UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 17, 2019

Ms. Tanya M. Hamilton
Site Vice President
Shearon Harris Nuclear Power Plant
Duke Energy Progress, LLC
5413 Shearon Harris Road
M/C HNP01
New Hill, NC 27562-0165

SUBJECT: SHEARON HARRIS NUCLEAR POWER PLANT, UNIT 1 - ISSUANCE OF AMENDMENT NO. 174 RE: ADOPT TITLE 10 OF THE CODE OF FEDERAL REGULATIONS 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS (SSCs) FOR NUCLEAR POWER REACTORS" (EPID L-2018-LLA-0034)

Dear Ms. Hamilton:

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 174 to Renewed Facility Operating License No. NPF-63 for the Shearon Harris Nuclear Power Plant, Unit 1. This amendment adds a new license condition to allow for the implementation of the provisions of Title 10 of the *Code of Federal Regulations* Section 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," in response to your application dated February 1, 2018, as supplemented by letters dated October 18, 2018, and April 23, 2019 (Agencywide Documents Access and Management System Accession Nos. ML18033B768, ML18291A606, and ML19113A285, respectively).

A copy of the related Safety Evaluation is also enclosed. Notice of Issuance will be included in the Commission's biweekly *Federal Register* notice.

Sincerely,

Martha Barillas, Project Manager
Plant Licensing Branch II-2
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. 50-400

Enclosures:
1. Amendment No. 174 to NPF-63
2. Safety Evaluation

cc: Listserv

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

DUKE ENERGY PROGRESS, LLC

DOCKET NO. 50-400

SHEARON HARRIS NUCLEAR POWER PLANT, UNIT 1

AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 174
Renewed License No. NPF-63

1. The U.S. Nuclear Regulatory Commission (the Commission) has found that:

   A. The application for amendment by Duke Energy Progress, LLC (the licensee), dated February 1, 2018, as supplemented by letters dated October 18, 2018, and April 23, 2019, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I;

   B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;

   C. There is reasonable assurance (i) that the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations;

   D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public; and

   E. The issuance of this amendment is in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied.

2. Accordingly, the license is amended by changes to the Renewed Facility Operating License as indicated in the attachment to this license amendment,

3. This license amendment is effective as of the date of its issuance and shall be implemented within 60 days of issuance.

FOR THE NUCLEAR REGULATORY COMMISSION

FOR US

Undine Shoop, Chief
Plant Licensing Branch II-2
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Attachment:
Changes to the Renewed License
and Appendix D, "Additional Conditions"

Date of Issuance: September 17, 2019

ATTACHMENT TO LICENSE AMENDMENT NO. 174

SHEARON HARRIS NUCLEAR POWER PLANT, UNIT 1

RENEWED FACILITY OPERATING LICENSE NO. NPF-63

DOCKET NO. 50-400

Replace the following pages of the renewed facility operating license with the revised pages. The revised pages are identified by amendment number and contain marginal lines indicating the areas of change:

Renewed Facility Operating License

Remove	Insert
Page 4	Page 4
Page 12	Page 12

Appendix D, Additional Conditions

Remove Page	Insert Page
----	Appendix D-1

C. This license shall be deemed to contain and is subject to the conditions specified in the Commission's regulations set forth in 10 CFR Chapter I and is subject to all applicable provisions of the Act and to the rules, regulations, and orders of the Commission now or hereafter in effect, and is subject to the additional conditions specified or incorporated below.

(1) Maximum Power Level

Duke Energy Progress, LLC, is authorized to operate the facility at reactor Core power levels not in excess of 2948 megawatts thermal (100 percent rated core power) in accordance with the conditions specified herein.

(2) Technical Specifications and Environmental Protection Plan

The Technical Specifications contained in Appendix A and the Environmental Protection Plan contained in Appendix B, both of which are attached hereto, as revised through Amendment No. 174, are hereby incorporated into this license. Duke Energy Progress, LLC shall operate the facility in accordance with the Technical Specifications and the Environmental Protection Plan.

(3) Antitrust Conditions

Duke Energy Progress, LLC. shall comply with the antitrust conditions delineated in Appendix C to this license.

(4) Initial Startup Test Program (Section 14)[1]

Any changes to the Initial Test Program described in Section 14 of the FSAR made in accordance with the provisions of 10 CFR 50.59 shall be reported in accordance with 50.59(b) within one month of such change.

(5) Steam Generator Tube Rupture (Section 15.6.3)

Prior to startup following the first refueling outage, Carolina Power & Light Company* shall submit for NRC review and receive approval if a steam generator tube rupture analysis, including the assumed operator actions, which demonstrates that the consequences of the design basis steam generator tube rupture event for the Shearon Harris Nuclear Power Plant are less than the acceptance criteria specified in the Standard Review Plan, NUREG-0800, at 15.6.3 Subparts II (1) and (2) for calculated doses from radiological releases. In preparing their analysis Carolina Power & Light Company* will not assume that operators will complete corrective actions within the first thirty minutes after a steam generator tube rupture.

[1]The parenthetical notation following the title of many license conditions denotes the section of the Safety Evaluation Report and/or its supplements wherein the license condition is discussed.

* On April 29, 2013, the name of "Carolina Power & Light Company" (CP&L) was changed to "Duke Energy Progress, Inc." On August 1, 2015, the name "Duke Energy Progress, Inc." was changed to "Duke Energy Progress, LLC."

L. This license is effective as of the date of issuance and shall expire at midnight on October 24, 2046.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Eric J. Leeds, Director
Office of Nuclear Reactor Regulation

Attachments/Appendices:
1. Attachment 1 – TDI Diesel Engine Requirements
2. Appendix A – Technical Specifications
3. Appendix B – Environmental Protection Plan
4. Appendix C – Antitrust Conditions
5. Appendix D – Additional Conditions

Date of Issuance: December 17, 2008

APPENDIX D

ADDITIONAL CONDITIONS

RENEWED LICENSE NO. NPF-63

Duke Energy Progress, LLC shall comply with the following conditions on the schedule noted below:

Amendment Number	Additional Conditions	Implementation Date
174	Duke Energy is approved to implement 10 CFR 50.69 using the processes for categorization of Risk Informed Safety Class (RISC)-1, RISC-2, RISC-3, and RISC-4 structures, systems, and components (SSCs) using: Probabilistic Risk Assessment (PRA) models to evaluate risk associated with internal events, including internal flooding, and internal fire; the shutdown safety assessment process to assess shutdown risk; the Arkansas Nuclear One, Unit 2 (ANO-2) passive categorization method to assess passive component risk for Class 2 and Class 3 SSCs and their associated supports; and the results of non PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards, i.e., seismic margin analysis (SMA) to evaluate seismic risk, and a screening of other external hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009; as specified in Unit 1 License Amendment No. 174 dated September 17, 2019. Duke Energy will complete the implementation items list in Attachment 1 of Duke Energy letter to the NRC dated April 23, 2019 prior to implementation of 10 CFR 50.69. All issues identified in the attachment will be addressed and any associated changes will be made, focused-scope peer reviews will be performed on changes that are PRA upgrades as defined in the PRA standard (ASME/ANS RA-Sa-2009, as endorsed by RG 1.200, Revision 2), and any findings will be resolved and reflected in the PRA of record prior to implementation of the 10 CFR 50.69 categorization process. Prior NRC approval, under 10 CFR 50.90, is required for a change to the categorization process specified above (e.g., change from a seismic margins approach to a seismic probabilistic risk assessment approach).	Prior to implementation of 10 CFR 50.69.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. 174

TO RENEWED FACILITY OPERATING LICENSE NO. NPF-63

DUKE ENERGY PROGRESS, LLC

SHEARON HARRIS NUCLEAR POWER PLANT, UNIT 1

DOCKET NO. 50-400

1.0 INTRODUCTION

By letter dated February 1, 2018 (Reference 1), as supplemented by letter dated October 18, 2018 (Reference 2), and April 23, 2019 (Reference 3), Duke Energy Progress, LLC (Duke Energy, the licensee) submitted a license amendment request (LAR) regarding the Shearon Harris Nuclear Power Plant, Unit 1 (Harris). The licensee proposed to add a new license condition to its Renewed Facility Operating License to allow the implementation of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors." The provisions of 10 CFR 50.69 allow adjustment of the scope of structures, systems, and components (SSCs) subject to special treatment requirements (e.g., quality assurance, testing, inspection, condition monitoring, assessment, and evaluation) based on a method of categorizing SSCs according to their safety significance.

The letters dated October 18, 2018 (Reference 2), and April 23, 2019 (Reference 3), provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the U.S. Nuclear Regulatory Commission (NRC or the Commission) staff's original proposed no significant hazards consideration determination as published in the *Federal Register* on May 22, 2018 (83 FR 23731).

2.0 REGULATORY EVALUATION

2.1 Risk-Informed Categorization and Treatment of Structures, Systems, and Components

A risk-informed approach to regulation enhances and extends traditional deterministic regulation by considering risk in a comprehensive manner. Specifically, a risk-informed approach allows consideration of a broader set of potential challenges to safety, providing a logical means for prioritizing these challenges based on safety significance, and allowing consideration of a broader set of resources to defend against these challenges. Probabilistic risk assessments (PRAs) address credible initiating events by assessing the event frequency. Mitigating system reliability is then assessed, including the potential for common cause failures.

To take advantage of the safety enhancements available through the use of PRA, the NRC promulgated a new regulation, 10 CFR 50.69, in the *Federal Register* on November 22, 2004 (69 FR 68008), which became effective on December 22, 2004. The provisions of 10 CFR 50.69 allow adjustment of the scope of SSCs subject to special treatment requirements. Special treatment refers to those requirements that provide increased assurance beyond normal industry practices that SSCs perform their design-basis functions. For SSCs categorized as low safety significance, alternative treatment requirements may be implemented in accordance with the regulation. For SSCs determined to be of high safety significance, the requirements set forth in 10 CFR 50.69(b)(1)(i) through 50.69(b)(1)(xi), and 10 CFR 50.69(g) shall apply.

Section 50.69 of 10 CFR contains requirements regarding how a licensee categorizes SSCs using a risk-informed process, adjusts treatment requirements consistent with the relative significance of the SSC, and manages the process over the lifetime of the plant. A risk-informed categorization process is employed to determine the safety significance of SSCs and place the SSCs into one of four risk-informed safety class (RISC) categories. The determination of safety significance is performed by an integrated decision-making process that uses both risk insights and traditional engineering insights. The safety functions include the design-basis functions, as well as functions credited for severe accidents (including external events). Special or alternative treatment for the SSCs is applied as necessary to maintain functionality and reliability, and is a function of the SSC categorization results and associated bases. Finally, periodic assessment activities are conducted to make adjustments to the categorization and/or treatment processes as needed so that SSCs continue to meet all applicable functional requirements.

