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

August 23, 2022

Mr. David P. Rhoades
Senior Vice President
Constellation Energy Generation, LLC
President and Chief Nuclear Officer
Constellation Nuclear
4300 Winfield Road
Warrenville, IL 60555

SUBJECT: JAMES A. FITZPATRICK NUCLEAR POWER PLANT – ISSUANCE OF AMENDMENT NO. 352 RE: ADOPTION OF 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS AND COMPONENTS FOR NUCLEAR POWER REACTORS" (EPID L-2021-LLA-0142)

Dear Mr. Rhoades:

The U.S. Nuclear Regulatory Commission (the Commission) has issued the enclosed Amendment No. 352 to Renewed Facility Operating License No. DPR-59 for the James A. FitzPatrick Nuclear Power Plant (FitzPatrick) in response to your application dated July 30, 2021, as supplemented by letter dated March 4, 2022.

The amendment added a new license condition to the FitzPatrick Renewed Facility Operating License to allow the implementation of risk-informed categorization and treatment of structures, systems, and components for nuclear power reactors in accordance with Title 10 of the *Code of Federal Regulations* Section 50.69.

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

Sincerely,

/RA/

Justin C. Poole, Project Manager
Plant Licensing Branch I
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. 50-333

Enclosures:
1. Amendment No. 352 to DPR-59
2. Safety Evaluation

cc: Listserv

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

CONSTELLATION FITZPATRICK, LLC

AND

CONSTELLATION ENERGY GENERATION, LLC

DOCKET NO. 50-333

JAMES A. FITZPATRICK NUCLEAR POWER PLANT

AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 352
Renewed Facility Operating License No. DPR-59

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

   A. The application for amendment by Constellation FitzPatrick, LLC and Constellation Energy Generation, LLC (collectively, the licensees) dated July 30, 2021, as supplemented on March 4, 2022, 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 as indicated in the attachment to this license amendment with the addition of paragraph 2.X of Renewed Facility Operating License No. DPR-59 that reads as follows:

> Constellation Energy Generation, LLC 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 and non-Class SSCs and their associated supports; the results of the non-PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009 for other external hazards except seismic; and the alternative seismic approach as described in the Exelon Generation Company, LLC submittal letter dated July 30, 2021, and all its subsequent associated supplements as specified in License Amendment No. 352 dated August 23, 2022.
>
> 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).

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

FOR THE NUCLEAR REGULATORY COMMISSION

Hipolito J. Gonzalez

Digitally signed by Hipolito J. Gonzalez
Date: 2022.08.23 15:04:03 -04'00'

Hipolito J. Gonzalez, Chief
Plant Licensing Branch I-1
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Attachment:
Changes to the Renewed Facility
Operating License

Date of Issuance: August 23, 2022

ATTACHMENT TO LICENSE AMENDMENT NO. 352

JAMES A. FITZPATRICK NUCLEAR POWER PLANT

RENEWED FACILITY OPERATING LICENSE NO. DPR-59

DOCKET NO. 50-333

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

Remove Page	Insert Page
Page 9	Page 9
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W. Constellation Energy Generation, LLC shall, no later than the date the closing of the transaction approved on November 16, 2021, occurs, enter into a Support Agreement of approximately $85 million with Constellation FitzPatrick. Constellation FitzPatrick shall not take any action to cause Constellation Energy Generation, LLC, or its successors and assigns, to void, cancel, or materially modify the Constellation Energy Generation, LLC Support Agreement or cause it to fail to perform, or impair its performance under the constellation Energy Generation, LLC Support Agreement, without the prior written consent of the NRC. The Constellation Energy Generation, LLC Support Agreement may not be amended or modified without 30 days prior written notice to the Director of the Constellation Energy Generation, LLC Support Agreement shall be submitted to the NRC no later than 30 days after the completion of the proposed transaction. Constellation Energy Generation, LLC shall inform the NRC in writing no later than 14 days after any funds are provided to or for Constellation FitzPatrick under the Constellation Energy Generation, LLC Support Agreement.

X. Constellation Energy Generation, LLC 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 and non-Class SSCs and their associated supports; the results of the non-PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009 for other external hazards except seismic; and the alternative seismic approach as described in Exelon Generation Company, LLC's submittal letter dated July 30, 2021, and all its subsequent associated supplements as specified in License Amendment No. 352 dated August 23 , 2022.

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).

3. This renewed operating license is effective as of the date of issuance and shall expire at midnight October 17, 2034.

FOR THE NUCLEAR REGULATORY COMMISSION

\RA\

Eric J. Leeds, Director
Office of Nuclear Reactor Regulation

Attachments/Appendices:
1. Appendix A – Technical Specifications
2. Appendix B – Deleted
3. Appendix C – Additional Conditions

Date of Issuance: September 8, 2008

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

SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

RELATED TO AMENDMENT NO. 352

TO RENEWED FACILITY OPERATING LICENSE NO. DPR-59

CONSTELLATION FITZPATRICK, LLC

CONSTELLATION ENERGY GENERATION, LLC

DOCKET NO. 50-333

JAMES A. FITZPATRICK NUCLEAR POWER PLANT

1.0 INTRODUCTION

By letter dated July 30, 2021 (Reference 1), as supplemented by letter dated March 4, 2022 (Reference 2), Exelon Generation Company, LLC (Exelon)[1] submitted a license amendment request (LAR) for James A. FitzPatrick Nuclear Power Plant (FitzPatrick). The licensee proposed to add a license condition to the renewed facility operating license for FitzPatrick 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 as specified in 10 CFR 50.69(b) (e.g., quality assurance, testing, inspection, condition monitoring, assessment, and evaluation) based on an integrated and systematic risk-informed process that includes several approaches and methods for categorizing SSCs according to their safety significance.[2]

