level 3 PRA) should consider all severe accident types from the Level 1 PRA and apply all source terms from the Level 2 PRA. The Level 2 PRA information for the transition from radioactive material release to Level 3 PRA needs to have clear traceability of the release category quantifications back to the radioactive material release analysis. This would ensure that the necessary event information (e.g. event frequencies, source term release fractions and plume segments) from internally initiated events, fire events, flooding events, low power and shutdown events, and externally initiated events that could affect the Level 3 PRA analysis is provided in a suitable form for the NRC staff environmental review.

The ER should estimate the risks applying an acceptable methodology that uses onsite and regional meteorology, population, and land-use data (see Chapter 2 of this RG for relevant site-specific meteorological, population and land-use guidance.) Relevant environmental pathways that lead to radiation dose should be considered in the consequence assessment, including the air, ground, food, surface water, and groundwater. The applicant should provide the following information to support the NRC staff's environmental review of severe accidents:

• reference for the reactor design and the associated PRA (through Level 2) used in the severe accident risk analysis;

• list of severe accident release sequences and their associated core damage frequencies (CDFs) from the Level 1 PRA and source terms for internally initiated events, fire events, flooding events, low power and shutdown events, and externally initiated events as are appropriate for the application (e.g., high winds and other external hazards) as determined from the Level 2 PRA;

• description of the methodology used to estimate site-specific severe accident risks (i.e., Level 3 PRA), including the computer code(s) to be used in the analyses, such as MELCOR Accident Consequence Code System (MACCS) code package (see NUREG/CR-6613, "Code Manual for MACCS2: Users Guide, Volume 1, (Ref. 81)).

• sufficient descriptions of key models, assumptions, parameters, conditions, input data, resulting output, and approaches to allow for NRC staff's evaluation. If there is relevant information in other supporting documentation (i.e., FSAR, DCD or other references), indicate where in those documents this information can be found.

• description of the meteorological data and years used in the analysis and an estimate of severe accident population dose risks from the air pathway

• description of any emergency response scenarios, including evacuation, sheltering, and dose-dependent relocation assumptions used in the analysis;

• description of the demographic and population data used in the analysis based on the 50-mi population estimate for the year operation is expected to cease;

• description of the land-use characterization (e.g., farmland) and land fractions used in the analysis and an estimate of the contaminated land area risks from severe accidents;

• description of the food pathway model information for the nuclides to be considered, crop categories to be used, transfer factors, and possible mitigative actions;

• description of the economic input data (e.g., land values, relocation costs, and cleanup costs) used in the analysis and an estimate of the economic cost risks from severe accidents;

• description of surface-water users and watershed data used in the analysis and an estimate of severe accident population dose risks from the surface-water pathway;

• description of aquifers used in the analysis and an estimate of severe accident population dose risks from the groundwater pathway;

• description of the comparison of the core damage frequencies estimated for the reactor to those for current-generation reactors and the comparison of the population dose risks to the mean and median values for current-generation reactors undergoing license renewal;

• description of individual (i.e., early fatality and latent cancer) risks and population dose risks from severe accidents; these risks should be compared to the Commission's Safety Goals (51 FR 30028 (Ref. 82)) and with dose risks from routine and anticipated operational releases,

• description of the methodology used to estimate site-specific accident risks (i.e., Level 3 PRA) including the computer code applied, such as MACCS code package, and

• description of the parameter information applied in the Level 3 PRA. Note that NUREG/CR-4551, "Evaluation of Severe Accident Risks: Quantification of Major Input Parameters" (Ref. 83), demonstrates the development of the parameter information for the offsite environmental risk analysis of severe accidents (i.e., Level 3 PRA) that supported NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants" (Ref. 84).

Per RG 4.2, Section 5.11.3, "Severe Accident Mitigation Alternatives:"

The applicant should evaluate SAMAs, including procedures, training activities, and plant-design alternatives (i.e., SAMDAs), that could significantly reduce the environmental risks from a severe accident. … In preparing SAMA analyses, the applicant should apply the latest regulatory guidance as it relates to the determination and estimation of values and impacts, including a sensitivity analysis. …

The applicant should provide the following information to support the NRC staff's environmental review of SAMAs:

• reference for the reactor design and the associated PRA used in the SAMA analysis;

• list of leading contributors to the reactor design core damage frequency (e.g., from dominant severe accident sequences or initiating events) and site-specific risks (e.g. population dose) for each release class and associated source term for both internal and external events;

• methodology, process, and rationale used to identify, screen, and select SAMAs that can reduce severe accident dose consequence risk, considering internal events, fire, flooding, low power and shutdown, and external events;

• methodology, process, and rationale used to further analyze any selected SAMAs to determine the amount of risk reduction that the SAMA could reasonably achieve;

• estimated cost and risk reduction for the selected SAMAs and the assumptions used to make these estimates; and

• description and list of any SAMAs that have been or will be implemented to prevent or mitigate severe accidents or reduce the risk of a severe accident.

RG 4.2, Appendix A, "Part 50 and Part 52 Licenses and Authorizations," denotes that the level of information expected for a CPA is different than an OLA:

> The requirements for the information to be included in the ER or ERs for a CP application are set forth in 10 CFR 51.45 and 51.50(a). All the information described in Part C of this RG should be considered for a CP application. While a complete reactor design may not be developed at the CP stage, an applicant should consult with the NRC staff in accordance with 10 CFR 51.40, "Consultation with NRC staff" to discuss the appropriate level of information which is required for severe accident mitigation alternatives (SAMAs), including available probabilistic risk assessment information, procedures, training activities, and plant-design alternatives (i.e., SAMDAs), that could significantly reduce the environmental risks from a severe accident.
>
> … Therefore, a CP application should provide information derived from the preliminary design to address these topics. A CP application should provide the best available information to assess SAMAs/SAMDAs. The applicant of an OL referencing the CP is required in the OL application to provide new and significant information, including any such information related to SAMAs/SAMDAs. Therefore, the staff recommends that any prospective applicant for a CP engage with the staff during pre-application activities in accordance with 10 CFR 51.40 regarding the extent to which it plans to address SAMAs/SAMDAs at the CP and OL stages.

Section 4 describes X-energy's proposed approach for implementing these guidelines. This white paper provides the vehicle for NRC engagement and feedback.

3. PRA Technical Adequacy Approach

This section describes the Xe-100 approach to establishing PRA technical adequacy for a CPA, OLA, and standard design. RG 1.247 describes one acceptable approach that the NRC staff has developed for determining whether a design-specific or plant-specific PRA used to support an application is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decision-making for NLWRs. In RG 1.247, the term "application" includes initial licensing applications and risk-informed applications. Also, it endorses, with staff exceptions, a national consensus PRA standard provided by standards development organizations.