Section 50.69 of 10 CFR does not allow for the elimination of SSC functional requirements or allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, 10 CFR 50.69 enables licensees to focus their resources on SSCs that make a significant contribution to plant safety. For SSCs that are categorized as high safety significant (HSS), existing treatment requirements are maintained or potentially enhanced. Conversely, for SSCs categorized as low safety significant (LSS) that do not significantly contribute to plant safety on an individual basis, the regulation allows an alternative risk-informed approach to treatment that provides a reasonable level of confidence that these SSCs will satisfy functional requirements.

In 2004, when promulgating the 10 CFR 50.69 rule, the Commission stated:

> It is important to note that this rulemaking effort, while intended to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed, is not intended to allow for the elimination of SSC functional requirements or to allow equipment that is required by the deterministic design basis to be removed from the facility (i.e., changes to the design of the facility must continue to meet the current requirements governing design change; most notably § 50.59). Instead, this rulemaking should enable licensees and the staff to focus their resources on SSCs that make a significant contribution to plant safety by restructuring the regulations to allow an alternative risk-informed approach to special treatment. Conversely, for SSCs that do not significantly contribute to plant safety on an individual basis, this approach should allow an acceptable, though reduced, level of confidence (i.e., "reasonable confidence") that these SSCs will satisfy functional requirements. However, continued maintenance of the health and safety of the public will depend on effective implementation of § 50.69 by the licensee or applicant applying the rule at its nuclear power plant.

Final Rule, Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors, 69 Fed. Reg. 68008, 68011 (Nov. 2, 2004).

2.2 Licensee's Proposed Changes

The licensee proposed to amend its Renewed Facility Operating License. The NRC staff requested further clarification of the license change in PRA-Request for Additional Information (RAI)-02.e, 02.f, and 06 (Reference 4). The licensee responded by adding and updating (Reference 2 and Reference 3) with the following license condition, which would allow for the implementation of 10 CFR 50.69:

> Duke Energy is approved to implement 10 CFR 50.69 using the processes for categorization of Risk Informed Safety Class (RISC)-1, RISC-2, RISC-3, and RISC-4 structures, systems, and components (SSCs) using: Probabilistic Risk Assessment (PRA) models to evaluate risk associated with internal events, including internal flooding, and internal fire; the shutdown safety assessment process to assess shutdown risk; the Arkansas Nuclear One, Unit 2 (ANO-2) passive categorization method to assess passive component risk for Class 2 and Class 3 SSCs and their associated supports; and the results of non PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards, i.e., seismic margin analysis (SMA) to evaluate seismic risk, and a screening of other external hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009; as specified in the Unit 1 License Amendment No. 174 dated September 17, 2019.
>
> Duke Energy will complete the implementation items listed in Attachment 1 of Duke Energy letter to the NRC dated April 23, 2019 prior to implementation of 10 CFR 50.69. All issues identified in the attachment will be addressed and any associated changes will be made, focused-scope peer reviews will be performed on changes that are PRA upgrades as defined in the PRA standard (ASME/ANS RA-Sa-2009, as endorsed by RG 1.200, Revision 2), and any findings will be resolved and reflected in the PRA of record prior to implementation of the 10 CFR 50.69 categorization process.
>
> Prior NRC approval, under 10 CFR 50.90, is required for a change to the categorization process specified above (e.g., change from a seismic margins approach to a seismic probabilistic risk assessment approach).

2.3 Regulatory Review

The NRC staff reviewed the licensee's application to determine whether (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) activities proposed will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or the health and safety of the public. The staff considered the following regulatory requirements and guidance during its review of the proposed changes.

Regulatory Requirements

Section 50.69 of 10 CFR provides an alternative approach for establishing requirements for treatment of SSCs for nuclear power reactors using a risk-informed method of categorizing

SSCs according to their safety significance. This regulation permits power reactor licensees to implement an alternative regulatory framework with respect to special treatment. Section 50.69 of 10 CFR permits licensees to remove SSCs of low safety significance from the scope of certain identified special treatment requirements and to revise requirements for SSCs of greater safety significance.

Paragraph 50.69(c) of 10 CFR requires licensees to use an integrated decision-making panel (IDP) to categorize safety-related and non-safety-related SSCs according to the safety significance of the functions they perform into one of the following four RISC categories, which are defined in 10 CFR 50.69(a), as follows:

RISC-1: Safety-related SSCs with safety significant functions[1]

RISC-2: Non-safety-related SSCs with safety significant functions

RISC-3: Safety-related SSCs with low safety significant functions

RISC-4: Non-safety related SSCs with low safety significant functions

SSCs are classified as having either HSS functions (i.e., RISC 1 and RISC-2 categories) or LSS functions (i.e., RISC-3 and RISC-4 categories). For HSS SSCs, 10 CFR 50.69 maintains current regulatory requirements (i.e., it does not remove any requirements from these SSCs) for special treatment. For LSS SSCs, licensees can implement alternative treatment requirements in accordance with 10 CFR 50.69(b)(1) and 10 CFR 50.69(d). For RISC-3 SSCs, licensees can replace special treatment with an alternative treatment. For RISC-4 SSCs, 10 CFR 50.69 does not impose new treatment requirements, and RISC-4 SSCs are removed from the scope of any applicable special treatment requirements identified in 10 CFR 50.69(b)(1).

Paragraph 50.69(c)(1) of 10 CFR states that SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 SSCs using a categorization process that determines if an SSC performs one or more safety significant functions and identifies those functions. The process must:

(i) Consider results and insights from the plant-specific PRA. This PRA must at a minimum model severe accident scenarios resulting from internal initiating events occurring at full power operation. The PRA must be of sufficient quality and level of detail to support the categorization process, and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC.

(ii) Determine SSC functional importance using an integrated, systematic process for addressing initiating events (internal and external), SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design-bases functions and functions credited for mitigation and prevention of severe accidents. All aspects of the integrated, systematic process used to characterize SSC importance must reasonably reflect the current plant

[1] Nuclear Energy Institute (NEI) 00-04 uses the term "high-safety significant (HSS)" to refer to SSCs that perform safety significant functions. The NRC understands HSS to have the same meaning as "safety significant" (i.e., SSCs that are categorized as RISC-1 or RISC-2), as used in 10 CFR 50.69.

configuration and operating practices, and applicable plant and industry operational experience.

(iii) Maintain defense-in-depth.

(iv) Include evaluations that provide reasonable confidence that for SSCs categorized as RISC–3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of § § 50.69(b)(1) and (d)(2) are small.

(v) Be performed for entire systems and structures, not for selected components within a system or structure.

Paragraph 50.69(c)(2) of 10 CFR states:

> The SSCs must be categorized by an Integrated Decision-Making Panel (IDP) staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering.

Paragraph 50.69(b)(3) of 10 CFR states that the Commission will approve a licensee's implementation of this section by issuance of a license amendment if the Commission determines that the categorization process satisfies the requirements of 10 CFR 50.69(c). As stated in 10 CFR 50.69(b), after the NRC approves an application for a license amendment, a licensee may voluntarily comply with 10 CFR 50.69 as an alternative to compliance with the following requirements for LSS SSCs: (i) 10 CFR Part 21, (ii) a portion of 10 CFR 50.46a(b), (iii) 10 CFR 50.49, (iv) 10 CFR 50.55(e), (v) certain requirements of 10 CFR 50.55a, (vi) 10 CFR 50.65, except for paragraph (a)(4), (vii) 10 CFR 50.72, (viii) 10 CFR 50.73, (ix) Appendix B to 10 CFR Part 50, (x) certain containment leakage testing requirements, and (xi) certain requirements of Appendix A to 10 CFR Part 100.

Guidance

Nuclear Energy Institute (NEI) 00-04, Revision 0, "10 CFR 50.69 SSC Categorization Guideline" (Reference 5), describes a process for determining the safety significance of SSCs and categorizing them into the four RISC categories defined in 10 CFR 50.69. This categorization process is an integrated decision-making process that incorporates risk and traditional engineering insights. NEI 00-04, Revision 0, provides options for licensees implementing different approaches depending on the scope of their PRA models. It also allows the use of non-PRA approaches when PRAs have not been performed. NEI 00-04 identifies non-PRA approaches such as fire-induced vulnerability evaluation to address fire risk, seismic margin analysis (SMA) to address seismic risk, and guidance in Nuclear Management and Resource Council (NUMARC) 91-06, "Guidelines for Industry Actions to Assess Shutdown Management" (Reference 6), to address shutdown operations. As stated in Regulatory Guide (RG) 1.201 (for Trial Use), Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants according to Their Safety Significance" (Reference 7), such non-PRA-type evaluations will result in more conservative categorization in that special treatment requirements will not be allowed to be relaxed for SSCs that are relied upon in such evaluations.

Sections 2 through 10 of NEI 00-04 describe a method for meeting the requirements of 10 CFR 50.69(c), as follows:

- Sections 3.2 and 5.1 provide specific guidance corresponding to 10 CFR 50.69(c)(1)(i).
- Sections 3, 4, 5, and 7 provide specific guidance corresponding to 10 CFR 50.69(c)(1)(ii).
- Section 6 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(iii).
- Section 8 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(iv).
- Section 2 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(v).
- Sections 9 and 10 provide specific guidance corresponding to 10 CFR 50.69(c)(2).

Additionally, Section 11 of NEI 00-04 provides guidance on program documentation and change control related to the requirements of 10 CFR 50.69(e), and Section 12 of NEI 00-04 provides guidance on periodic review related to the requirements in 10 CFR 50.69(f). Maintaining change control and periodic review provides confidence that all aspects of the program reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operational experience, as required by 10 CFR 50.69(c)(1)(ii).

RG 1.201, Revision 1, endorses the categorization method described in NEI 00-04, Revision 0, with clarifications, limitations, and conditions. RG 1.201 states that the applicant is expected to document, at a minimum, the technical adequacy of the internal initiating events PRA. Licensees may use either PRAs or alternative approaches for hazards other than internal initiating events. RG 1.201 clarifies that the NRC staff expects that licensees proposing to use non-PRA approaches in their categorization should provide a basis in the submittal for why the approach and the accompanying method employed to assign safety significance to SSCs is technically adequate. It further states that as part of the NRC's review and approval of a licensee's or applicant's application requesting to implement 10 CFR 50.69, the NRC staff intends to impose a license condition that will explicitly address the scope of the PRA and non-PRA methods used in the licensee's categorization approach. If a licensee or applicant wishes to change its categorization approach, and the change is outside the bounds of the NRC's license condition (e.g., switch from a seismic margins analysis to a seismic PRA), the licensee or applicant will need to seek NRC approval by a license amendment of the implementation of the new approach in its categorization process. RG 1.201 also states that all aspects of NEI 00-04 must be followed to achieve reasonable confidence in the evaluations required by 10 CFR 50.69(c)(1)(iv).