The proposed amendment would adopt the methodology described in the U.S. Nuclear Regulatory Commission (NRC, the Commission)-approved licensing actions related to 10 CFR 50.69. These include the Arkansas Nuclear One, Unit 2 (ANO-2) methodology for passive components described in Alternative ANO2-R&R-004 (Reference 14) and in

[1] By letter dated February 1, 2022 (Reference 3), Constellation Energy Generation, LLC (CEG, the licensee) notified the NRC that CEG had completed a license transfer and reorganization that resulted in Exelon being renamed CEG, and requested that the NRC continue processing pending NRC actions previously requested by Exelon.

[2] Regulatory Guide (RG) 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance," May 2006 (Reference 4), describes the SSC categorization process in its entirety as an overarching approach that includes multiple approaches and methods identified for a PRA hazard and non-PRA methods.

Amendment Nos. 249 and 235 for LaSalle County Station, Unit Nos. 1 and 2 (LaSalle, Units 1 and 2), respectively, dated May 27, 2021 (Reference 21). For the purposes of 10 CFR 50.69 categorization, passive components are those components that have a pressure retaining function.

By letter dated October 22, 2021 (Reference 5), the NRC staff issued a regulatory audit plan. The staff participated in the regulatory audit in January 2022. The staff performed the audit to ascertain the information needed to support its review of the LAR and to develop requests for additional information, as needed. The licensee responded to the audit questions in a supplement to the LAR dated March 4, 2022.

The supplemental letter dated March 4, 2022, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the *Federal Register* on November 30, 2021 (86 FR 67988).

2.0 REGULATORY EVALUATION

2.1 Applicable Regulations

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 (LSS), alternative treatment requirements may be implemented in accordance with the regulation. For SSCs determined to be of high safety significance (HSS), requirements may not be changed.

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.

SSC categorization 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 HSS, existing treatment requirements are maintained or potentially enhanced. Conversely, for SSCs categorized as 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. Implementation of 10 CFR 50.69 allows licensees to improve focus on equipment that has HSS.

2.2 Applicable Regulatory Guidance

The NRC staff considered the following regulatory guidance during its review of the LAR:

1. RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment [PRA] in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis" (Reference 6)

2. RG 1.200, Revision 2, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment for Risk-Informed Activities," and Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities" (References 7 and 8, respectively)

3. RG 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance."

4. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR [Light-Water Reactor]Edition" (the SRP), Section 19.2, "Review of Risk Information Used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidance" (Reference 9)

5. NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking" (Reference 10)

6. NUREG-1921, "EPRI/NRC-RES Fire Human Reliability Analysis Guidelines: Final Report" (Reference 11).

2.3 Applicable NRC-Endorsed Guidance

The Committee on Nuclear Risk Management of the American Society of Mechanical Engineers (ASME) and the American Nuclear Society (ANS) issued a consensus standard for nuclear power plant PRA, ASME/ANS RA-Sa–2009, "Addenda to RA-S–2008, Standard for Level 1 / Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications" (the PRA Standard, Reference 12), which was endorsed by the NRC in RG 1.200.

The Nuclear Energy Institute (NEI) issued NEI 00-04, Revision 0, "10 CFR 50.69 SSC Categorization Guideline" (Reference 13), as endorsed by RG 1.201 with clarifications, which describes a process that the NRC staff considers acceptable for complying with 10 CFR 50.69. This process determines the safety significance of SSCs and categorizes them into one of the four RISC categories defined in 10 CFR 50.69.

Sections 2 through 10 of NEI 00-04 describe the following steps/elements of the SSC categorization process for meeting the requirements of 10 CFR 50.69:

1. Sections 3.2 and 5.1 provide specific guidance corresponding to 10 CFR 50.69(c)(1)(i).

2. Sections 3, 4, 5, and 7 provide specific guidance corresponding to 10 CFR 50.69(c)(1)(ii).

3. Section 6 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(iii).

4. Section 8 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(iv).

5. Section 2 provides specific guidance corresponding to 10 CFR 50.69(c)(1)(v).

6. 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(f). Section 12 of NEI 00-04 provides guidance on the periodic review related to the requirements in 10 CFR 50.69(e).

Maintaining change control and periodic review provides confidence that all aspects of the program reasonably reflect the current as-built, as-operated plant configuration and applicable plant and industry operational experience as required by 10 CFR 50.69 (c)(1)(ii).

The proposed amendment would use methodology from the NRC approved LARs related to 10 CFR 50.69 from the ANO-2. For the purposes of 10 CFR 50.69 categorization, passive components are those components that have a pressure retaining function.

Passive components and the passive function of active components were evaluated using the (ANO-2) Risk-Informed Repair/Replacement Activities (RI-RRA) methodology contained in NRC letter to Use Risk-Informed Safety Classification (RISC) and Treatment for Repair/Replacement Activities in Class 2 and 3 Moderate and High Energy Systems (Reference 14).

3.0 TECHNICAL EVALUATION

3.1 Method of NRC Staff Review

An acceptable approach for making risk-informed decisions about proposed licensing basis changes, including both permanent and temporary changes, is to show that the proposed licensing basis changes meet the five key principles stated in Section C of RG 1.174, Revision 3. These key principles are:

Principle 1: The proposed licensing basis change meets the current regulations unless it is explicitly related to a requested exemption.