The Xe-100 PRA is developed in accordance with the requirements of the ASME/ANS NLWR PRA Standard. As stated in RG 1.247 Regulatory Position C.3.2, "Development and Use of an Acceptable Probabilistic Risk Assessment," "If the ASME/ANS NLWR PRA standard is used, as endorsed by the NRC in Appendix A to this RG, Regulatory Positions C.1 through C.2 are considered to be met."

This section outlines X-energy's intended approach for demonstrating PRA technical adequacy through compliance with RG 1.247.

3.1 Regulatory Guidance C.1, an Acceptable Probabilistic Risk Assessment

As stated in RG 1.247 Regulatory Position C.3.2, "Development and Use of an Acceptable Probabilistic Risk Assessment," "If the ASME/ANS NLWR PRA standard is used, as endorsed by the NRC in Appendix A to this RG, Regulatory Positions C.1 through C.2 are considered to be met." The Xe-100 PRA will be developed in accordance with the requirements of the ASME/ANS NLWR PRA Standard. The trial use regulatory guidance from RG 1.247 Appendix A will be considered as discussion in Section 3.3.2 of this document.

3.2 Regulatory Guidance C.2, National Consensus Standards and Industry Programs for Probabilistic Risk Assessment

As stated in RG 1.247 Regulatory Position C.3.2, "Development and Use of an Acceptable Probabilistic Risk Assessment," "If the ASME/ANS NLWR PRA standard is used, as endorsed by the NRC in Appendix A to this RG, Regulatory Positions C.1 through C.2 are considered to be met." The Xe-100 PRA will be developed in accordance with the requirements of the ASME/ANS NLWR PRA Standard. The trial use regulatory guidance from RG 1.247 Appendix A will be considered as discussion in Section 3.3.2 of this document.

3.3 Regulatory Guidance C.3, Demonstrating the Acceptability of a Probabilistic Risk Assessment Used to Support an Application

The following sections provide more detailed guidance on each of the aspects of the staff assessment considered in this staff guidance. PRA technical adequacy for the license submittals will be determined in the context of the staff positions in RG 1.247 and relevant application-specific regulatory guidance.

3.3.1 Regulatory Guidance C.3.1, Probabilistic Risk Assessment Scope, Level of Detail, and Degree of Plant Representation

RG 1.247 describes that:

> The scope of a PRA needed to support an application will depend on the application-specific regulatory requirements, and the acceptability of the scope will be measured in terms of whether the applicant or holder of a license, certification, or permit meets those requirements. Application-specific guidance documents are expected to provide direction on meeting such requirements.
>
> For plants in the preoperational stages of the plant life cycle, the PRA and its results used to support an application are expected to reflect the as-designed, as-to-be-built, or as-to-be-operated plant. ... When used for risk-informed decision-making, the PRA should always reflect the best available information for the plant. For most applications, an applicant or holder of a license, certification, or permit should address all radiological sources, all hazards, all POSs, and all levels of analysis, as discussed in Regulatory Position C.1.1 of this RG. The staff will assess the appropriateness of the justification for any deviations from this scope.

Regulatory Position C.1.1 describes that:

> The scope of a PRA used to support an application is defined by the set of initiating events included in the analysis; the set of computed risk metrics; and its intended use for representing the as-built and as-operated plant or the as-designed, as-to-be-built, and as-to-be-operated plant. The process of developing a PRA and its results used to support an application should be complete and comprehensive through consideration of the following:
>
> • All radiological sources at the plant (e.g., reactor cores, spent fuel, fuel reprocessing facilities for molten salt reactors) should be addressed, including accident scenarios that lead to a radioactive release from multiple radiological sources.
>
> • All internal and external hazards should be addressed. For licensing activities, a PRA for the seismic hazard group must always be developed; other hazards should also be included if they cannot be screened out with appropriate justification. Appendix B to this RG lists hazards to consider when developing the PRA.
>
> • All POSs (e.g., at-power and low-power and shutdown (LPSD) types of POSs) should be addressed.
>
> • The frequencies of event sequences should be developed based on the occurrence of an initiating event, evaluation of plant response, evaluation of releases of radioactive material, and the consequences that result from those releases (i.e., an NLWR PRA should address all levels of PRA analysis, analogous to Level 1, 2, and 3 PRAs for LWRs).

The Xe-100 PRA, developed in accordance with the ASME/ANS NLWR PRA Standard, has a significantly larger scope than historical advanced LWR PRAs, including:

- treatment of event sequences both within and beyond the design basis
- event sequences involving multiple reactors and non-reactor radiological sources
- mechanistic source terms for event sequences involving a release

- quantification of radiological consequences
- risk metrics that include quantification of both frequencies and consequences of event sequences
- evaluation of risk for all plant operating modes

NRC regulations provide applicants with multiple approaches for obtaining regulatory approvals leading to an OL for a nuclear power reactor. The scope and level of detail of a PRA is inherently limited by the level of detail in specifying the design, site, and operational characteristics of the plant and the intended PRA applications. The scope and quality of a PRA model will evolve with the evolving design, an idea that's characterized by Figure 1-4 from the ASME/ANS NLWR PRA Standard.

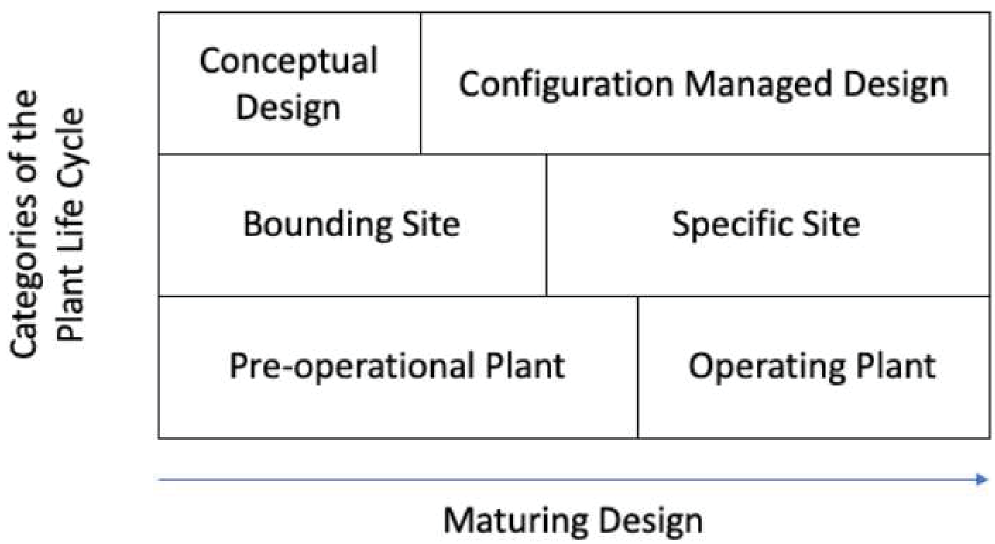

Figure 1: Major Phases of a New Reactor Development for Which Applicability of Various SRs May Change in this Standard.