RG 1.200, Revision 2, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities" (Reference 8), describes an acceptable approach for determining whether the quality of the PRA, in total or the parts that are 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 light-water reactors. It endorses, with clarifications, the American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) PRA Standard ASME/ANS RA-Sa-2009 ("ASME/ANS 2009 standard" or "PRA standard") (Reference 9). This RG provides guidance for determining the technical adequacy of a PRA by comparing the PRA to the relevant parts of the ASME/ANS RA-Sa-2009 using a peer review process. In accordance with the guidance, peer reviews should be used for PRA upgrades. A PRA upgrade is defined in the PRA Standard as "the incorporation into a PRA model of a new methodology or significant changes in scope or capability that impact the significant accident sequences or the significant accident progression sequences."

RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Reference 10), provides guidance on the use of PRA findings and risk insights in support of changes to a plant's licensing basis. This RG provides risk acceptance guidelines for evaluating the results of such evaluations.

3.0 TECHNICAL EVALUATION

3.1 NRC Staff's Method of Review

The NRC staff evaluated the licensee's application to determine if the proposed changes are consistent with the regulations and guidance discussed in Section 2 of this safety evaluation (SE). The NRC staff's review and the documentation of that review in this SE uses the framework of NEI 00-04, Revision 0.

3.2 Overview of the Categorization Process (NEI 00-04, Section 2)

Paragraph 50.69(b)(2)(i) of 10 CFR 50.69 states that a licensee voluntarily choosing to implement 10 CFR 50.69 shall submit an application for a license amendment under 10 CFR 50.90 that contains a description of the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs. In addition, 10 CFR 50.69(c)(1)(v) states that the process for categorization must be performed for entire systems and structures, not for selected components within a system or structure.

RG 1.201 states that the categorization process described in NEI 00-04, with any noted exceptions or clarifications, is acceptable for implementation of 10 CFR 50.69. RG 1.201 also states that the implementation of all processes described in NEI 00-04 (i.e., Sections 2 through 12) is integral to providing reasonable confidence in the evaluations required by 10 CFR 50.69(c)(1)(iv) and that all aspects of NEI 00-04 must be followed to achieve reasonable confidence in the evaluations required by 10 CFR 50.69(c)(1)(iv).

The licensee stated in the LAR that it will implement the risk categorization process in accordance with NEI 00-04, as endorsed by RG 1.201. The LAR provides details of the categorization process as follows: (1) summarization of the categorization process, (2) order of the sequence of elements or steps that will be performed (function/component level), (3) explanation of the difference between preliminary HSS and assigned HSS, and (4) identification of which inputs can and which cannot be changed by the IDP from preliminary HSS to LSS. In the LAR, the licensee summarizes the process that is outlined in Table 1 (Table 3-1 of the LAR) below.

As summarized in the licensee's LAR, the categorization process contains the following elements/steps:

- Defining system boundaries (see Section 3.3 of this SE).
- Defining system function and assigning components to functions (see Section 3.4 of this SE).
- Risk Characterization. Safety significance of active components is assessed through a combination of PRA and non-PRA methods, covering all hazards (see Section 3.5 of this SE).

- Defense-in-depth characterization performed in accordance with Section 6 of NEI 00-04 (see Section 3.6 of this SE).

- Passive Characterization. Passive components are not modeled in the PRA, and therefore, a different assessment method is used to assess the safety significance of these components, as described in Section 3.5.4 of this SE. This process addresses those components that have only a pressure retaining function and the passive function of active components such as the pressure/liquid retention of the body of a motor operated valve.

- Qualitative Characterization. System functions are qualitatively categorized as HSS or LSS based on the seven questions in Section 9.2 of NEI 00-04 (see Section 3.9 of this SE). The licensee confirmed in its response to PRA-RAI-03 (Reference 2) that the IDP will independently determine that if any of the seven considerations cannot be confirmed for a function, then the final categorization of that function is HSS.

- Cumulative risk sensitivity study. For PRA-modeled components, an overall risk sensitivity study is used to confirm that the population of LSS components results in acceptably small increases to CDF and LERF and meets the acceptance guidelines of RG 1.174 (see Section 3.8 of this SE).

- Review by the IDP. The categorization results are presented to the IDP for review and approval. The IDP reviews the categorization results and makes the final determination on the safety significance of system functions and components (see Section 3.9 of this SE).

In Table 3-1 in Section 3.1.1 of the LAR, the licensee provided details on how some steps of the process are performed at the component level (e.g., all PRA and non-PRA-modeled hazards, containment defense in depth, passive categorization), how some steps are performed at the function level (e.g., qualitative criteria), and how some steps are performed at the function and component level (e.g., shutdown, core damage defense in depth).

In LAR Section 3.1.1, the licensee explained that consistent with NEI 00-04, the categorization of a component or function is "preliminary" until it has been confirmed by the IDP (see also Section 3.9 of this SE). This LAR section includes a discussion and associated table (Table 3-1, repeated as Table 1 below) summarizing what mechanisms are available to assign functions and components to preliminarily HSS and how this designation can or cannot be changed to LSS, as appropriate.

As illustrated in the table, all components that are assigned HSS based on risk significance as determined by the internal events importance measures, non-PRA risk models, defense-in-depth considerations, passive categorization, or cumulative impact of the qualitative considerations must be assigned HSS. Components may or may not be assigned HSS based on other PRA-modeled risk results. The licensee stated that a function is preliminarily categorized as HSS if any component supporting the function is assigned HSS. The qualitative considerations generally categorize functions directly. Therefore, if the IDP determines that any one of the seven considerations is false for a system function, then the function will be assigned HSS. Once a system function is identified as HSS, then all the components supporting that function are preliminary HSS and will be presented to the IDP for review. Many functions are design-basis functions, and some components supporting those functions may not be necessary to achieve success of the safety significant mitigating function, and these components may not be required to be HSS based on their risk significance. Therefore, any component supporting an HSS function but not requiring an HSS assignment based on risk significance may be assigned LSS by the IDP.

The NRC staff has evaluated the categorization steps and the associated clarifications provided by the licensee in the LAR and RAI responses and finds that the licensee's process is consistent with all aspects of the process in NEI 00-04, as endorsed by RG 1.201.

Table 1

Element	Categorization Step - NEI 00-04 Section	Evaluation Level	IDP Change HSS to LSS	Drives Associated Functions
Risk (PRA Modeled)	Internal Events Base Case – Section 5.1	Component	Not Allowed	Yes
	Fire, Seismic, and Other External Events Base Case		Allowable	No
	PRA Sensitivity Studies		Allowable	No
	Integral PRA Assessment – Section 5.6		Not Allowed	Yes
Risk (Non-modeled)	Fire, Seismic, and Other External Hazards	Component	Not Allowed	No
	Shutdown – Section 5.5	Function/ Component	Not Allowed	No
Defense-in-Depth	Core Damage – Section 6.1	Function/ Component	Not Allowed	Yes
	Containment – Section 6.2	Component	Not Allowed	Yes
Qualitative Criteria	Considerations – Section 9.2	Function	Allowable for Considerations	N/A
Passive	Passive – Section 4	Segment/ Component	Not Allowed	No

3.3 Assembly of Plant-Specific Inputs (NEI 00-04, Section 3)

Section 3 of NEI 00-04 states that the assembly of plant-specific inputs involves the collection and assessment of the key inputs to the risk-informed categorization process. This includes design and licensing information, PRA analyses, and other relevant plant data sources. In addition, this step includes the critical evaluation of plant-specific risk information to ensure that the information is adequate to support this application. The guidance in Section 3 of NEI 00-04 summarizes the use of risk information and the general quality measures that should be applied to the risk analyses supporting the 50.69 categorization. These quality measures include characterization of technical acceptability of both the internal events at-power PRA and other risk analyses necessary to implement 10 CFR 50.69.

The licensee's risk categorization process uses PRAs to assess risks from internal events (including flooding), and from fire. For the other applicable hazard groups, the licensee's process uses non-PRA methods for the risk categorization. The licensee uses its Seismic Safe Shutdown Equipment List (SSEL) from the seismic margin analysis (SMA) to assess seismic risk, its individual plant examination of external events (IPEEE) screening process to assess other external hazards (high winds and external floods), and its qualitative defense-in-depth shutdown model to assess shutdown risk. The use of risk information and quality of the licensee's PRA is reviewed in Section 3.5 of this SE.

3.4 System Engineering Assessment (NEI 00-04, Section 4)

Paragraph 50.69(c)(1)(ii) of 10 CFR requires licensees to determine SSC functional importance using an integrated, systematic process for addressing initiating events (internal and external), SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design-basis functions and functions credited for mitigation and prevention of severe accidents. Section 4 of NEI 00-04 provides guidance for developing a systematic engineering assessment involving the identification and development of base information necessary to perform the risk-informed categorization. The assessment includes the following elements: system selection and system boundary definition, identification of system functions, and a mapping of components to functions.

Section 4 of NEI 00-04 states that system selection and boundary definition include defining system boundaries where the system interfaces with other systems. NEI 00-04 states that the next step is the identification of system functions, including design-basis and beyond design-basis functions identified in the PRA, and that system functions should be consistent with the functions defined in design-basis documentation and maintenance rule functions. NEI 00-04 states that the coarse mapping of components to functions involves the initial breakdown of system components into system functions they support. The licensee should then identify and document system components and equipment associated with each function. The guidance in NEI 0-04 also includes consideration of interfacing functions. Section 7.1 of the NEI 00-04 guidance states, in part, "[d]ue to the overlap of functions and components, a significant number of components support multiple functions. In this case, the SSC or part thereof should be assigned the highest risk significance for any function that the SSC or part thereof supports." Furthermore, Section 4 of NEI 00-04 states, in part, "There may be circumstances where the categorization of a candidate low safety significant SSC within the scope of the system being considered cannot be completed because it also supports an interfacing system. In this case, the SSC will remain uncategorized until the interfacing system is categorized."

Section 2.2 of the LAR states that the safety functions in the categorization process include the design-basis functions, as well as functions credited for severe accidents (including external events). Section 3.1.1 of the LAR summarizes the different hazards and plant states for which functional and risk-significant information will be collected. Section 3.1.1 of the LAR also states that the SSC categorization process documentation will include, among other items, system functions identified and categorized with the associated bases and mapping of components to support function(s).