Principle 2: The proposed licensing basis change is consistent with the defense-in-depth [DID] philosophy.

Principle 3: The proposed licensing basis change maintains sufficient safety margins.

Principle 4: When the proposed licensing basis changes result in an increase in risk, the increases should be small and consistent with the intent of the Commission’s policy statement on safety goals for the operations of nuclear power plants.

Principle 5: The impact of the proposed licensing basis change should be monitored using performance measurement strategies.

3.2 Traditional Engineering Evaluation

The following traditional engineering evaluation addresses the first three key principles of RG 1.174, Revision 3 that are pertinent to: (1) compliance with current regulations, (2) evaluation of DID, and (3) evaluation of safety margins.

3.2.1 Key Principle 1: Licensing Bases Change Meets the Current Regulations

Section 50.69(c) of 10 CFR requires licensees to use an integrated decision-making process 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 that perform safety-significant functions[3]

RISC–2: Non-safety-related SSCs that perform safety-significant functions

RISC–3: Safety-related SSCs that perform LSS functions

RISC–4: Non-safety-related SSCs that perform LSS functions

The 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 for special treatment (i.e., it does not remove any requirements from these SSCs). In addition, 10 CFR 50.69(d)(1) requires that the licensee or applicant ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance. For LSS SSCs, licensees may implement alternative treatment requirements in accordance with 10 CFR 50.69(b)(1) and 10 CFR 50.69(d)(2). For RISC-3 SSCs, licensees can replace certain special treatment requirements with an alternative treatment approach that must meet 10 CFR 50.69(d)(2). For RISC-4 SSCs, 10 CFR 50.69 does not impose new treatment requirements.

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 certain 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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50
(x) certain requirements for containment leakage testing

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[3] NEI 00-04, Revision 0, uses the term "high-safety-significant" 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.

(xi) certain requirements of Appendix A, "Seismic and Geologic Siting Criteria for Nuclear Power Plants," to 10 CFR Part 100

The NRC staff reviewed the licensee's SSC categorization process against the categorization process described in NEI 00-04, Revision 0, as endorsed in RG 1.201, Revision 1, and the acceptability of the licensee's PRA for use in the application of the 10 CFR 50.69 categorization process. The NRC staff's review, as documented in this safety evaluation (SE), used the framework provided in RG 1.174, and NEI 00-04, Revision 0, as endorsed in RG 1.201, Revision 1 with specific clarifications.

Section 2 of NEI 00-04, Revision 0 states, in part, that the categorization process includes the following eight primary steps:

1. Assembly of Plant-Specific Inputs (Section 3 of NEI 00-04, Revision 0)

2. System Engineering Assessment (Section 4 of NEI 00-04, Revision 0)

3. Component Safety Significance Assessment (Section 5 of NEI 00-04, Revision 0)

4. Defense-In-Depth Assessment (Section 6 of NEI 00-04, Revision 0)

5. Preliminary Engineering Categorization of Functions (Section 7 of NEI 00-04, Revision 0)

6. Risk Sensitivity Study (Section 8 of NEI 00-04, Revision 0)

7. Integrated Decisionmaking Panel (IDP) Review and Approval (Section 9 of NEI 00-04, Revision 0)

8. SSC Categorization (Section 10 of NEI 00-04, Revision 0)

In Section 3.1, "Categorization Process Description (10 CFR 50.69(b)(2)(i))," of the LAR, the licensee stated that it will implement the risk-informed categorization process in accordance with NEI 00-04, Revision 0, as endorsed in RG 1.201, Revision 1. In Sections 3.1 and 3.2.3 of the LAR, the licensee proposed an alternative seismic method, referred to as the alternative approach. The NRC staff notes that the use of this method is a deviation from the guidance in NEI 00-04. A more detailed staff review of the alternative approach is provided in Section 3.3.1.2 of this SE.

The licensee provided further discussion of specific elements within the 10 CFR 50.69 categorization process that are delineated in the NEI 00-04, Revision 0, as endorsed by RG 1.201, Revision 1. The categorization process is performed for entire systems and structures, rather than for selected components within a system or structure, as reviewed in this SE, and therefore, the requirements in 10 CFR 50.69(c)(1)(v) will be met upon implementation.

The regulatory requirements in 10 CFR 50.69 and 10 CFR Part 50, Appendix B, and the monitoring outlined in NEI 00-04, Revision 0 and clarifications in RG 1.201, Revision 1, ensure that the SSC categorization process is sufficient to ensure that the SSC functions continue to be met and that any performance deficiencies will be identified and appropriate corrective actions taken. The licensee's SSC categorization program includes the appropriate steps/elements prescribed in NEI 00-04, Revision 0, to ensure that SSCs specified are appropriately categorized consistent with 10 CFR 50.69. The NRC staff performed a more detailed review of specific steps/elements of the licensee's SSC categorization process where necessary to confirm its consistency with the NEI 00-04 guidance, as endorsed. In light of the above, the staff concludes that the proposed 10 CFR 50.69 program meets the first key principle for risk-informed decisionmaking prescribed in RG 1.174, Revision 3.