The Xe-100 PRA will use the best available design information for each license application, meaning that the PRA scope and quality may vary depending on the license application and design maturity. That is to say, the Xe-100 PRA will implement the guidance of Regulatory Position C.3.1, however, the approach for demonstrating conformance will vary based on design maturity and the specific application. The following sections qualitatively describe how X-energy expects the Xe-100 PRA scope, level of detail, and degree of plant representation to vary based on license application and how each approach conforms to Regulatory Position C.3.1.

3.3.1.1 Construction Permit Application

Per NEI 21-07:

> The application content for all licensing paths will be impacted by the overall licensing strategy. This impact is particularly pronounced for the CP licensing path because the degree of information which is needed in an application is highly dependent on the finality of the decision requested from NRC at the CP stage. Therefore, to optimize the applicability of the CP

guidance provided in this document, it is assumed that the applicant will seek the minimum possible level of decision finality when applying for the CP.

X-energy does not currently expect to request any design finality as part of a CPA. The Xe-100 PRA scope, level of detail, and degree of plant representation for a CPA will meet requirements selected for this application but will not meet all the requirements of the ASME/ANS NLWR PRA Standard. The Xe-100 PRA, however, will still be sufficient to develop a risk-informed licensing basis using the NEI 18-04 process. For a CPA, the Xe-100 PRA will meet Regulatory Position C.3.1 by:

- identifying all radiological sources at the plant. For radiological sources that lack the design detail necessary to address them according to the requirements of the NLWR PRA Standard, X-energy will use supplementary analysis and supplementary requirements as described in Section 3 of the NLWR PRA Standard.
  - Sources of radionuclides within the helium pressure boundary are expected to have the necessary design detail to meet the technical requirements of the NLWR PRA Standard.
  - Analysis will be used to justify screening out non-core radiological sources from detailed PRA modeling, if possible.
  - For non-core radiological sources that do not screen out, Section 3 of the ASME/ANS NLWR PRA Standard will be used to justify risk-informed decision making, which may involve using supplementary analysis and supplementary requirements.
- addressing all internal and external hazards in Appendix B of RG 1.247. The PRA will characterize the hazards that are applicable to the specific site and inform selection of Design Basis Hazard Levels.
- meeting the supporting requirements of the NLWR PRA Standard POS-A1 element at CC I, using the approach described in Section 3.3.1.1.1. Only at-power events and sources of radionuclides within the helium pressure boundary are expected to have the necessary design detail to meet the technical requirements of the NLWR PRA Standard.
  - Non-core radiological sources will be addressed as described above
  - Low-power modes will be addressed using supplementary analysis and requirements in accordance with Section 3 of the ASME/ANS NLWR PRA Standard
- providing the frequencies and consequences of AOOs, DBEs, and BDBEs and implement a fully integrated statement of risk using the NLWR PRA Standard.

The Xe-100 PRA documentation will identify limitations in the scope and level of detail of the CP-stage PRA and disposition the impact on risk-informed decisions for a CPA.

3.3.1.1.1 Justification for Limiting Scope of POSs Addressed in Xe-100 PRA

This section justifies limiting the scope of the Xe-100 PRA to only at-power operations for a CPA based on the NLWR PRA Standard POS element requirements. The NRC staff position on the POS element is provided in NLWR PRA Standard, Table A-2, “Staff Position on ASME/ANS RA-S-1.4-2021, Technical Requirements for Plant Operating State Analysis.”

The Xe-100 will not have sufficient design maturity at a CPA stage to scope non-power POSs into the PRA and meet the applicable technical requirements of the ASME/ANS NLWR PRA Standard. As the design matures, future versions of the PRA will include all operating modes in the scope, addressing the risk by applying the screening criteria of the ASME/ANS NLWR PRA Standard or modeling non-power modes in the PRA using the applicable technical requirements

For the PRA supporting the risk-informed applications included in a CPA, the Xe-100 PRA will be limited to at-power operations, which allows X-energy to meet SR POS-A1 at Capability Category I (CC I). Specifically, POS-A1 requires that the Xe-100 PRA, "IDENTIFY a representative set of plant evolutions to be analyzed. INCLUDE, at a minimum, plant evolutions from at-power operations. See Note POS-N-1, POS-N-2, POS-N-3, POS-N-4." These notes provide additional detail:

Table 1: Notes Supporting Plant Operating State Analysis Requirements

Number	Notes
POS-N-1	An example of plant evolution form at-power operations is taking down train(s) of operation for maintenance while operating at power. See POS-A1
POS-N-2	Early pre-operational stage PRAs are typically limited to at-power PRAs only. See POS-A1
POS-N-3	Examples of plant evolutions include power changes (e.g., load-following, transitions to low power or shutdowns) and transitions to maintenance of configurations, refueling outages, and forced outages. See POS-A1
POS-N-4	The plant operating states and plant evolutions to be analyzed depend on the PRA scope, pre-operational stage, and application. Depending on the application, the evolution to be addressed may range from at-power only to all plant operating states outage types. See POS-A1

In RG 1.247 Table A-2, the NRC offers no objection to SR POS-A1, however, X-energy acknowledges that RG 1.247 does not endorse the nonmandatory appendices containing the notes. Per RG 1.247:

> The NRC understands that the nonmandatory appendices (NMAs) provided in ASME/ANS RA-S-1.4-2021 are not requirements. Rather, based on discussions with the JCNRM, the NRC understands that the JCNRM's underlying purpose for providing the NMA notes and commentary was to help ensure that PRA analysts are apprised of certain known characteristics, challenges, and issues associated with the NLWR PRA model. While some of the discussion includes "primer-like" information, the language should not be viewed as prescriptive. The analyst should not interpret NMAs as limiting flexibility in the conduct of the technical analyses, or in the application of expert and engineering judgement. A broad range of tools, techniques, implicit/explicit analysis, and judgement may be required to address the diverse modeling required. With respect to the NMAs that provide notes on specific supporting requirements (SRs), the NRC understands that the JCNRM's underlying purpose was to clarify the intent of a supporting requirement (SR), explain jargon that might be used in an SR, and/or provide examples of analysis approaches that would meet the intent of the SR.