Paragraph 50.69(c)(1)(ii) of 10 CFR requires, in part, that the functions to be identified and considered in the categorization process include design-basis functions and functions credited for mitigation and prevention of severe accidents. NEI 00-04 includes guidance to identify all functions performed by each system and states that the IDP will categorize all system functions. All system functions include all functions involved in the prevention and mitigation of design-basis accidents and may include additional functions not credited as design-basis hazard mitigating functions, depending on the system. The LAR summarizes the applicable guidance in NEI 00-04 and states that the guidance in NEI 00-04 will be followed. Therefore, the NRC staff finds that the licensee described a systematic process that will identify design-basis functions and functions credited for mitigation and prevention of severe accidents consistent with the requirements of 10 CFR 50.59(c)(1)(ii), because all system functions will be identified and evaluated through the categorization process in accordance with NEI 00-04.

3.5 Component Safety Significance Assessment (NEI 00-04, Section 5)

This step in the licensee's categorization process is to assess the safety significance of components using quantitative or qualitative risk information from a PRA or other risk assessment method. In the NEI 00-04 guidance, component risk significance is assessed separately for five hazard groups:

- Internal event risk
- Fire
- Seismic
- Other external risks (tornadoes, external floods)
- Shutdown risks

Paragraph 50.69(c)(1)(i) of 10 CFR requires, in part, the use of PRA to assess risk from internal events as a minimum. The paragraph further specifies that the PRA used in the categorization process must be of sufficient quality and level of detail and subject to an acceptable peer review process. For the hazards other than internal events, including fire, seismic, other external hazards (high winds, external floods, etc.), and shutdown, 10 CFR 50.69(b)(2) allows, and the NEI 00-04 guidance summarizes, the use of PRA if such PRA models exist, or, in the absence of quantifiable PRA, the use of other methods (e.g., fire-induced vulnerability evaluation, SMA, IPEEE screening, and shutdown safety plan).

LAR Sections 3.1.1 and 3.2.1 through 3.2.5 explain that the licensee's categorization process uses PRA to assess risks from internal events (including internal flooding) and fire. For the other three risk hazard groups, the licensee's process uses non-PRA methods for the risk characterization, as follows:

- SMA SSEL as a screening process result
- IPEEE screening to assess the risk from other external hazards (high winds, external floods)
- Shutdown safety plan to assess shutdown risk

The approaches used by the licensee to assess internal and external hazards are consistent with the approaches included in the NEI 00-04 guidance, as endorsed by RG 1.201, and therefore, acceptable to the NRC staff. The guidance considers the results and insights from the plant-specific PRA peer reviews as required by 10 CFR 50.69(c)(1)(i), and non-PRA risk characterization as required by 10 CFR 50.69(c)(1)(ii). The application of these approaches is reviewed in the following SE subsections: PRA in Subsections 3.5.1 and 3.5.2, and the non-PRA methods in Subsection 3.5.3.

3.5.1 Capability and Quality of the PRA to Support the Categorization Process

The licensee's PRA comprises (1) an internal events PRA that calculates CDF and LERF from internal events, including internal flooding at full power, and (2) a fire PRA. Paragraph 50.69(c)(1)(i) of 10 CFR requires, in part, that the PRA must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC.

The peer review process compares the characteristics of all the analysis tasks in a licensee's PRA against characteristics summarized in the ASM/ANS PRA standard endorsed in RG 1.200. Revision 2 of RG 1.200 endorses the ASME/ANS RA-Sb-2009 standard. Each of the several hundred tasks is labelled a supporting requirement. For many supporting requirements, there are three sets of generally increasingly complex and realistic task characteristics referred to as Capability Categories (CC) (i.e., I, II, and III). The characteristics labelled CC-I are the minimum acceptable, CC-II characteristics are considered widely acceptable, and CC-III characteristics indicate the maximum achievable scope/level of detail, plant specificity, and realism. For other supporting requirements, the CCs may be combined (e.g., the requirement for meeting CC-I may be combined with II), or the requirement may be the same across all CCs so that the requirement is simply met or not met. For each supporting requirement, the PRA peer review team assigns the appropriate CC or indicates that the supporting requirement is met or not met.

Paragraph 50.69(b)(2)(iii) of 10 CFR requires the results of the PRA review process conducted to meet 10 CFR 50.59(c)(1)(i) be submitted as part of the application. The licensee has submitted this information, and the NRC staff's review of this information is presented below.

Internal Events PRA

The NRC staff review of the internal events PRA was based on the results of the peer review of the internal events PRA, the associated facts and observations (F&Os) closure review described in LAR Section 3.3, and previously docketed information on PRA quality submitted to the NRC for relocation of surveillance frequencies to licensee control, Technical Specifications Task Force (TSTF) Traveler TSTF-425, dated November 29, 2016 (Reference 11), and request to adopt National Fire Protection Association (NFPA) Standard 805 (Reference 12).

The internal events model was subject to a full scope peer review in 2002 in accordance with the guidance in NEI 00-02, "Industry Probabilistic Risk Assessment (PRA) Peer Review Process Guidelines" (Reference 13), and Appendix B of RG 1.200, Revision 2 (Reference 8). In the LAR, the licensee further stated that in March 2017, an F&Os closure review was performed by an independent team on all internal events and internal flooding finding-level F&Os. This F&Os closure review was performed as detailed in Appendix X (Reference 14) to the guidance in NEI 05-04 (Reference 15), NEI 07-12 (Reference 16), and NEI 12-13 (Reference 17), concerning the process "Close-Out of Facts and Observations." The NRC staff accepted, with conditions, a final version of Appendix X to NEI 05-04, NEI 07-12, and NEI 12-13, in the NRC letter dated May 3, 2017 (Reference 18). The March 2017 closure review closed out all open internal events F&Os. Although the Harris F&Os closure was performed prior to the NRC's acceptance of the F&Os closure process, Harris was one of the pilot plants for the F&Os closure process, and the NRC staff observed the Harris F&Os closure process. Based on the NRC staff's observation, the staff finds the March 2017 F&Os closure at Harris was performed in accordance with the NRC-accepted version of Appendix X.

Paragraph 50.69(c)(1)(i) of 10 CFR requires, in part, that any plant-specific PRA used in the categorization must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard that is endorsed by the NRC. RG 1.200 provides guidance for determining the technical adequacy of internal events PRA by comparing the PRAs to the relevant parts of the ASME/ANS 2009 standard using a peer review process. Based on its review, the NRC staff finds that the licensee has followed the guidance in RG 1.200 and submitted the results of the peer review, and therefore, meets the requirement in 10 CFR 50.69(b)(2)(iii). The NRC staff has reviewed the peer review results and finds that the quality and level of detail of the internal events PRA is sufficient to support the categorization of SSCs as required by 10 CFR 50.69 (b)(2)(ii) and use the process endorsed by the NRC staff in RG 1.201. Therefore, the NRC staff concludes that the internal events PRA meets the internal events PRA requirement in 10 CFR 50.69(c)(1)(i).

Internal Flooding PRA

The internal flooding model was subject to a self-assessment and a full scope peer review in August 2014. In March 2017, an F&Os closure review was performed by an independent team on all internal events finding-level F&Os.

The licensee submitted a list of all the open F&Os from the self-assessments and peer reviews, including the F&Os that remained open after the F&Os closure review in LAR Attachment 3. The licensee provided for each F&Os a disposition for the F&Os for this application.
The NRC staff reviewed the licensee's resolution of all the peer review findings and assessed the potential impact of the findings on the categorization. The NRC staff requested additional information to clarify the licensee's disposition for some of the findings as described in the following paragraphs.

F&Os 1-9 stated that the floor drain capacity evaluations did not include consideration of the reduced drain capacity when multiple floor drains are connected to a common drain line. As reported in the LAR, the F&Os closure team noted that the licensee had completed an analysis for the Reactor Auxiliary Building and limited credit for floor drains to relatively small flood rates, but only for the Reactor Auxiliary Building. The F&Os team also commented that the licensee did not consider flood propagation via backflow through the drains. In PRA-RAI-02.a, the NRC staff requested further clarification of the floor drain analyses. In response to PRA-RAI-02.a, the licensee summarized the results of its floor drain evaluation for the Turbine Building and Diesel Generator Building, the only two other buildings that the licensee concluded could be impacted by floor drain interactions. The analysis concluded the open-air structure of the Turbine Building makes it insensitive to floor drain operation, and that flood propagation thought the drains was less important than through stairwells and other large penetrations. The licensee's analysis determined that the floor drains in both trains of the emergency diesel generator rooms are interconnected, which could result in the flooding of both rooms and loss of both emergency diesel generators. This scenario would not result in an automatic or manual plant trip, and any eventual shutdown required by TSs would be a controlled manual shutdown. The licensee screened this scenario from the internal flooding analysis based on the very low frequency of the flooding scenario and concurrent, but independent, extended loss of offsite power during a controlled manual shutdown. The NRC staff finds that the licensee has appropriately evaluated the impact of floor drains on flooding scenarios and that this issue is resolved.

F&Os 1-18 stated that the licensee did not identify the assumptions used to determine its flood-induced door failures heights. As reported in the LAR, the F&Os closure team stated that the licensee's subsequent evaluation did not include all critical failure modes that would cause the doors to fail at different heights. The NRC staff requested justification for the use of a single generic door failure height in PRA-RAI-02.b. In response to PRA-RAI-02.b, the licensee stated that all applicable doors are modeled in the PRA, and the non-catastrophic door failure modes (e.g., warping) associated with lower height door failures are generally akin to water flowing under the door and need not be separately modeled. The licensee further stated that an Electric Power Research Institute (EPRI) guideline for performing internal flooding PRA provides a single height for standard plant hollow metal door, which is near the value used by the licensee. The NRC staff finds that the licensee has included door failures in its PRA, and that the door failure modes are modeled adequately with respect to the expected contribution of flooding-induced door failure to risk and are consistent with the resolution described in flooding PRA methods documents.

F&Os 1-19 stated that flood associated alarms credited as cues in the human reliability analysis (HRA) analysis are neither listed nor corelated with different flood areas. The F&Os closure team did not close this finding, stating that the evaluation of alarms and alarm timing continued to be incomplete. Therefore, the NRC staff requested justification in using this timing for the application in PRA-RAI-02.c. In response to PRA-RAI-02.c, the licensee stated that the timing is judged to be a reasonable upper bound time based on expected control room indications initially associated with the specific rupture followed by various sump and tank level alarms. The licensee further stated that the human error sensitivity study required by Section 5 of NEI 00-04 increases the error probability to the 95th percentile value, and this increase would address the lack of detailed analysis on the available alarms. The NRC staff finds that the human action error sensitivity study would illustrate the impact of a higher human error probability associated with delayed alarms, and is, therefore, adequate to support the risk categorization process.