3.2.2 Key Principle 2: Licensing Basis Change is Consistent with the Defense-In-Depth Philosophy

In RG 1.174, Revision 3, the NRC identified the following considerations used for evaluating how the licensing basis change is maintained for the DID philosophy:

- Preserve a reasonable balance among the layers of defense.
- Preserve adequate capability of design features without an overreliance on programmatic activities as compensatory measures.
- Preserve system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to the system, including consideration of uncertainty.
- Preserve adequate defense against potential common-cause failures.
- Maintain multiple fission product barriers.
- Preserve sufficient defense against human errors.
- Continue to meet the intent of the plant's design criteria.

RG 1.201, Revision 1, endorses the guidance in Section 6 of NEI 00-04, but notes that the containment isolation criteria in this section of the guidance 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 Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR Part 50. The criteria provided in 10 CFR 50.69(b)(1)(x) are not to determine the proper RISC category for containment isolation valves or penetrations.

In Section 3.1.1 of the LAR, the licensee clarified that it would require an SSC to be categorized as HSS based on the DID assessment performed in accordance with NEI 00-04, Revision 0. Based on the above, the NRC staff concludes that the proposed change is consistent with the DID philosophy described in the second key principle of RG 1.174, Revision 3, and is, therefore, acceptable. The staff finds that the licensee's process is consistent with the NRC-endorsed guidance in NEI 00-04 and would meet the 10 CFR 50.69(c)(1)(iii) criterion that requires DID to be maintained.

3.2.3 Key Principle 3: Licensing Basis Change Maintains Sufficient Safety Margins

The regulations in 10 CFR 50.69(c)(1)(iv) require the evaluations to 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 are small. The NRC staff reviewed the licensee's established procedure(s) to be implemented prior to the use of the categorization process on a plant system. The procedure(s) will ensure that the evaluations conducted by the licensee under 10 CFR 50.69 for SSC categorization will assess the design function(s) and risk significance of the SSC to ensure that sufficient safety margins are maintained. With sufficient safety margins, (1) the codes and standards or their alternatives approved for use by the NRC are met and

(2) safety analysis acceptance criteria in the licensing basis (e.g., Updated Final Safety Analysis Report (UFSAR), supporting analyses) are met or proposed revisions provide sufficient margin to account for uncertainty in the analysis and data. RG 1.174, Revision 3, provides guidelines for making that assessment, including evaluations to ensure that the categorization of the SSC does not adversely affect any assumptions or inputs to the safety analysis; or, if such inputs are affected, justification is provided to ensure that sufficient safety margin will continue to exist.

The NRC staff concludes that the licensee has established a program to ensure that sufficient safety margins are maintained in accordance with the third key principle of RG 1.174, Revision 3 and would therefore meet 10 CFR 50.69(c)(1)(iv). There is no impact to safety analysis acceptance criteria as described in the plant licensing basis. In addition, the SSCs design basis functions as described in the plant's licensing basis, including the UFSAR will continue to be met.

3.3 Risk-Informed Evaluation

3.3.1 Key Principle 4: Change in Risk is Consistent with the Safety Goals

The risk-informed considerations prescribed in NEI 00-04, Revision 0, endorsed by RG 1.201, Revision 1, address the fourth and fifth key principles of the standards for risk-informed decisionmaking, pertaining to the assessment for change in risk and monitoring the impact of the licensing basis change.

A summary of how the licensee's SSC categorization process is consistent with the guidance and methodology prescribed in NEI 00-04, Revision 0, and RG 1.201, Revision 1, is provided in the following sections.

In Section 3.1.1 of the LAR, the licensee stated that the FitzPatrick categorization process uses PRA-modeled hazards to assess risks for both internal fires and internal events (which includes internal flooding). For the other risk contributors, the licensee's process uses the following non-PRA methods to characterize the risk:

- Seismic Hazard: Alternative seismic method documented in Electric Power Research Institute (EPRI) Report 3002017583 dated February 29, 2020 (Reference 15).

- Other External Hazards: Screening analysis performed for the Individual Plant Examination of External Events (IPEEE) (Reference 16) updated using criteria from Part 6 of the PRA Standard, as endorsed by the NRC.

- Shutdown Events: Safe Shutdown Risk Management program consistent with NUMARC 91-06 (Reference 17).

- Passive Components: ANO-2 passive categorization methodology.

The approaches and methods proposed by the licensee to address internal events, including internal flooding, seismic, other external events, DID, and shutdown events are consistent with the approaches and methods included in the guidance in NEI 00-04, Revision 0. The non-PRA method for the categorization for passive components is consistent with the ANO-2 methodology for passive components approved for risk-informed safety classification and treatment for repair/replacement activities in ASME Boiler and Pressure Vessel (BPV) Code

Class 2 and 3 moderate- and high-energy systems. The NRC staff concludes that the internal events PRA with the completion of the proposed implementation items meets the internal events PRA requirement in 10 CFR 50.69(c)(1)(i). The licensee's use of this methodology in the SSC categorization process is provided in Section 3.3.1.2 of this SE. To address seismic hazard in the SSC categorization process, the licensee proposed to use an alternative method not included in NEI 00-04. A detailed staff review of the licensee's proposed alternative seismic approach is evaluated in Section 3.3.1.2 of this SE.

3.3.1.1 Scope of PRA

The FitzPatrick PRA comprises a full-power, internal events PRA (which includes internal flooding[4]) and a fire PRA and evaluates CDF and LERF. Section 3.3 of the LAR states that the models for the internal events PRA and fire PRA have been assessed against RG 1.200.