> Accordingly, this RG does not endorse or approve for use any of the NMAs contained in ASME/ANS RA-S-1.4-2021. This lack of endorsement or approval for use does not necessarily mean that the NRC disapproves the substance nor limits the use of the information provided in the NMAs or that the NRC is limiting the use of that information. Applicants and licensees should meet the applicable requirements of ASME/ANS RA-S-1.4-2021 regardless of whether they use some or all of the information provided in the NMAs.

As described in note POS-N-2, "Early pre-operational stage PRAs are typically limited to at-power PRAs only." At this stage of design maturity, there is not enough design information to scope non-power modes into the PRA. Future versions of the PRA will include all operating modes in the scope, addressing the risk by applying the screening criteria of the ASME/ANS NLWR PRA Standard or modeling non-power modes in the PRA using the applicable technical requirements. By interpreting SR POS-A1 with the context of note POS-N-2, Xe-100 PRA will be able to meet the applicable SRs for the POS element at CC I for a CPA despite limiting the PRA scope to at-power operations.

X-energy will use supplementary analyses and requirements to assess the risk of non-power modes to disposition potential impact on NEI 18-04 risk-informed decisions for a CPA. At this stage of design maturity, however, there is insufficient design information to screen out the risk of non-power modes using the ASME/ANS NLWR PRA Standard or model non-power modes in the PRA to meet the applicable requirements in the POS element. Therefore, at this stage of the design, the Xe-100 PRA will not include non-power modes in its scope.

Since the Xe-100 PRA will not address all POSs for a CPA, as discussed in Regulatory Position C.1.1, X-energy requests that the staff provide feedback on the appropriateness of the justification for these deviations.

3.3.1.2 Operating License Application

The Xe-100 PRA scope, level of detail, and degree of plant representation for an OLA will aim to meet all the requirements of the ASME/ANS NLWR PRA Standard. The Xe-100 PRA will meet Regulatory Position C.3.1 by:

- considering all radiological sources at the plant.
    - The PRA will model sources of radionuclides within the helium pressure boundary and meet the applicable technical requirements of the NLWR PRA Standard.
    - Analysis will be used to justify screening out non-core radiological sources from detailed PRA modeling, if possible.
    - The PRA will model sources of radionuclides within the helium pressure boundary and meet the applicable technical requirements of the NLWR PRA Standard.
    - For non-core radiological sources that do not screen out, the PRA will meet the applicable technical requirements of the NLWR PRA Standard.
- addressing all internal and external hazards identified in Appendix B of RG 1.247. Section 2.3.2 provides more information on how the Xe-100 PRA will address hazards.
- considering all POSs (e.g., at-power and low-power and shutdown (LPSD) types of POSs).

- PRA modeling of POSs will be justified using the applicable screening criteria in the ASME/ANS NLWR PRA Standard. For radionuclides within the helium pressure boundary, non-power modes will be analyzed and potentially screened out using the screening requirements of the ASME/ANS NLWR PRA Standard.
- Non-core radiological sources will be addressed as described above.
- For plant operating states that do not screen out, the PRA will meet the applicable technical requirements of the NLWR PRA Standard.

- addressing all levels of NLWR PRA analysis by implementing the ASME/ANS NLWR PRA Standard Section 3, "Risk Assessment Application Process." This process will involve meeting all the applicable supporting requirements of the ASME/ANS NLWR PRA Standard at a specified capability category. This includes event sequences involving multiple reactor modules and non-core radiological sources, quantification of mechanistic source terms and radiological consequences, and risk characterization and integration using technology inclusive risk metrics.

3.3.1.3 Standard Design

The Xe-100 PRA scope, level of detail, and degree of plant representation for the standard design will aim to meet all the requirements of the ASME/ANS NLWR PRA Standard. The Xe-100 PRA will meet Regulatory Position C.3.1 in the same way as a PRA for an OLA, except for treatment of external hazards, by:

- addressing all internal and external hazards identified in Appendix B of RG 1.247. Seismic risk analysis and external hazards events analysis performed for a bounding site selected to cover a range of sites, mechanistic source terms, and off-site radiological doses.

Other aspects of PRA scope, level of detail, and degree of plant representation will match the approach outlined for an OLA described in Section 3.3.1.2.

3.3.2 Regulatory Guidance C.3.2, Development and Use of an Acceptable Probabilistic Risk Assessment

Per RG 1.247:

> The staff positions in Regulatory Positions C.1 through C.1.4 represent the minimum capability the staff has determined that a PRA should possess to support risk-informed regulatory activities. When this RG is used to determine the acceptability of a PRA, all staff positions in this RG should be met for a more efficient review by the staff and for a PRA to be considered acceptable. One acceptable approach for demonstrating conformance with regulatory positions in this RG and thereby reducing the need for an in-depth staff review of the PRA is to use an NRC-endorsed national consensus standard during the development of the PRA and to have the PRA peer reviewed through an NRC-endorsed process. The ASME/ANS NLWR PRA standard provides the technical requirements for this purpose. If the ASME/ANS NLWR PRA standard is used, as endorsed by the NRC in Appendix A to this RG, Regulatory Positions C.1 through C.2 are considered to be met. Deviations from a staff endorsement of a PRA technical requirement or a staff position are evaluated for acceptability on a case-by-case basis.

> When the exceptions raised by the staff are taken into account, the national consensus standard or PRA peer review process in question is considered to be acceptable for its intended purpose. If the PRA is demonstrated to have met the requirements of these documents, with attention paid to the NRC's exceptions, it can be assumed that the analysis is technically correct.

The Xe-100 PRA will be developed in accordance with the requirements of the ASME/ANS NLWR PRA Standard, however, the Xe-100 PRA may not incorporate all of the exceptions raised by the staff in RG 1.247 Appendix A. The NRC issued trial use RG 1.247 for public comment, with a public meeting May 11, 2022, following a draft trial use RG 1.247 published in 2021. X-energy provided eight comments on the latest revision of the regulatory guide in Reference [10], which constitute potential deviations from RG 1.247 Appendix A, and Table 1 provides a summary of the NRC exceptions and clarifications from which the Xe-100 PRA may deviate. Only two comments, repeated in this document, provide substantial objection or clarification to the NRC positions.