RG 1.200 provides guidance for determining the technical adequacy of internal flooding PRA by comparing the PRAs to the relevant parts of the ASME/ANS 2009 standard using a peer review process. Based on its review, the NRC staff finds that the licensee has followed the guidance in RG 1.200 and submitted the results of the peer review, and therefore, meets the requirement in 10 CFR 50.69(b)(2)(iii). The NRC staff has reviewed the peer review results and finds that the quality and level of detail of the internal flooding PRA is sufficient to support the categorization of SSCs as required by 10 CFR 50.69 (b)(2)(ii) and use the process endorsed by the NRC staff in RG 1.201. Therefore, the NRC staff concludes that the internal flooding PRA meets the internal flooding PRA requirement in 10 CFR 50.69(c)(1)(i).

Fire PRA

The NRC staff reviewed the results of the peer review of the fire PRA and associated F&Os closure review described in LAR Section 3.3 and presented in LAR Attachment 3. The licensee's fire PRA was subject to both an NRC review and full-scope industry peer review in 2008 during the review associated with approval of a license amendment to implement 10 CFR 50.48(c). The 2008 review was conducted using the ANSI/ANS-58.23-2007 standard, whereas RG 1.200, Revision 2, references the 2009 ASME/ANS RA-Sa-2009. The ASME/ANS-RA-Sa-2009 standard states that it was assembled from the ANSI/ANS-58.23-2007 fire PRA standard. The licensee stated that it assessed the differences between ANSI/ANS-58.23-2007 and the current version of the fire PRA standard in ASME/ANS RA-Sa-2009 and confirmed there were no technical differences between the two versions of the standard. In October 2017, an F&Os closure review was performed by an independent team on fire events finding-level F&Os.

During the review of the Harris submittal regarding relocation of surveillance frequency requirements, the NRC staff noted that several supporting requirements were determined to have been assessed at Capability Category (CC)-I with no associated F&Os. The guidance in RG 1.200 is for supporting requirements to have been assessed at CC-II. Therefore, the NRC staff requested in PRA-RAI-01, the licensee to provide justification that each of the supporting requirements was assessed to be CC-I or "not met" (instead of CC-II) do not have an impact on the risk categorization process. In response to PRA-RAI-01, the licensee provided six supporting requirements that are CC-I or not met with dispositions related to this application.

Assessing Supporting Requirement FSS-D7 at CC-II requires a review to confirm that detection systems have not experienced outlier behavior before generic estimates of system unavailability are used. In response to PRA-RAI-01, the licensee stated that there has been no comparison of plant-specific unavailability with the generic estimates, but that fire protection and detection systems are monitored in accordance with applicable NFPA codes, and this monitoring ensures that the systems do not experience outlier behavior. The NRC staff finds the current assessment of CC-I instead of CC-II for this supporting requirement is acceptable because the future ongoing monitoring program will identify any outlier behaviors or modification of the generic estimates, resulting in the generally acceptable CC-II assessment.

Assessing Supporting Requirement FSS-D9 at CC-II requires a qualitative evaluation of the potential for smoke damage to fire PRA equipment and that any damage be incorporated into the fire scenario. In its response to PRA-RAI-01, the licensee summarized a qualitative evaluation of smoke damage on equipment and stated that targets that can be potentially damaged in the fire scenario are included in the fire PRA model. The NRC staff finds that smoke damage has been qualitatively evaluated, and therefore, the current evaluation is acceptable.

Assessing Supporting Requirement FSS-F2 (and related FSS-F3) at CC-II require that if a fire scenario could damage exposed structural steel, that (1) criteria for structural collapse of exposed steel be developed and documented and (2) a quantitative assessment of the risk of each of the selected fire scenarios be incorporated into the fire PRA model. The licensee stated in response to PRA-RAI-01 that the criteria for structural collapse has been developed and documented, but changes to the PRA have not yet been evaluated. The NRC staff finds the current assessment of CC-I instead of CC-II for this supporting requirement is acceptable because the licensee has identified the applicable fire scenarios and will perform a quantitative assessment in accordance with implementation item iii, as discussed in Section 3.5.5 of this SE, resulting in the generally acceptable CC-II assessment.

Assessing Supporting Requirements FSS-H5 and FSS-H6 at CC-II require documenting the fire modeling output results for each fire scenario, including the "results of parameter uncertainty evaluations (as performed)." The NRC staff finds the assessment of CC-I instead of CC-II for this supporting requirement due to missing parameter uncertainty evaluation is acceptable because NEI 00-04 and RG 1.201 discuss the use of sensitivity studies to address the impact of parameter and model uncertainties instead of parameter uncertainty propagation.

Assessing Supporting Requirement IGN-A4 at CC-II requires a review of plant-specific experience for fire event outlier experience. The licensee stated in response to PRA-RAI-01 that this review was conducted and no outlier events were found; therefore, this supporting requirement is now met at CC-II. The NRC staff finds that the licensee's review and evaluation of this supporting requirement is sufficient and considers this supporting requirement met at CC-II because the required evaluation is a straightforward review of operating experience.

The licensee submitted a list of all the open F&Os from the self-assessments and peer reviews, including the F&Os that remained open after the F&Os closure review in LAR Attachment 3. The licensee provided for each F&Os a disposition for the F&Os for this application. The NRC staff reviewed the licensee's resolution of all the peer review findings and assessed the potential impact of the findings on the categorization.

In LAR Attachment 3, the disposition to F&Os HRA-C1-3 stated that "some significant HFEs were not selected for detailed analysis and were instead conservatively assumed to be failed or left at a screening value." In PRA-RAI-02.e, the NRC requested justification for excluding this analysis and demonstration that it would have no impact on this application. In response to PRA-RAI-02.e, the licensee identified four conservatively quantified human failure events (HFEs) that might impact the categorization process and provided implementation item i (discussed in Section 4 of this SE) to analyze and incorporate this analysis into the fire PRA model prior to the licensee's implementation of 10 CFR 50.69.

The disposition to Assumption/uncertainty No. 5 in LAR Attachment 6 regarding the use of the very early warning fire detection systems states the licensee use the guidance provided in Frequently Asked Question (FAQ) 08-0046. The NRC staff notes that the guidance provided in FAQ 08-0046 has been superseded by NUREG-2180. Therefore, the NRC staff requested in PRA-RAI-06 that the licensee provide the status of the methodology used for very early warning fire detection systems and assess its impact on the application. In response to PRA-RAI-06, the licensee provided implementation item ii (discussed in Section 3.5.5 of this SE) to incorporate an NRC-approved method for incipient fire detection prior to the licensee's implementation of 10 CFR 50.69. The NRC staff finds this implementation item to be acceptable because the licensee will incorporate NRC-approved methodology in NUREG-2180 for incipient fire detection prior to implementation of 10 CFR 50.69.

Paragraph 50.69(c)(1)(i) of 10 CFR requires, in part, that any plant-specific PRA used in the categorization must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard that is endorsed by the NRC. RG 1.200 provides guidance for determining the technical adequacy of a fire PRA by comparing the PRA to the relevant parts of the ASME/ANS 2009 standard using a peer review process. Based on its review, the NRC staff finds that the licensee has followed the guidance in RG 1.200 and submitted the results of the peer review, and therefore, meets the requirement in 10 CFR 50.69(b)(2)(iii). The NRC staff has reviewed the peer review results and finds that the quality and level of detail of the fire PRA is sufficient to support the categorization of SSCs as required by 10 CFR 50.69 (b)(2)(ii) and use the process endorsed by the NRC staff in RG 1.201. The NRC staff identified certain specific errors and weaknesses with the fire PRA that will be resolved by Duke Energy with the completion of implementation items i, ii, and iii, as referenced in the proposed license condition (see Section 4.0 of the SE). Therefore, the NRC staff concludes that the quality of the fire PRA with the completion of implementation items i, ii, and iii, meets the requirement in 10 CFR 50.69(c)(1)(i).

3.5.2 Importance Measures and Sensitivity Studies

Paragraph 50.69(c)(1)(i) of 10 CFR requires the results and insights from the PRA be used during categorization. These requirements are met, in part, by using importance measures and sensitivity studies as described in the methodology in NEI 00-04, Section 5.

The Fussell-Vesely importance measure is the fractional contribution to the total of a selected figure of merit for all accident sequences containing that failure of the SSC. The Risk Achievement Worth importance measures reflect the increase in a selected figure of merit when an SSC is assumed to be unable to perform its function due to testing, maintenance, or failure. These importance measures are obtained for each component and each PRA-modeled hazard (i.e., separately for the internal events PRA and for the fire PRA), and the values are compared to specified criteria. Components that have internal event importance measure values exceeding the criteria are assigned HSS. Components that have fire event importance measures exceeding the criteria are assigned preliminary HSS. Integrated importance measures over all PRA-modeled hazards are calculated per Section 5.6 of NEI 00-04, and components for which these measures exceed the criteria are assigned preliminary HSS.

The guidance in NEI 00-04 specifies sensitivity studies to be conducted for each PRA model. The sensitivity studies are performed to ensure that assumptions associated with these specific uncertain parameters (i.e., human error, common cause failure, and maintenance probabilities) are not masking the importance of a component. The NEI 00-04 guidance further states that any additional applicable sensitivity studies from characterization of PRA adequacy should be considered. LAR Section 3.2.7 summarized how the licensee searched for additional issues in the internal events (including internal flooding) PRA that should be evaluated with a sensitivity study. The licensee stated that it used the NRC guidance in NUREG-1855, Revision 0, "Guidelines on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decision-Making" (Reference 19), supplemented with EPRI Technical Report (TR)-1016737, "Treatment of Parameter and Modeling Uncertainty for Probabilistic Risk Assessments" (Reference 20), to identify sources of uncertainty in the internal events PRA.

The NRC staff noted in RAI 5.a that NUREG-1855, Revision 0, which was referenced in the LAR, has been superseded by NUREG-1855, Revision 1 (Reference 21), which references additional EPRI guidance (TR-1016737). The original EPRI guidance (TR-1016737) provided a generic list of assumptions for internal events PRA, while the additional EPRI Guidance (TR-1026511) (Reference 22) added generic assumptions for external events (e.g., fire PRAs). NUREG-1855 suggests that any assumption/uncertainties identified during the peer reviews should also be addressed. In PRA-RAIs 05.a and 5.01, the NRC staff requested the licensee describe its process to determine the candidates for key sources of uncertainty, and how this process is either consistent with NUREG-1855, Revision 1, or is technically acceptable and adequate to identify and disposition the key sources of uncertainty to support the categorization process.