The NRC staff finds that the information provided in the LAR on the internal events and fire PRAs is sufficient to support the staff's review of their technical acceptability and meets the requirements set forth in 10 CFR 50.69(b)(2)(iii).

3.3.1.1.1 Internal Events PRA Peer-Review History

In Section 3.3, "PRA Review Process Results (10 CFR 50.69(b)(2)(iii)," of the LAR, the licensee stated that the internal events PRA model was subjected to a full-scope peer review in September 2009 using the PRA Standard and RG 1.200. Subsequently, a focused-scope peer review was conducted in November 2019. Independent assessments for closure of the finding-level facts and observations (F&Os) were conducted in November 2019 and July 2020 using the Appendix X process. All open findings were reviewed and closed using the NRC-accepted process documented in the NEI letter to the NRC, "Final Revision of Appendix X to NEI 05-04/07-12/12-16, Close-out of Facts and Observations (F&Os)," dated February 21, 2017 (Reference 18).

In Section 3.2, "Technical Adequacy Evaluation (10 CFR 50.69(b)(2)(ii))," of the LAR, the licensee stated that for the internal events PRA "there are no PRA upgrades that have not been peer reviewed." During the audit, the NRC staff reviewed the closure review documents and concluded that the closed F&Os were appropriately assessed by the independent assessment team to ensure that no new methods or upgrades were inadvertently incorporated into the internal events PRA without a peer review. In the supplement to the LAR, the licensee confirmed that the modeling resolutions to close out the F&Os will be incorporated in the PRA models used for categorization.

Based on the above, the NRC staff concludes that the licensee's internal events PRA was appropriately peer reviewed, consistent with RG 1.200, and that the F&Os have been closed appropriately. Therefore, the staff finds that the licensee's 10 CFR 50.69 program uses an internal events PRA that is of sufficient quality to meet the requirements set forth in 10 CFR 50.69(c)(1)(i).

3.3.1.1.2 Fire PRA Peer-Review History

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[4] The fact that the FitzPatrick internal events PRA includes internal flooding should be recognized but will not be restated in this safety evaluation.

The licensee's fire PRA was subject to a full-scope industry peer review in January 2020, consistent with RG 1.200. In July 2020 and March 2021, finding closure reviews were conducted using the Appendix X process as accepted by the NRC. All open findings were reviewed and closed.

In Section 3.2 of the LAR, for the fire PRA, the licensee stated that, in part, "there are no PRA upgrades that have not been peer reviewed." During the audit, the NRC staff reviewed the closure review documents and concluded that the closed F&Os were appropriately assessed by the independent assessment team to ensure that no new methods or upgrades were inadvertently incorporated into the fire PRA without a peer review. In the LAR supplement, the licensee confirmed that the modeling resolutions to close out the F&Os will be incorporated in the PRA models used for categorization.

The NRC staff reviewed the fire PRA peer review results and the licensee's resolution of the results and concludes that the licensee's fire PRA was appropriately peer reviewed, consistent with RG 1.200, and that the F&Os have been dispositioned appropriately.

3.3.1.1.3 Appendix X Independent Assessment Process for F&O Closure

Section X.1.3 of Appendix X to NEI 05-04, NEI 07-12 and NEI 12-16 provides guidance to perform an independent assessment for the closure of F&Os identified from a full-scope or focused-scope peer review.

During the audit, the NRC staff reviewed the closure report and concluded that all closed F&Os were appropriately assessed by the independent assessment team to ensure that no new methods or upgrades were inadvertently incorporated into the internal events and fire PRA without a peer review. Therefore, the staff finds that the FitzPatrick internal events and fire PRAs were appropriately peer reviewed consistent with RG 1.200 and meet the requirements set forth in 10 CFR 50.69(c)(1)(i).

3.3.1.1.4 Credit for FLEX Equipment

The NRC memorandum dated May 30, 2017, "Assessment of the Nuclear Energy Institute16-06, 'Crediting Mitigating Strategies in Risk-Informed Decision Making,' Guidance for Risk-Informed Changes to Plants Licensing Basis" (Reference 19), provides the NRC staff's assessment of challenges to incorporating FLEX equipment and strategies into a PRA model. This may be desirable to support risk-informed decisionmaking in accordance with the guidance of RG 1.200.

In Attachment 6 to the LAR, the licensee stated that the PRA credits FLEX equipment. (The FLEX diesel generator is modeled with a basic event that assumes that human error probability is the dominant contributor to failure.) A sensitivity study demonstrated that FLEX credit did not significantly impact relevant PRA results. During the audit, the NRC staff reviewed the sensitivity study and concluded that the uncertainties related to FLEX do not significantly impact the categorization process.

Based on the above, the NRC staff concludes that the licensee's treatment of FLEX strategies is acceptable for this application because the FLEX modeling uncertainty was determined not to be a key source of uncertainty for the categorization process.

3.3.1.1.5 Identification of Key Assumptions and Sources of Uncertainty

In Section 3.2 of the LAR, the licensee confirmed that sensitivity studies will be performed consistent with Section 5 of NEI 00-04. In accordance with Section 9 of NEI 00-04, the licensee's IDP will use information and risk insights compiled in the initial categorization process, which is to include understanding of the limitations and assumptions of the PRA. The IDP combines that awareness with other information from design bases, DID, and safety margins to finalize the categorization of the SSCs.