Table 2: Deviations from RG 1.247 Appendix A, "NRC REGULATORY POSITION ON ASME/ANS RA-S-1.4-2021".

No.	Page/Section	Comment	Xe-100 Proposed Resolution
1	A-13, HLR-HR-E & A-16, HR-E4	The clarifications on HLR-HR-E and HR-E4 are not consistent with the current PRA State of practice and represents a new requirement above and beyond the requirement for the current operating fleet. Errors of commission are already captured in FHR-A1 at CC-II for fires where operating experience supports consideration of spurious signals. Note that the Reg Guide 1.247 position on HR-E4 requiring EOC at CC-1 is not internally consistent with the Reg Guide position on FHR-A1 requiring EOC only at CC-II. For non-Fire Hazards spurious signals should occur with low frequency and would require significant operator error due to the redundancy of information available to the operator.	This requirement should be removed from HR-E4 (and the HLR-E) or be considered for inclusion at CC-II.
5	9-10, B. Discussion & 55-56, C.2.1, National Consensus PRA Standards & C.2.2 Industry Peer review Program, C.4.1	The discussion of PRA acceptability for risk informed decision-making focuses on peer review. While the language is flexible in indicating that peer review is one acceptable method, NEI 21-07 indicates that a peer review should not be required for PRAs at the construction permit application. Guidance on PRA acceptability for construction permit applicants would be appreciated. In addition, Section 3 of the PRA standard provides detail on additional analysis as an alternate means for establishing PRA technical adequacy for parts of the PRA that cannot meet CC-I. This guidance should be reflected in the RG.	Suggest referencing a self-assessment against the standard following the process described in Section 3 of the PRA standard as an alternate means of establishing PRA acceptability for a construction permit application if design finality is not requested. This may be more appropriately addressed in the NRC endorsement of NEI 21-07. C.2.1 and C.2.2 should discuss the PRA Section 3 methodology of identifying supplemental analyses where the PRA standard requirements may not be met.

In general, the Xe-100 PRA quality will be commensurate with the maturity of the design and the intended license applications. The following sections describe the Xe-100 approach to demonstrating PRA technical adequacy for different license applications based on RG 1.247 and NRC inputs on NEI 21-07.

3.3.2.1 Construction Permit Application

For a CPA, the Xe-100 PRA will not be peer reviewed in accordance with the NEI 20-09 process. NEI 21-07 Revision 1 justifies the position that a peer reviewed PRA is not required for a CPA, stating:

> At the CP stage, neither the plant design nor the PRA is expected to have the level of maturity that will be necessary to support an OL application. At the CP application stage, the applicant should describe its ultimate intended approach for qualifying the PRA. … To be clear, consistent with the baseline for this guidance, to the extent that an applicant does not request any design finality as part of its CP application, no PRA peer review should be required at the CP application stage. However, if an applicant wishes to seek Commission approval of any design feature or specifications, then peer review for the scope of the PRA supporting those features or specifications would be required consistent with the NLWR PRA Standard ASME/ANS-RA-S-1.4-2021.

Although NRC has not formally endorsed NEI 21-07, Revision 1, in a Regulatory Guide, NRC has provided docketed feedback on Revision 0 and drafts that preceded Revision 1. Specifically, NRC provided feedback on NEI 21-07, Revision 0, in Reference [16], offering the following clarification and addition on Section 2.1.1c:

> Page 24 – Further discussion is necessary in either NEI 21-07, Revision 1, or in TICAP draft RG with paper to clarify the basis for omitting peer review for PRA for a CP application as follows (italics are used to set off the clarification – final text should be in regular font): To be clear, consistent with the baseline for this guidance, to the extent that an applicant does not request any design finality as part of its CP application, no PRA peer review should be required at the CP application stage.

NEI 21-07 was revised to incorporate this feedback into Revision 1, as noted in Reference [17]. X-energy interprets this interaction between NEI and the NRC to imply that a CPA does not require a peer-reviewed PRA as long as the applicant is not requesting design finality. X-energy acknowledges, however, that the NRC feedback on NEI 21-07 has not been formalized in regulatory guidance. Therefore, X-energy will incorporate future NRC input on NEI 21-07 into its approach for developing licensing submittals, especially formal regulatory guidance concerning NEI 21-07.

3.3.2.1.1 Proposed Self-Assessment Approach

This section provides a high-level description of X-energy's proposed approach to performing a PRA self-assessment to support a CPA. Instead of a peer review meeting the requirements of the PRA standard, X-energy will demonstrate PRA technical adequacy using the PRA self-assessment process following the guidance of NEI 20-09, which is described in:

- Section 3.2, "Performance of the Self-Assessment by the Host User,"
- Section 6.2, "Use of Self-Assessment in Assignment of CCs," and
- Sections A.3.1 and A.3.2, "Information Availability and Preparation via the Self-Assessment."

The results of the self-assessment will be used to help ensure that the PRA was developed in a technically correct manner as it relates to whether the technical requirements in the ASME/ANS NLWR PRA Standard as endorsed in RG 1.247 have been met. As discussed in Regulatory Position C.2.2 and its subsections, NEI 20-09, Revision 1, provides current industry guidance on self-assessments, which is endorsed in RG 1.247.

X-energy expects to complete the following tasks as part of a PRA self-assessment to support a CPA:

Documenting the intended PRA scope and CC for each SR, as well as applicability determination for HLRs and SRs within elements that are part of the PRA scope. This documentation will provide the basis for the scope of the self-assessment. This documentation could occur in a database or spreadsheet.

Developing a roadmap of where the bases for meeting the relevant PRA SRs for each technical element are documented. This roadmap could take the form of a database or spreadsheet.

Using the roadmap, the self-assessment team will identify and address, using guidance similar to that used by the peer reviewers, areas where the PRA may require additional technical analysis, process improvements, and additional or alternative documentation.

The self-assessment team will document the results of their assessment, including the CC that has been assigned to the SRs and the basis for this assessment. Also, the team should document determinations about the applicability of specific SRs to the PRA being reviewed. Similar to NEI 20-09, Section 9.1, the documentation should address the following:

- Clear definition of the scope of the self-assessment
- Summary of the results of the review for each technical element within the scope of the review, organized at the HLR level. The result summaries should focus on the general results of the reviews of the SRs, and, if applicable, the newly developed method review requirements as endorsed by the NRC.
- Summary of identification of assumptions and sources of uncertainty, their impacts, and the reviewers' opinions regarding their treatment.
- Identification of the assessed CC for each SR within the scope of the review and the basis for the assignment.
- The conclusions of the self-assessment team.
- Any recommendations to achieve the next higher CC (if applicable).
- If applicable, any resolved inquiries that are used as part of the self-assessment, along with the specific SRs that were interpreted using each inquiry.