In its response to RAIs 5.b and 5.01, the licensee states that, consistent with NUREG-1855, Revision 1, Stage E, it uses Table A.1 of EPRI 1016737, as well as the PRA documentation for plant-specific assumptions and uncertainties, to identify the assumptions and uncertainties used in the internal events and internal flood base PRA models supporting the categorization. For assumptions and uncertainties used in the fire base PRA model supporting the categorization, the licensee reviewed the generic issues identified in EPRI 1026511, as well as the PRA documentation for plant-specific assumptions and uncertainties. The response to RAIs 5.b and 5.01 summarized the considerations used to determine whether each assumption and uncertainty was key to this application or not. The licensee stated that the considerations were based on the definitions in RG 1.200, Revision 2; NUREG-1855, Revision 1; and related references (i.e., EPRI 1016737, EPRI 1013491, and EPRI 1026511). The NRC staff finds that the identified considerations are consistent with the referenced documents, and therefore, provide a reasonable basis for the evaluation.

In LAR Attachment 6, the licensee provided a list of assumptions and sources of modelling uncertainty that may be key for this application. The NRC staff found that the dispositions for 2 of the 13 assumptions and modeling uncertainties reported in the LAR did not appear to be complete and could impact the categorization process. Therefore, the NRC staff requested in PRA-RAI-07 that the licensee address the dispositions of the assumptions for cable types and joint human error probabilities (JHEP).

In response to PRA-RAI-07.a regarding the impact of updated cable fire damage temperatures, the licensee provided analysis that determined there was only a small increase in the zone of influence and it did not impact any fire scenarios. Based on this determination, the licensee stated the assumptions of the cable types and their associated fire damage temperature are unlikely to result in a change to the target sets. The NRC staff found that this determination of the small increase in the zone of influence is unlikely to impact the 50.69 categorization process. Therefore, the NRC staff found the licensee's response to be acceptable for this application.

In response to PRA-RAI-07.b regarding justification of JHEP, the licensee stated that there are five JHEP combinations below the suggested floor value of 1E-5 for the fire PRA model, which range from 2.3E-6 and 9.5E-6. For each of these JHEPs, there is a specific description of the combination and a justification for the assigned JHEP consistent with accepted guidance for JHEP below the suggested floor values. For the internal events and internal flooding PRA models, the licensee responded there are no JHEPs below the suggested floor value of 1E-6 floor. The NRC staff determined this response to be acceptable for this application because it is consistent with the guidance in NUREG-1921, "EPRI/NRC-RES Fire Human Reliability Analysis Guidelines - Final Report" (Reference 23), and in NUREG-1792, "Good Practices for Implementing Human Reliability Analysis (HRA)" (Reference 24).

Table-1 of the licensee's April 23, 2019 letter provides a final list and disposition for 15 key sources of uncertainty identified by the licensee. The specific assumption and resolutions differ from the list provided in LAR Attachment 6, and a related table provided in the response to PRA-RAI 05. The different response corresponds to the changing approach the licensee used to identify potential key assumptions and sources of uncertainties. Different results based on different approaches are expected, and Table 1 of the licensee's April 23, 2019, letter provides the final results. For each of the identified key sources of uncertainty related to internal events and internal fires, the licensee has shown that the uncertainty or assumptions will not affect the 50.69 categorization results. For key sources of uncertainties that are associated with HRA development, the licensee will perform sensitivity studies to evaluate human error events at the 5th and 95th percentile for all SSC categorizations, and will present the results and insights of the sensitivity studies to the IDP. These sensitivity studies will show the impact on SSC importance regarding human error probabilities. The NRC staff finds the proposed sensitivity studies to be in accordance with NEI 00-04, Section 5, Tables 5-2 and 5-3.

Given the licensee's assessment and its response, the NRC staff finds that the licensee searched for, identified, and evaluated sources of uncertainty in its PRA models consistent with the guidance in RG 1.200, Revision 2; NUREG-1855, Revision 1; and EPRI document

TR-1016737. Therefore, the NEI 00-04 guidance to identify additional "applicable sensitivity studies" is satisfied.

3.5.3 Non-PRA Methods

According to 10 CFR 50.69(c)(ii), one is to determine SSC functional importance using an integrated, systematic process for addressing initiating internal and external events, SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design-bases functions and functions credited for mitigation and prevention of severe accidents.

As described in the LAR, the licensee's categorization process uses the following non-PRA methods:

- SMA to assess seismic risk
- Screening during the IPEEE to assess risk from other external hazards
- Shutdown Safety Plan as described in NUMARC 91-06 (Reference 6) to assess shutdown risk

The NRC staff's review of these methods is discussed below.

Seismic Risk

To assess seismic risk for the 50.69 categorization process, the licensee will use the SMA method. SMA is a screening method that does not quantify core damage frequency. The licensee used the SMA method during its IPEEE in response to Generic Letter 88-20 (Reference 25 and Reference 26). The licensee stated in Section 3.2.3 of the LAR (Reference 1) that it will follow the NEI 00-04 (Reference 5) approach using the SSEL to identify credited equipment as HSS, regardless of its capacity, frequency of challenge, or level of functional diversity. The licensee stated in the LAR that it had conducted an updated evaluation of the SMA SSEL to reflect the current as-built and as-operated plant. The licensee further stated that future changes to the plant will be evaluated as needed to determine their impact on the SMA and risk categorization process.

Consistent with NEI 00-04, the licensee's 50.69 categorization process considers all components in the SSEL as HSS based on seismic risk. All components not listed in the SSEL are considered preliminary LSS with respect to seismic risk.

The approach proposed by the licensee to assess seismic risk is consistent with the NRC-endorsed approaches in NEI 00-04, and therefore, the NRC staff finds it acceptable for use in the licensee's 50.69 categorization process.

Other External Hazards

As indicated in the LAR, external hazards were initially evaluated by the licensee during the IPEEE. This hazard category includes all non-seismic external hazards such as high winds, external floods, transportation and nearby facility accidents, and other hazards. The IPEEE external hazard analysis used a progressive screening approach and concluded that all these other hazards are negligible contributors to overall plant risk. Further, the licensee indicated that it had reevaluated these other external hazards using the criteria in the ASME/ANS 2009 standard (Reference 9).

Section 3.2.4 of the LAR states that an evaluation is performed to determine if there are SSCs being categorized that participate in screened scenarios and whose failure would result in an unscreened scenario. Consistent with the flow chart in Figure 5-6 in Section 5.4 of NEI 00-04, these components would be considered HSS. Section 3.2.4 concludes that all remaining hazards were screened from applicability and considered insignificant for every SSC, and therefore, will not be considered during the categorization process.

The conclusion of 3.2.4 implies that the external hazard assessment has been completed (based on the IPEEE) and that all external hazards will never need evaluation during categorization. PRA-RAI-09 requested that the licensee clarify when and how it is going to determine when failure of SSCs would result in an unscreened scenario. In response to PRA-RAI-09, the licensee clarified that per NEI 00-04, the external hazard assessment is required for each SSC categorization. Therefore, each SSC being categorized will be assessed in accordance with NEI 00-04, Figure 5-6, for the external hazards. If the failure of the SSC results in the screening criterion from LAR Attachment 5 not being met, then the scenario would become unscreened, and the SSC would become a candidate for HSS. The NRC staff finds this clarification acceptable for the application because it is consistent with the guidance of Section 5.4 of NEI 00-04.

Because the licensee confirmed that the other external hazard risk evaluation is consistent with the NRC-endorsed NEI 00-04, the staff finds the licensee's treatment of other external hazards acceptable, and 10 CFR 50.69(c)(1)(ii) is met.

<u>Shutdown Risk</u>

Consistent with the NEI 00-04 guidance endorsed by the NRC, the licensee proposes to use the shutdown safety assessment process based on NUMARC 91-06. NUMARC 91-06 provides considerations for maintaining defense in depth for the five key safety functions during shutdown. These functions are namely decay heat removal capability, inventory control, power availability, reactivity control, and containment - primary/secondary. NUMARC 91-06 specifies that a defense-in-depth approach should be used with respect to each defined shutdown key safety function. This is accomplished by designating a running and an alternative system/train to accomplish the given key safety function.

The licensee's process is consistent with the guidance in NEI 00 04, Section 5.5. The licensee indicated that components are categorized with respect to shutdown risk using a non-PRA shutdown assessment as follows:

- If a system/train supports a key safety function as the primary or first alternate means, then it is considered to be a "primary shutdown safety system" and is categorized as preliminary HSS. NEI 00-04 defines a "primary shutdown safety system" as also having the following attributes:
- It has a technical basis for its ability to perform the function.
- It has margin to fulfill the safety function.
- It does not require extensive manual manipulation to fulfill its safety function.

- If the SSC's failure would initiate an event during shutdown plant conditions (e.g., loss of shutdown cooling, drain down), then that SSC is categorized as preliminary HSS.

As explained above, the shutdown safety assessment method proposed by the licensee is consistent with the guidance in NEI 00-04. In addition, the method meets 10 CFR 50.69(c)(1)(ii) by using an integrated and systematic process that could identify HSS components, if they existed, consistent with the shutdown evaluation process, as described in the NRC-endorsed NEI 00-04. Therefore, the NRC staff finds the licensee's proposed method acceptable.

3.5.4 Component Safety Significance Assessment for Passive Components

Passive components are not modeled in the PRA, and therefore, a different assessment method is necessary to assess the safety significance of these components. Passive components are those components having only a pressure retaining function. This process also includes the passive function of active components such as the pressure/liquid retention of the body of a motor-operated valve.

In the LAR, the licensee proposed using a categorization method for passive components not cited in NEI 00-04 for passive component categorization but approved by the NRC for Arkansas Nuclear One, Unit 2 (ANO-2) (Reference 27). The ANO-2 methodology is a risk-informed safety classification and treatment program for repair/replacement activities for Class 2 and 3 pressure retaining items and their associated supports (exclusive of Class CC and metal containment items), using a modification of the ASME Code Case N-660, "Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities, Section XI, Division 1" (Reference 28). The ANO 2 methodology relies on the conditional core damage and large early release probabilities associated with pipe ruptures. Safety significance is generally measured by the frequency and the consequence of, in this case, pipe ruptures. Treatment requirements (including repair/replacement) only affect the frequency of passive component failure. Categorizing solely based on consequences, which measures the safety significance of the pipe if it ruptures, is conservative compared to including the rupture frequency in the categorization. The categorization will not be affected by changes in frequency arising from changes to the treatment.