In Attachment 6 to the LAR, the licensee dispositioned sources of uncertainty for the internal events PRA, internal flooding PRA, and fire PRA models. The licensee clarified how this was done in its supplement to the LAR and confirmed that there were no key sources of uncertainty that impacted the categorization process. The NRC staff determined that the licensee's approach was consistent with NEI 00-04 and other guidance including NUREG-1921. Therefore, the staff finds that the licensee's review and disposition of sources of uncertainty is adequate for this application.

3.3.1.1.6 PRA Acceptability Conclusions

Pursuant to 10 CFR 50.69(c)(1)(i), the categorization process must consider results and insights from a plant-specific PRA. The use of the internal events and fire PRAs to support SSC categorization is endorsed by RG 1.201. The PRAs must be acceptable to support the categorization process and must be subjected to a peer-review process assessed against a standard that is endorsed by the NRC. Guidance for determining the acceptability of the PRA is provided in RG 1.200. The PRA is compared to the relevant parts of the PRA Standard using a peer-review process.

The licensee has subjected the internal events PRA and fire PRA to peer-review and submitted the results. The licensee provided the results and findings of the peer-review to the NRC staff. The staff reviewed the peer-review history, the licensee's resolution of findings, and the identification and disposition of key assumptions and sources of uncertainty. The staff finds that key assumptions for the PRAs have been identified consistent with the guidance in RG 1.200 and NUREG-1855.

Based on the above, the NRC staff concludes that the licensee's internal events and fire PRAs are acceptable to support the categorization of SSCs using the process endorsed by the NRC in RG 1.201. Therefore, the licensee meets the requirements set forth in 10 CFR 50.69(c)(1)(i) and (ii).

3.3.1.2 Evaluation of the Use of Non-PRA Methods in SSC Categorization

As part of its proposed integrated decisionmaking process to categorize SSCs according to safety significance, the licensee proposed to use a non-PRA method to consider seismic hazards. 10 CFR 50.69(c)(1)(ii) and 50.69(b)(2)(ii) permit the use of non-PRA methods in a risk-informed categorization process.

3.3.1.2.1 External Hazards and Other Hazards (Non-Seismic)

This hazard category includes all non-seismic external hazards such as high winds, external floods, transportation, and nearby facility accidents, and other hazards.

In Section 3.2.4 of the LAR, the licensee stated, in part, that all other external hazards (i.e., not seismic or fire hazards) were screened from applicability using a plant-specific evaluation. The NRC staff SE for the FitzPatrick IPEEE addresses how the evaluation was done:

> The licensee evaluated HFO [high winds, floods, transportation and other external events] … screening these events either by showing compliance with the 1975 Standard Review Plan (SRP) criteria or by the use of bounding analyses to demonstrate a CDF contribution of less than the IPEEE screening criterion (1E-6 per reactor-year (RY)). Since JAF [FitzPatrick] was designed and granted its operating license prior to the issuance of the 1975 SRP criteria, JAF was not designed according to the SRP; however, analyses were performed to determine if the plant design conforms to the 1975 SRP criteria. Plant walkdowns were also performed to identify changes in the plant design or operation that occurred since the plants were licensed.

This screening was updated to use the criteria in the PRA Standard. The licensee provided the results of its plant-specific evaluation for hazards listed in Tables D-1 and D-2 in Appendix D of RG 1.200, Revision 3.

The NRC staff notes that this plant-specific evaluation was not peer-reviewed in accordance with Section 6.3 of the PRA Standard. However, the licensee stated in its supplement to the LAR that SSCs will be evaluated during categorization of the SSCs using guidance in Figure 5-6 of NEI 00-04 to confirm that the SSCs are not credited in screening an external hazard.

Based on the above, the NRC staff finds that assessment of risk from all other external hazards is consistent with Section 5 of NEI 00-04 and is, therefore, acceptable, consistent with 10 CFR 50.69(c)(1)(ii).

3.3.1.2.2 Component Safety Significance Assessment for Passive Components

In Section 3.1.2 of the LAR, the licensee proposed using the ANO-2 methodology to address passive components, a categorization method not cited in NEI 00-04. The ANO-2 methodology is a risk-informed safety classification and treatment program for repair and replacement activities for ASME BPV Code Class 2 and 3 pressure retaining items and their associated supports (exclusive of Class CC and MC items), using a modification of the ASME Code Case N-660, “Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities,” (Reference 20). The NRC approved its use for ANO-2 in a letter.

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 events—in this case, pipe ruptures. Treatment requirements (including repair or replacement) only affect the frequency of passive component failure. Categorizing the safety significance of a pipe based on the consequence of failure (assuming that it ruptures) is conservative compared to including the rupture frequency in the categorization of risk. The categorization will not be affected by changes in frequency arising from changes to the treatment. Therefore, the NRC staff finds that the use of the ANO-2 methodology is acceptable and appropriate for passive component categorization of ASME BPV Class 2 and Class 3 SSCs.

In Section 3.1.2 of the LAR, the licensee stated that the “passive categorization process is intended to apply the same risk-informed process accepted by the NRC in the ANO2-R&R-004 for the passive categorization of Class 2, 3, and non-class components.”

Consistent with ANO2-R&R-004, ASME BPV Code Class 1 pressure retaining SSCs in the scope of the system being categorized will be assigned HSS and cannot be changed by the IDP.

Based on the above, the NRC staff finds that the licensee's proposed approach for passive categorization is acceptable for the 10 CFR 50.69 SSC categorization process.