The self-assessment documentation should provide pointers to the associated PRA documentation. This documentation will support the ability of outside reviewers, such as NRC auditors or a future peer review team, to understand the basis and review the associated documentation to a sufficient level of detail to make their own assessment. It may indicate where improvements are required for elements to be accepted at the next higher CC.

The self-assessment should be performed and initially completed with sufficient time to incorporate any necessary changes into the PRA prior to submitting a CPA.

Each identified item from the self-assessment (similar to F&Os) will be addressed by dispositioning the item with respect to the risk-informed decisions associated with the license application or by updating the PRA. X-energy will document how each identified item from the self-assessment is addressed.

X-energy will make the results of this self-assessment accessible to the NRC via audit along with other PRA documentation.

3.3.2.2 Operating License Applications and the Standard Design

Per RG 1.247:

> PRA self-assessments and peer reviews that follow an approved process should be used, as endorsed by the NRC, to demonstrate how the PRA meets the NRC-endorsed requirements in a national consensus standard. As discussed in Regulatory Position C.2.2 and its subsections, NEI 20-09, Revision 1, provides current industry guidance on self-assessments and peer review, which is endorsed in this RG.

For OLAs and the standard design, the Xe-100 PRA will be peer reviewed against the requirements of the ASME/ANS NLWR PRA Standard using the NEI 20-09 approach as endorsed in RG 1.247, with exceptions described in Table 2.

3.3.3 Application-Specific Acceptance Criteria and Guidelines

X-energy's "Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development" describes how X-energy will implement the risk-informed performance-based methodology for design, analysis, and licensing of the Xe-100. It provides a reproduction of the section headers of the guidance, with identification of conformance or interpretation where necessary, contained in NEI 18-04 [3] with clarifications identified in RG 1.233 [4]. It also provides implementation guidance used by X-energy for the safety design approach and analyses of the Xe-100 reactor.

The report readily demonstrates the applicability of the application-specific acceptance criteria or guidelines inherent to the Xe-100 license applications. The NRC issued a Safety Evaluation Report for the "Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development" (ML22187A267) [9].

3.4 Regulatory Guidance C.4, Probabilistic Risk Assessment Documentation in Support of a Regulatory Decision

The following sections discuss X-energy's approach to implementing Regulatory Guidance C.4. PRA technical adequacy will be determined in the context of the staff positions in RG 1.247 and relevant application-specific regulatory guidance.

3.4.1 Regulatory Guidance C.4.1, Archival Probabilistic Risk Assessment Documentation

X-energy intends to implement ASME/ANS NLWR PRA Standard Section 3, "Risk Assessment Application Process," to support the Xe-100 risk-informed licensing basis. Therefore, X-energy will document how the Xe-100 PRA and risk-informed licensing basis implements the ASME/ANS NLWR PRA Standard Section 3, "Risk Assessment Application Process," guidance. This documentation will also include a description of how the staff position in RG 1.247 is met for the associated license applications, which will account for NRC feedback provided in this white paper and future updates to RG 1.247. This documentation does not fall within the scope of ASME/ANS NLWR PRA Standard Section 4, "Risk Assessment Technical Requirements Contents," but still comprises documentation necessary to implement Regulatory Guidance C.4.1 for Xe-100 license applications.

For ASME/ANS NLWR PRA Standard Section 4, "Risk Assessment Technical Requirements Contents," the Xe-100 PRA documentation will be developed in accordance with the documentation SRs of the ASME/ANS NLWR PRA Standard technical requirements. NEI 20-09 provides the following general guidance regarding the review of documentation elements, which X-energy will use to assess conformance with the ASME/ANS NLWR PRA Standard:

> 6.9 Review of Documentation Elements
>
> Each technical element has an HLR and a number of associated SRs with respect to documentation. In general, the requirement for documentation of the HLRs is that they be sufficient to facilitate peer reviews by describing the processes used, providing the assumptions used and their bases, and providing the associated SRs specific details for each technical element. Assessing the CC for the documentation SRs does not require a separate review for each SR. At the start of the review for a given technical element, the peer review team should review the documentation HLR and SRs for that element to identify any unique documentation aspects for that technical element. At the completion of the review of the technical element, the reviewers for that element may assess the PRA compliance with the documentation SRs based on availability, scope and completeness of the documentation that they used to review the technical SRs for the technical element. Findings against a documentation SR should not include an assessment of the related technical SRs. If the review team cannot assess a technical element due to inadequate documentation, a finding against the technical element and the corresponding documentation supporting requirement is appropriate. If the review team can independently assess the technical element, but the documentation requirements are not met, a finding should be written against the documentation SR.

Consistent with the ASME/ANS NLWR PRA Standard requirements in the Configuration Control technical element, "For PRAs performed during a pre-operational stage, the user has the option to decide when the PRA has matured sufficiently to apply the requirements in this Section. These requirements shall be invoked prior to the performance of the first peer review." The NRC staff position provides no clarifications or objections to the CC element provided in NLWR PRA Standard, as described in Table A-20, "Staff Position on ASME/ANS RA-S-1.4-2021, Technical Requirements for PRA Configuration Control." X-energy expects the Xe-100 PRA to meet these requirements prior to the performance of the first peer review.

Consistent with the ASME/ANS NLWR PRA Standard requirements in the Newly Developed Methods technical element, "For PRAs performed on plants in the pre-operational stage, these requirements apply for newly developed methods that are introduced following the first peer review." The Xe-100 PRA is expected to meet the NM requirements following the first peer review and it will not meet the NM requirements prior to the first peer review.

3.4.2 Regulatory Guidance C.4.2, Submittal of Probabilistic Risk Assessment Documentation

The Xe-100 submittal documentation includes and will include LTRs and formal license applications developed in accordance with NEI 21-07. Consistent with NEI 21-07, Revision 1, "It is not intended that the PRA information in the SAR be sufficient to enable the NRC to reproduce independently PRA calculations and results. The supporting methods, data, and detailed information used in the PRA will not be included in the SAR but will be available for NRC audit. "

X-energy will implement the guidance in RG 1.247, Section C.4.2, for LTRs and license applications, but does not expect to separately submit PRA documentation to the NRC. PRA risk insights will be documented in accordance with the guidance in NEI 21-07 for SARs or as appropriate for the given application.