In Section 3.1.2 of the LAR, the licensee states that it will apply the ANO-2 methodology to ASME Class 1 SSCs since the consequence evaluation and deterministic considerations are independent of the ASME classification when determining the SSC's safety significance. The NRC staff noted that the ANO-2 passive categorization methodology excluded all Class 1 pressure boundary components and understands that the industry is planning to limit the scope of this process to Class 2 and 3 SSCs. Therefore, the NRC staff requested in PRA-RAI-04 that the licensee justify using the ANO-2 methodology for Class 1 SSCs or confirm the intent to apply the ANO-2 passive categorization methodology to only Class 2 and 3 SSCs. In response to PRA-RAI-04, the licensee confirmed that all ASME Code Class 1 SSCs with a pressure retaining function, as well as supports, will be assigned HSS. Therefore, the NRC staff finds that the use of the repair/replacement methodology is acceptable because it will only be used for passive component categorization of Class 2 and 3 SSCs.

3.5.5 Summary

The NRC staff reviewed the PRA and the non-PRA approaches used by the licensee in its 50.69 categorization process to assess the safety significance of active and passive components and finds these approaches acceptable and consistent with RG 1.201 and the NRC-endorsed guidance in NEI 00-04. The NRC staff approves the use of the following approaches in the licensee's 50.69 categorization process:

- PRA to assess internal events, including internal flooding risk
- Fire PRA to assess fire risk
- SMA to assess seismic risk
- Screening using IPEEE to assess risk from other external hazards (high winds, external floods)
- Shutdown safety assessment process to assess shutdown risk
- ANO-2 (Reference 27) passive categorization method to assess passive component risk for Class 2 and 3 SSCs and their associated supports

Based on its review of the LAR and the licensee's responses to the staff's RAIs, the NRC staff identified certain specific actions necessary to support its conclusion that the proposed program meets the requirements in 10 CFR 50.69 and the guidance in RG 1.201 and NEI 00-04. The licensee proposed the addition of a license condition for the implementation of 10 CFR 50.69. The NRC staff's evaluation of the proposed license condition is in Section 4.0 of this SE. The license condition identifies four implementation items (contained in Reference 3) that shall be completed prior to the implementation of the 50.69 categorization process and are included in Section 4.0 of this SE.

3.6 Defense-in-Depth (NEI 00-04, Section 6)

Paragraph 50.69(c)(1)(iii) of 10 CFR requires that the process used for categorizing SSCs must maintain defense in depth. NEI 00-04, Section 6, provides guidance on assessment of defense in depth. In Section 3.1.1 of the LAR, the licensee stated that it will require an SSC categorized as HSS based on the defense-in-depth assessment in NEI 00-04, Section 6, to be categorized as HSS.

Figure 6-1 in NEI 00-04 provides guidance to assess design-basis defense in depth based on the likelihood of the design-basis internal initiating event and the number of redundant and diverse trains nominally available to mitigate the initiating event. The likelihood of the initiating events is binned and, for different likelihood bins, HSS is assigned if fewer than the indicated number of mitigating trains are nominally available. Section 6 of NEI 00-04 also provides guidance to assess containment defense in depth based on preserving containment isolation and long-term containment integrity and on preventing containment bypass and early hydrogen burns. Defense in depth for beyond design-basis initiating events is addressed by the PRA categorization process.

RG 1.201 endorses the guidance in NEI 00-04, Section 6, but notes that the containment isolation criteria in this section of NEI 00-04 are separate and distinct from those set forth in 10 CFR 50.69(b)(1)(x). The criteria in 10 CFR 50.69(b)(1)(x) are to be used in determining which containment penetrations and valves may be exempted from the Types B and C leakage testing requirements in both Options A and B of Appendix J to 10 CFR Part 50, but the

10 CFR 50.69(b)(1)(x) criteria are not used to determine the proper RISC category for containment isolation valves or penetrations.

Based on its review, the NRC staff finds the licensee's categorization process is consistent with the NRC-endorsed NEI 00-04 guidance and fulfills the 10 CFR 50.69(c)(1)(iii) criteria that defense in depth is maintained.

3.7 Preliminary Engineering Categorization of Functions (NEI 00-04, Section 7)

All the information collected and evaluated in the different engineering evaluations is collected, organized, and provided to the IDP, as described in NEI 00-04, Section 7. The IDP will make the final decision about the safety significance of SSCs based on guidelines in NEI 00-04, the information it receives, and its expertise.

In LAR Section 3.1.1, the licensee stated that if any component is identified as HSS from either the integrated risk component safety significance assessment (Section 5 of NEI 00-04), the defense-in-depth assessment (Section 6 of NEI 00-04), or the Qualitative Criteria (Section 9 of NEI 00-04), the associated system function(s) would be identified as HSS. Once a system function is identified as HSS, then all the components that support that function are categorized as preliminary HSS.

The NRC staff finds that the default assignment of HSS to functions associated with components that have been assigned HSS by non-PRA deterministic methods is consistent with NEI 00-04, and therefore, acceptable.

3.8 Risk Sensitivity Study (NEI 00-04, Section 8)

Paragraph 50.69(c)(1)(iv) of 10 CFR requires, in part, that any potential increases in CDF and LERF resulting from changes to treatment are small. The categorization process described in the NRC-endorsed NEI 00-04 guidance includes an overall risk sensitivity study for all the LSS components to confirm that if the unreliability of the components were increased, the increase in risk would be small (i.e., meet the acceptance guidelines of RG 1.174). LAR Sections 3.1.1 and 3.2.7 clarify that in the sensitivity study, the unreliability of all LSS SSCs modeled in the PRA(s) will be increased by a factor of 3. Separate sensitivity studies are to be performed for each system categorized, as well as a cumulative sensitivity study for all the SSCs categorized through the 10 CFR 50.69 process.

This sensitivity study, together with the periodic review process discussed in Section 3.11 of this SE, assure that the potential cumulative risk increase from the categorization is small. The performance monitoring process monitors the component performance to ensure that potential increases in failure rates of categorized components are detected and addressed before reaching the rate assumed in the sensitivity study. The NRC staff finds that the licensee will perform the risk sensitivity study consistent with the guidance in NEI 00-04, Section 8.0, and therefore, will assure that the potential cumulative risk increase from the categorization is small, as required by 10 CFR 50.69(c)(1)(iv).

3.9 Integrated Decision-making Panel Review and Approval (NEI 00-04, Sections 9 and 10)

Paragraph 50.69(c)(2) of 10 CFR requires that the SSCs be categorized by an IDP staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering. LAR Section 3.1.1

clarifies that the IDP will be composed of a group of at least five experts who collectively have expertise in plant operation, design (mechanical and electrical) engineering, system engineering, safety analysis, and PRA. Therefore, the required expertise will be found in the IDP.

The guidance in NEI 00-04, endorsed in RG 1.201, ensures that the IDP expertise is sufficient to perform the categorization and that the results of the different evaluations (PRA and non-PRA) are used in an integrated, systematic process, as required by 10 CFR 50.69(c)(1)(ii). As provided by the NEI 00-04 guidance, and as indicated in LAR Attachment 1, the process used by the IDP for the categorization of SSCs will be described and documented in a plant procedure.

LAR Section 3.1.1 states that at least three members of the IDP will have a minimum of 5 years of experience at the plant, and there will be at least one member of the IDP who has a minimum of 3 years of experience in modeling and updating of the plant-specific PRA. In addition, LAR Section 3.1.1 states that the IDP will be trained in the specific technical aspects and requirements related to the categorization process. Training will address, at a minimum, the purpose of the categorization; present treatment requirements for SSCs, including requirements for design-basis events; PRA fundamentals; details of the plant-specific PRA, including the modeling, scope, and assumptions; the interpretation of risk importance measures and the role of sensitivity studies and the change-in-risk evaluations; and the defense-in-depth philosophy and requirements to maintain this philosophy.

Based on its review, the NRC staff finds that the licensee's IDP areas of expertise meet the requirements in 10 CFR 50.69(c)(2), and the additional descriptions of the IDP characteristics, training, processes, and decision guidelines are consistent with NEI 00-04, as endorsed by RG 1.201. Therefore, all aspects of the integrated, systematic process used to characterize SSCs will reasonably reflect current plant configuration and operating practices, and applicable plant and industry operational experience as required by 10 CFR 50.69(c)(1)(ii).

Paragraph 50.69(c)(1)(iv) of 10 CFR requires, in part, reasonable confidence that sufficient safety margins are maintained for SSCs categorized as RISC-3. The licensee addresses safety margins through an integrated engineering evaluation that would nominally be addressed by the IDP. Consistent with the discussion in the NEI 00-04 guidance endorsed by RG 1.201, the IDP need not explicitly consider safety margins. Sufficient safety margin will be maintained because the RISC-3 SSCs will remain capable of performing their safety-related functions as required by 10 CFR 50.69(d)(2), and because any potential increases in CDF and LERF that might stem from changes in RISC–3 SSC reliability due to reduced treatment permitted by 10 CFR 50.69 will be maintained small, as required by 10 CFR 50.69(c)(1)(iv). Therefore, the NRC staff finds that the program implemented by the licensee, consistent with the endorsed guidance in NEI 00-04, fulfills the 10 CFR 50.69(c)(1)(iv) criteria that sufficient safety margins are maintained.

3.10 Program Documentation, Change Control, and Periodic Review (NEI 00-04, Sections 11 and 12)

Paragraph 50.69(c)(1)(ii) of 10 CFR requires, in part, that all aspects of the integrated, systematic process used to characterize SSC importance must reasonably reflect the current plant configuration and operating practices and applicable plant and industry operating experience. NEI 00-04, Section 11, provides guidance on program documentation and change control, and Section 12 provides guidance on periodic review. These sections are described in

NEI 00-04 with respect to satisfying 10 CFR 50.69(e) and 10 CFR 50.69(f), respectively. Maintaining change control and periodic review will also maintain confidence that all aspects of the program reflect current plant operation.

Paragraph 50.69(e) of 10 CFR requires periodic updates to the licensee's PRA and SSC categorization. The NRC staff finds that changes over time to the PRA and SSC reliabilities are inevitable, and such changes are recognized by the 10 CFR 50.69(e) provision requiring periodic updates. As provided in RG 1.200, the NRC staff's review of the PRA quality and level of detail reported in this SE is based primarily on determining how the licensee has resolved key assumptions and areas identified by peer reviewers as being of concern (i.e., F&Os). As discussed above in this SE, the NRC staff has concluded that its identified weaknesses and errors in the PRA will be addressed through the implementation items that shall be completed prior to implementation of the 50.69 categorization.