3.3.1.2.3 Seismic Approach

The licensee proposed an alternative seismic approach in Section 3.2.3 of the LAR and supplied clarifying information in its supplement to the LAR. The licensee's alternative seismic approach has two important bases: (1) the impact of the seismic risk in categorization due to the relative contribution of seismic risk to the overall plant risk and (2) the conclusions from the case studies in the EPRI alternative seismic method report (Reference 15).

In the LAR, the licensee stated that its basis for the classification of FitzPatrick as a "Tier 2" plant is that consideration of the full range of the seismic hazard produces limited unique insights to the categorization process. The licensee explained that the basis for using the proposed alternative seismic approach is that the special seismic risk evaluation process for the proposed approach can identify the appropriate seismic insights to be considered with the other categorization insights by the IDP for the final HSS determinations.

The licensee stated in its supplement to the LAR that its proposed alternative seismic approach is identical to the one approved for LaSalle (Reference 21). The licensee further stated that its proposed approach is specified in the EPRI report with the revision markups included in previous Exelon submittals (References 22 and 23).

To capture the potential impact of seismic risk in the categorization process the licensee's alternative seismic approach includes both quantitative and qualitative assessments of plant SSC-specific seismic insights and their presentation to the IDP as part of its decisionmaking. The proposed approach includes focused walkdowns and quantification of PRA importance measures, based on a surrogate sensitivity study, for selected SSCs using the licensee's internal events PRA. The proposed approach also includes consideration of seismic risk through insights from plant-specific seismic information.

Summary of Case Studies in the EPRI Alternative Seismic Method Report

The EPRI report includes the results from case studies performed to determine the extent and type of unique HSS SSCs from a seismic PRA. The case studies were performed for four plants, designated as Plants A through D in the report. Description and evaluation of these case studies were documented in the NRC staff's SE for the LaSalle's 10 CFR 50.69 approval, which is identified by the licensee as a precedent for its proposed alternative seismic approach in the supplement to the LAR.

Evaluation of the Information Provided for the Proposed Alternative Seismic Approach

In Section 3.2.3 of the LAR, the licensee provided a description of its proposed alternative seismic approach for considering seismic risk in the categorization process and how the proposed alternative seismic approach would be used in the categorization process. The licensee cited the LaSalle 10 CFR 50.69 approval as the precedent for its proposed alternative seismic approach and stated that its proposed approach follows that of the precedent without deviation. In addition, the licensee based the acceptability of its proposed alternative seismic approach on the conclusions from the case studies performed in the EPRI report and, therefore, indirectly, on the acceptability of the PRAs used for those case studies.

The information presented in the LAR and the supplement to the LAR, as well as that in the EPRI report, taken together, provides sufficient details for the licensee's proposed alternative seismic approach at FitzPatrick, how the licensee's proposed alternative seismic approach would be used in the categorization process, and the measures for ensuring that the quality and level of detail for the licensee's proposed alternative seismic approach are adequate for the categorization of SSCs. Therefore, the NRC staff finds that the requirements in 10 CFR 50.69 (b)(2)(ii) are met for the proposed alternative seismic approach.

The information presented in the supplement to the LAR, along with the documents that the licensee incorporated by reference in its LAR, provides a sufficient description and basis for the acceptability of the evaluations to be conducted to satisfy 10 CFR 50.69(c)(1)(iv) for the proposed alternative seismic approach. Therefore, the NRC staff finds that the requirements in 10 CFR 50.69(b)(2)(iv) are met for the alternative seismic approach.

It should be noted that Section 2.1 in the EPRI report defines "Tier 3" sites as:

> Plants where the GMRS to SSE [ground motion response spectra to safe shutdown earthquake] comparison between 1.0 Hz and 10 Hz is high enough that the NRC required the plant to perform [a seismic PRA] to respond to the Fukushima 50.54(f) letter.

Section 2.1 of the EPRI report lists the Tier 3 plants. The report states that several plants that have received extensions of their seismic PRA submittal dates are not included in this list. However, the completeness or accuracy of this list does not affect the NRC staff's conclusions on this LAR because the staff's review is specific to FitzPatrick, which is a Tier 2 plant.

Evaluation of Technical Acceptability of the PRAs Used for Case Studies Supporting the Proposed Alternative Seismic Approach

In the LAR, the licensee provided information concerning the case studies, mapping approach, and conclusions on the determination of unique HSS SSCs from the EPRI report case studies used by the licensee to support its proposed alternative seismic approach. The key categorization conclusion from the Plants A, C, and D case studies is that the only SSCs identified as HSS in the seismic PRA (that were not also HSS from internal events or fire PRA) were from unique, seismically induced failure modes. The remainder of HSS SSCs from the seismic PRA are captured by the corresponding internal events or fire PRAs or other aspects of the NEI 00-04 categorization process.

The licensee stated that it used the EPRI report case study information (termed "test case" by the licensee). The licensee also incorporated, by reference in its LAR, information related to the technical acceptability of the PRAs used (and the technical adequacy of certain technical details of the conduct of the case studies) for case study Plants A, C, and D (References 11–19 and 21–23 in the LAR). The NRC staff reviewed and evaluated the technical acceptability of the PRAs used in the case studies for Plants A, C, and D for the FitzPatrick LAR. The staff also evaluated the peer-review process and resolution of peer-review findings. Finally, the staff evaluated key assumptions and sources of uncertainty for Plants A, C, and D, which were incorporated by reference by the licensee.