4. Proposed Xe-100 Approach for Meeting Severe Accident Regulations

As described in Section 2.3.6, X-energy seeks NRC feedback on a proposed approach to meet the intent of the RG 4.2 guidance related to severe accidents contained in Section 5.11.2, "Severe Accidents." Consistent with RG 4.2, the Xe-100 PRA will serve as a major input to severe accident analysis. RG 4.2 Appendix C notes that, "there may be significant differences in the analysis of accidents [for NLWRs]. An applicant for such a design should consult with the NRC staff … to discuss the information and analysis that should be provided in the ER to support the evaluation of the impacts of accidents."

The term "severe accident" has historically been defined in a way that applies to LWRs, rather than a technology-inclusive definition that can be applied to Xe-100. For example, the following documents provide insight on the meaning of the term "severe accident:"

- NUREG-1070, NRC Policy on Future Reactor Designs: "A reactor accident more severe than design-basis accidents in which, as a minimum, substantial damage is done to the reactor core."
- NRC Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants: "Severe accidents are those in which substantial damage is done to the reactor core, regardless of whether serious offsite consequences occur."
- RG 4.2, Section 5.11: "The applicant should evaluate the radiological consequences to the environment from potential accidents at the proposed site. The term "accident" refers to any off-normal event due to equipment failure or malfunction that results in the release of radioactive materials into the environment."
- NUREG-1555 Environmental Standard Review Plan: "Severe accidents are those involving multiple failures of equipment or function and, therefore, the likelihood of occurrence is lower for severe accidents than for DBAs, but the consequences of such accidents may be higher."
- NRC Glossary: "A type of accident that may challenge safety systems at a level much higher than expected."
- NUREG-2122, Glossary of Risk-Related Terms in Support of Risk-Informed Decision-making: "Those BDBAs that do result in significant core damage are termed severe accidents. All severe accidents are by definition BDBAs since their challenges exceed the design envelope of the plant."
- NEI 91-04, Severe Accident Issue Closure Guidelines, Revision 1: "SEVERE ACCIDENTS are those that result in catastrophic fuel rod failure, core degradation and fission product release into the reactor vessel, containment or the environment."
- IAEA Safety Glossary: "Accident conditions more severe than a design basis accident and involving significant core degradation are termed severe accidents."

To meet the intent of RG 4.2, Section 5.11.2, X-energy will develop and apply a PRA as described in Section 3 to evaluate the environmental risks of Licensing Basis Events, some of which could align with the definitions in the 3rd, 4th, and 5th bullets above. For LWRs, selection and analysis of severe accidents depends on discretized PRA levels and intermediate PRA end states (also known as "plant damage states") to evaluate radiological consequences of an event sequence. The Xe-100 PRA does not use intermediate end states and calculates a mechanistic source term and radiological consequence for every LBE. Damage to the core is not expected for the Xe-100 design, and therefore X-energy proposes analyzing a subset of LBEs to meet the intent of RG 4.2, Section 5.11.2.

The “Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development” provides more information on the Xe-100 RIPB approach that will enable identification of LBEs. As part of implementing this approach, the Xe-100 PRA quantify the source term for LBEs that involves a release of radionuclides using the technical requirements of the Mechanistic Source Term Analysis (MS) element of the ASME/ANS NLWR PRA Standard. With the mechanistic source term information, the Xe-100 PRA will quantify radiological consequences for LBEs using the technical requirements of the Radiological Consequence Analysis (RC) element of the ASME/ANS NLWR PRA Standard to analyze radiological consequences for LBEs. This analysis will:

- be documented as part of the PRA
- use MACCS or similar codes to analyze the population dose surrounding the plant site with pedigree documented per the PRA Standard
- use environmental data for the specific site
- calculate the following consequence metrics:
    - population whole body dose risk
    - risk of early fatalities
    - risk of latent cancer fatalities
    - economic risk

The PRA will meet the applicable requirements of the RC elements to support calculation of these radiological consequences and integrate the results into the PRA documentation. In this way, the Xe-100 PRA will provide a fully integrated evaluation of the environmental risks of LBEs. The method and results of this approach will be included in the Environmental Reports to meet the intent of RG 4.2, Section 5.11.2.

Per RG 4.2, Section 5.11.3, “Severe Accident Mitigation Alternatives:”

> The applicant should evaluate SAMAs, including procedures, training activities, and plant-design alternatives (i.e., SAMDAs), that could significantly reduce the environmental risks from a severe accident. … In preparing SAMA analyses, the applicant should apply the latest regulatory guidance as it relates to the determination and estimation of values and impacts, including a sensitivity analysis. …

Within the NEI 18-04 approach, the Xe-100 design inherently considers risk-beneficial trade-offs in all stages of the design process to minimize radiological releases to the environment. X-energy intends to use NEI 21-07 to develop future license applications, which will include sections that specifically identify outcomes of implementing the NEI 18-04 approach. Per NEI 21-07, chapter 4 of an application “identifies safety-significant vulnerabilities where additional compensatory actions made a practical, significant improvement to the LBE risk profiles or risk-significant reductions in the level of uncertainty in characterizing the LBE frequencies and consequences.” NEI 21-07 outlines section 4.2, “Defense-in-Depth” in the following way [5]:

- 4.2. Defense-in-Depth
    - 4.2.1. Plant Capability Summary

- 4.2.1.1. LBE Margin
- 4.2.1.2. Layers of Defense Evaluation
- 4.2.1.3. Single Feature Reliance
- 4.2.1.4. Prevention-Mitigation Balance

- 4.2.2. Programmatic DID Summary
  - 4.2.2.1. Evaluation of Significant Uncertainties
  - 4.2.2.2. Programs Required for SR SSC Performance Monitoring
  - 4.2.2.3. Programs Required for NSRST SSC Performance Monitoring
- 4.2.3. Integrated DID Evaluation

The NEI 18-04 approach provides a systematic way to:

- identify LBEs and characterize their frequencies and radiological consequences;
- develop a fully integrated calculation of environmental risks for the LBEs, which provides risk insights for each release class and associated source term for both internal and external events;
- identify and select design alternatives that can reduce severe accident dose consequence risk, considering internal events, fire, flooding, low power and shutdown, and external events;
- explain the basis for design decisions that are necessary to achieve DID adequacy;
- justify the basis for excluding design alternatives that will not make a practical, significant improvement to the LBE risk profiles or risk-significant reductions in the level of uncertainty in characterizing the LBE frequencies and consequences

Overall, X-energy's implementation of the NEI 18-04 approach integrates risk-informed decision making throughout the design process and naturally enables extension of the PRA to analyze the environmental risk of severe accidents and SAMAs. The results of this approach will be captured in Xe-100 license applications that are developed using NEI 21-07. In this way, the Xe-100 applications will meet the intent of RG 4.2, Section 5.11.3, "Severe Accident Mitigation Alternatives."