As described in LAR Section 3.2.6, the licensee has administrative controls in place to ensure that the PRA models used to support the categorization reflect the as-built, as-operated plant over time. The licensee's process includes regularly scheduled and interim (as needed) PRA model updates. The process includes provisions for monitoring issues affecting the PRA models (e.g., due to changes in the plant, errors or limitations identified in the model, industry operational experience) for assessing the risk impact of unincorporated changes and for controlling the model and associated computer files. The process also includes reevaluating previously categorized systems to ensure the continued validity of the categorization. Routine PRA updates are performed every two refueling cycles at a minimum.

In PRA-RAI-08, the NRC staff requested further explanation about how the licensee will administer its periodic review of the impact of the PRA model changes on the results of risk-informed categorization. In response, the licensee explained that the review would be conducted at least once every other fuel cycle and be conducted by a senior engineer and a PRA engineer. The NRC staff finds that this description is consistent with the requirements for feedback and process adjustment required by 10 CFR 50.69(e), and is, therefore, acceptable.

Paragraph 50.69(f) of 10 CFR requires program documentation, change control, and records. In LAR Section 3.2.6, the licensee stated that it will implement a process that addresses the guidance in Section 11 of NEI 00-04 pertaining to program documentation and change control records. Section 3.1.1 of the LAR states that the RISC categorization process documentation will include the following ten elements:

- Program procedures used in the categorization
- System functions, identified and categorized with the associated bases
- Mapping of components to support function(s)
- PRA model results, including sensitivity studies
- Hazards analyses, as applicable
- Passive categorization results and bases
- Categorization results, including all associated bases and RISC classifications
- Component critical attributes for HSS SSCs
- Results of periodic reviews and SSC performance evaluations
- IDP meeting minutes and qualification/training records for the IDP members

In addition, LAR Attachment 1 (List of Categorization Prerequisites) states that the licensee will establish procedures for the use of the categorization process that contain the following elements: (1) IDP member qualification requirements, (2) qualitative assessment of system functions, (3) component safety significance assessment, (4) assessment of defense in depth and safety margin, (5) review by the IDP and final determination of safety significance for system functions and components, (6) risk sensitivity studies to confirm that the risk acceptance guidelines of RG 1.174 are met, (7) periodic review to ensure continued categorization validity and acceptable performance for SSCs that have been categorized, and (8) documentation requirements identified in LAR Section 3.1.1. Procedures are formal plant documents, and changes will be tracked providing change control and records of the changes. These categorization documents and records, as described by the licensee, include documentation and record change controls consistent with NEI 00-04 and endorsed by RG 1.201, and are in conformance with the requirements of 10 CFR 50.69(f)(1). Therefore, the NRC staff finds the documentation and records acceptable.

Based on its evaluation, the NRC staff finds that the change control and performance monitoring of categorized SSCs and PRA updates will sufficiently capture and evaluate component failures to identify significant changes in the failure probabilities. In addition, the PRA update program and associated reevaluation of component importance will appropriately consider the effects of changing failure probabilities and changing plant configuration on the component safety significant categories. As discussed above, the staff finds the process in NEI 00-04 and the LAR will meet the requirements of 10 CFR 50.69(e) and 10 CFR 50.69(f), respectively. Therefore, the process used to characterize SSC importance will reasonably reflect the current plant configuration and operating practices and applicable plant and industry operational experience required in 10 CFR 50.69(c)(1)(ii).

3.11 Technical Conclusion

The NRC staff reviewed the licensee's 50.69 categorization process and concludes that the licensee adequately implements 10 CFR 50.69 using models, methods, and approaches consistent with NEI 00-04, Revision 0, and RG 1.201, and therefore, satisfies the requirements of 10 CFR 50.69(c). Based on its review, the NRC staff finds the licensee's proposed categorization process acceptable for categorizing the safety significance of SSCs. Specifically, the staff concludes that the licensee's categorization process:

(1) considers results and insights from plant-specific internal events (including internal flooding) and fire PRAs that are of sufficient quality and level of detail to support the categorization process and that have been subjected to a peer review process against RG 1.200, Revision 2, as reviewed in Section 3.5.1 of this SE, and therefore, meets the requirements in 10 CFR 50.69(c)(1)(i);

(2) determines SSC functional importance using an integrated systematic process that reasonably reflects the current plant configuration, operating practices, and applicable plant and industry operational experience, as reviewed in Sections 3.3, 3.4, 3.5, 3.7, and 3.10 of this SE, and therefore, meets the requirements in 10 CFR 50.69(c)(1)(ii);

(3) maintains defense in depth, as reviewed in Section 3.6 of this SE, and therefore, meets the requirements in 10 CFR 50.69(c)(1)(iii);

(4) includes evaluations that provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in CDF and LERF resulting from changes in treatment are small, as reviewed in Sections 3.8 and 3.9 of this SE, and therefore, meets the requirements in 10 CFR 50.69(c)(1)(iv);

(5) is performed for entire systems and structures rather than for selected components within a system or structure, as reviewed in Section 3.3 of this SE, and therefore, the requirements in 10 CFR 50.69(c)(1)(v) will be met upon implementation; and

(6) includes categorization by IDP, staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering, as reviewed in Section 3.9 of this SE, and therefore, meets the requirements in 10 CFR 50.69(c)(2).

4.0 10 CFR 50.69 IMPLEMENTATION LICENSE CONDITION

Based on its review of the LAR and the licensee's responses to the NRC staff's RAIs, the NRC staff identified certain specific actions, as described below, that are necessary to support the staff's conclusion that the proposed program meets the requirements in 10 CFR 50.69 and the guidance in RG 1.201 and NEI 00-04.

The NRC staff's finding on the acceptability of the PRA evaluation in the licensee's proposed 10 CFR 50.69 process is conditioned on the completion of four changes to the PRA model. The four PRA model changes are identified as "Harris 50.69 PRA Implementation Items" in Attachment 1 of the licensee's letter dated April 23, 2019. The licensee and the NRC staff note the implementation items are required to be completed prior to the implementation of 10 CFR 50.69 at Harris.

The licensee proposed the following condition to its license:

> Duke Energy is approved to implement 10 CFR 50.69 using the processes for categorization of Risk Informed Safety Class (RISC)-1, RISC-2, RISC-3, and RISC-4 structures, systems, and components (SSCs) using: Probabilistic Risk Assessment (PRA) models to evaluate risk associated with internal events, including internal flooding, and internal fire; the shutdown safety assessment process to assess shutdown risk; the Arkansas Nuclear One, Unit 2 (ANO-2) passive categorization method to assess passive component risk for Class 2 and Class 3 SSCs and their associated supports; and the results of non PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards, i.e., seismic margin analysis (SMA) to evaluate seismic risk, and a screening of other external hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009; as specified in the Unit 1 License Amendment No. 174 dated September 17, 2019.
>
> Duke Energy will complete the implementation items listed in Attachment 1 of Duke Energy letter to NRC dated April 23, 2019 prior to implementation of 10 CFR 50.69. All issues identified in the attachment will be addressed and any associated changes will be made, focused-scope peer reviews will be performed on changes that are PRA upgrades as defined in the PRA standard (ASME/ANS RA-Sa-2009, as endorsed by RG 1.200, Revision 2), and any findings will be resolved and reflected in the PRA of record prior to implementation of the 10 CFR 50.69 categorization process.

Prior NRC approval, under 10 CFR 50.90, is required for a change to the categorization process specified above (e.g., change from a seismic margins approach to a seismic probabilistic risk assessment approach).

Duke Energy proposed the following implementation items in Attachment 1 of its supplement dated April 23, 2019:

i. Perform a detailed analysis in accordance with current methods for the four significant HFEs identified and incorporate the analysis into the Harris fire PRA model, as indicated in the Duke Energy letter dated October 18, 2018.

ii. Update the fire PRA model to credit incipient detection per NUREG-2180 or other NRC acceptable methodology, as described in the Duke Energy letter dated October 18, 2018.

iii. Update the fire PRA model to account for scenarios to address fire induced failure of structural steel in the Turbine Building, as indicated in response to RAI 02.f contained in the Duke Energy letter dated October 18, 2018.

iv. Update the PRA models to account for isolation of the reactor coolant system accumulators and steam generator safety relief valves, as indicated in response to RAI 5.01 of Duke Energy letter dated April 23, 2019.

Based on its evaluation in this SE, the NRC staff finds that the proposed license condition and its referenced implementation items are acceptable because they adequately implement 10 CFR 50.69 using models, methods, and approaches consistent with the applicable guidance that has previously been endorsed as acceptable by the NRC. For each implementation item, the licensee and the NRC staff have reached a satisfactory resolution involving the level of detail and main attributes that each remaining item will incorporate into the program upon its completion. Completion of these items does not change or impact the bases for the safety conclusions made by the NRC staff in this SE. The NRC staff, through an onsite audit or during future inspections, may choose to examine the closure of the implementation items with the expectation that any variations discovered during this review, or concerns regarding adequate completion of the implementation item, would be tracked and dispositioned appropriately under the licensee's corrective action program, and could be subject to appropriate NRC enforcement action, as completion of the implementation items would be required by the proposed license conditions.

5.0 STATE CONSULTATION

In accordance with the Commission's regulations, the State of North Carolina official was notified of the proposed issuance of the amendment on July 1, 2019. The State official had no comments.

6.0 ENVIRONMENTAL CONSIDERATION

The amendment changes a requirement with respect to installation or use of a facility component located within the restricted area as defined in 10 CFR Part 20. The NRC staff has determined that the amendment involves no significant increase in the amounts, and no significant change in the types, of any effluents that may be released offsite, and that there is no significant increase in individual or cumulative occupational radiation exposure. The

Commission has previously issued a proposed finding that the amendment involves no significant hazards consideration, and there has been no public comment on such finding (83 FR 23731). Accordingly, the amendment meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendment.

7.0 CONCLUSION

The Commission has concluded, based on the considerations discussed above, that: (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

8.0 REFERENCES

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Date: September 17, 2019

SUBJECT: SHEARON HARRIS NUCLEAR POWER PLANT, UNIT 1 - ISSUANCE OF AMENDMENT NO. 174 RE: ADOPT TITLE 10 OF THE CODE OF FEDERAL REGULATIONS 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS (SSCs) FOR NUCLEAR POWER REACTORS" (EPID L-2018-LLA-0034) DATED SEPTEMBER 17, 2019

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