The approach to addressing RG 4.2, Section 5.11.3, depends on the available design information, which increases between a CPA and OLA. As described in RG 4.2, Appendix A.3:

> A CP application should provide the best available information to assess SAMAs/SAMDAs. …
>
> While a complete reactor design may not be developed at the CP stage, an applicant should consult with the NRC staff in accordance with 10 CFR 51.40, "Consultation with NRC staff" to discuss the appropriate level of information which is required for severe accident mitigation alternatives (SAMAs), including available probabilistic risk assessment information, procedures, training activities, and plant-design alternatives (i.e., SAMDAs), that could significantly reduce the environmental risks from a severe accident.

Per NEI 21-07, the level of information included in a CPA versus an OLA will vary. X-energy intends to implement the NEI 21-07 guidance, meaning the amount of information available to address the intent of RG 4.2, Section 5.11.3, will increase from the CPA to the OLA. For example, guidance for chapter 4 states:

The DID CP discussion should be plant capability-centric (Section 4.2.1). While not all of the plant capability DID attributes can be fully addressed at the CP stage, qualitative performance-based objectives for DID may be useful in establishing performance boundaries for FSAR results. It will not be practical to address programmatic DID (Section 4.2.2) and the integrated evaluation of DID adequacy (Section 4.2.3) in the PSAR, and those areas should be reserved for the FSAR developed as part of the OL application unless fundamental to the CP LMP-based affirmative safety case envelope.

The Xe-100 license applications will implement NEI 18-04 and NEI 21-07 to analyze the environmental risks of severe accidents and communicate the basis for design alternatives that prevent and mitigate these risks. In this way, the Xe-100 license applications will meet the intent of RG 4.2, Section 5.11.3.

5. Conclusions and NRC Review Objectives

X-energy's objective is to license the Xe-100 reactor design for construction and operation using a risk-informed and performance-based approach that relies on a technically adequate PRA. This approach will rely on a PRA that conforms to RG 1.247. X-energy is requesting the NRC to review and comment on the contents of this white paper, most notably the following:

- The approach and the methodology used for determining the appropriate site characteristics, PRA scope, level of detail, and quality for a technically adequate PRA supporting the Xe-100 TI-RIPB licensing basis.
- X-energy's approach and methodologies for PRA technical adequacy to obtain NRC feedback for license submittals.
- The proposed approach to evaluating environmental risks associated with severe accidents to support development of Xe-100 Environmental Reports

This white paper initiates feedback between X-energy and the NRC to enable demonstration of PRA technical adequacy that ultimately supports successful licensing of the Xe-100.

6. Cross References and References

	Document Title Cross References: X-energy documents that may impact the content of this document. References: X-energy or other documents that will not impact the content of this document	**Document No.**	**Rev.**	**Cross Reference/ Reference**
[1]	Trial use RG 1.247, Acceptability of Probabilistic Risk Assessment Results for Advanced Non-Light Water Reactor Risk-Informed Activities	n/a	n/a	Reference
[2]	ASME/ANS RA-S-1.4-2021, Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants	n/a	2021	Reference
[3]	NEI 18-04, Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development	n/a	Aug. 2019	Reference
[4]	RG 1.233, Guidance for a Technology-Inclusive, Risk-Informed and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors	n/a	Rev 0	Reference
[5]	NEI 21-07, Technology Inclusive Guidance for Non-Light Water Reactor Safety Analysis Report: For Applicants Utilizing NEI 18-04 Methodology	n/a	Rev 1	Reference
[6]	SECY-15-0002, Updating New Reactor Licensing Policies, Rules and Guidance	n/a	2015	Reference
[7]	SECY-19-0084, New Reactor Licensing Rulemaking	n/a	2019	Reference
[8]	Xe-100 Licensing Topical Report Risk-Informed Performance-Based Licensing Basis Development	001522	Rev 2	Cross Reference
[9]	X ENERGY, LLC – SAFETY EVALUATION OF XE-100 LICENSING TOPICAL REPORT: RISK-INFORMED PERFORMANCE-BASED LICENSING BASIS DEVELOPMENT, REVISION NO. 2 (EPID L-2021-TOP-0019)	n/a	Aug. 2022	Reference
[10]	Submission of X Energy, LLC (X-energy) Comments on Regulatory Guide 1.247, "Acceptability of Probabilistic Risk Assessment Results for Advanced Non-Light Water Reactor Risk-Informed Activities (For Trial Use)"	002281	Rev 2	Cross Reference
[11]	NEI 20-09, Performance of PRA Peer reviews Using the ASME/ANS Advanced NLWR PRA Standard	n/a	Aug. 2020	Reference
[12]	RG 4.2, Preparation of Environmental Reports for Nuclear Power Stations	n/a	Sep. 2018	Reference
[13]	NEI 05-01, Revision A, “Severe Accident Mitigation Alternatives (SAMA) Analysis Guidance Document”	n/a	Rev A	Reference
[14]	NEI 91-04, Severe Accident Issue Closure Guidelines	n/a	Rev 1	Reference
[15]	Xe-100 Principal Design Criteria Licensing Topical Report	004799	Rev 1	Cross Reference
[16]	APPENDIX X, NRC REGULATORY POSITION ON NEI 21-07, REVISION 0, “TECHNOLOGY INCLUSIVE GUIDANCE FOR NON-LIGHT WATER	ML21274A 032	Oct. 2021	Reference

	REACTORS SAFETY ANALYSIS REPORT CONTENT FOR APPLICANTS USING THE NEI 18-04 METHODOLOGY”			
[17]	Preliminary List of Exceptions, Clarifications, and Additions to NEI 21-07, Revision 0-B, “Technology Inclusive Guidance for Non-Light Water Reactors: Safety Analysis Report for Applicants Utilizing the NEI 18-04 Methodology” (ADAMS Accession No. ML21343A292)	ML22013B 183	Jan. 2022	Reference
[18]	Use of Probabilistic Risk Assessment Methods In Nuclear Regulatory Activities; Final Policy Statement (Federal Register Vol. 60, No. 158)	ML021980 535	Aug. 1995	Reference
[19]	Xe-100 White Paper Physical Protection System Approach	001573	Rev 2	Cross Reference