Based on the above, the NRC staff finds that the technical acceptability of PRAs used for the Plant A, C, and D case studies in the EPRI report, the mapping approach used in those case studies, and the conclusions on the determination of unique HSS SSCs from the case studies are applicable to the licensee's proposed plant-specific alternative seismic approach. Therefore, the staff concludes that the Plant A, C, and D PRAs were technically acceptable and are applicable for use in support of the licensee's proposed alternative seismic approach. The staff determined the mapping of SSCs between the seismic PRA, the full-power internal events PRA (and, as applicable, the fire PRA) for the Plant A, C, and D case studies was appropriate. The staff finds that the licensee's plant-specific evaluation is sufficient to determine unique HSS SSCs from seismic PRAs in the Plant A, C, and D case studies in the EPRI report.

Evaluation of the Implementation of the Proposed Alternative Seismic Approach

The categorization conclusions from the case studies in the EPRI report indicate that seismic-specific failure modes resulted in HSS categorization uniquely from seismic PRAs. Therefore, such seismic-specific failure modes, such as correlated failures, interaction failures, relay-chatter, and passive component structural failure mode, can influence the categorization process. The licensee discussed the implementation of its alternative seismic approach in the LAR. The NRC staff reviewed this information to evaluate whether the categorization related conclusions from the EPRI report were appropriately included and implemented.

The proposed alternative seismic approach includes a combination of qualitative and quantitative considerations of the mitigation capabilities as well as seismic failure modes of SSCs in the categorization process. These considerations are based on plant-specific walkdowns for the SSCs undergoing categorization, quantification of the impact of seismic failure of SSCs subject to correlated or interaction failures, and insights obtained from prior seismic evaluations performed for FitzPatrick.

Qualitative Evaluation for the Alternative Seismic Approach

The licensee stated that in applying the alternative seismic approach, a categorization team will prepare a system categorization document (SCD). At several steps of the process, the categorization team will consider the available seismic insights relative to the system being categorized and document their conclusions in the SCD. When the SCD is presented to the IDP, a section of the document will provide the basis for the proposed alternative seismic approach including the seismic hazard for the plant and the criteria for use of the proposed alternative seismic approach. The IDP will be informed of plant SSC-specific seismic insights that it may choose to consider in its deliberations on the categorization of SSCs as LSS or HSS.

Section 3.2.3 of the LAR states that the categorization evaluation for seismic hazard would be performed at either the functional or component level, using the alternative seismic approach proposed in the supplement to the LAR.

The licensee explained that the categorization team would review available FitzPatrick plant-specific seismic information and other resources to identify plant-specific seismic insights relevant to the SSCs being categorized such as:

- Impact of relay-chatter;

- Implications related to potential seismic interactions such as with block walls;

- Seismic failures of passive SSCs such as tanks and heat exchangers;
- Any known structural or anchorage issues with a particular SSC; and
- Components that are implicitly part of PRA-modeled functions (including relays).

The licensee stated that, for each system categorized, the categorization team will evaluate correlated seismic failures and seismic interactions between SSCs. The licensee further explained that these insights would provide the IDP a means to consider potential impacts of seismic events in the categorization process. The licensee stated that the IDP could challenge, from a seismic perspective, any candidate LSS recommendation for any SSC if it believed that there was a basis for doing so and that any decision by the IDP to downgrade preliminary HSS components to LSS would also consider the applicable seismic insights.

The licensee explained that sources of the insights related to seismic events would be prior plant-specific seismic evaluations such as the seismic hazard screening, spent fuel pool assessment, expedited seismic evaluation process as well as the seismic high frequency evaluation performed for Near-Term Task Force (NTTF) recommendation 2.1, seismic walkdowns performed for NTTF recommendation 2.3, and seismic mitigation strategy assessment performed for NTTF recommendation 4.2.

In the LAR, the licensee stated that for SSCs that were uniquely HSS from the fire PRA but not HSS from internal events PRA, the categorization team would review design-basis functions of the SSCs during seismic events or functions credited for mitigation and prevention of severe accidents caused by seismic events. The results of the review would be presented to the IDP as additional qualitative inputs and would be described in the SCD. The licensee further clarified that the discussion with the IDP would focus on SSCs that are uniquely HSS from fire PRA because such SSCs may not be categorized as HSS following the integrated importance measure determination.

The NRC staff, based on its review of the qualitative evaluations for seismic risk in the licensee's proposed alternative seismic approach, concludes that: (1) the evaluations will include potentially important seismically induced failure modes, as well as mitigation capabilities of SSCs during seismically induced design basis and severe accident events consistent with the conclusions on the determination of unique HSS SSCs from seismic PRAs in the EPRI report, (2) the licensee will provide system-specific qualitative seismic insights to the IDP for consideration as part of the IDP review process as each system is categorized, (3) the insights will use plant-specific prior seismic evaluations, which, in conjunction with the performance monitoring for the proposed alternative seismic approach, reasonably reflect the current plant configuration, and (4) the qualitative evaluation will complement focused walkdowns and quantitative evaluations identified for the SSCs. Further, the recommendation for categorizing civil structures in the proposed alternative seismic approach provides appropriate consideration of such failures from a seismic event.

Focused Walkdowns for the Alternative Seismic Approach

In the LAR, the licensee stated that the proposed alternative seismic approach includes focused walkdowns of SSCs undergoing categorization. The purpose of the walkdowns is to identify, for the SSCs that are being categorized, the conditions for occurrence of correlated failures, failure of more than one SSC due to interactions with other SSCs, and single component failures.

The NRC staff evaluated the focused walkdowns for the proposed alternative seismic approach, as described in the licensee's LAR and in the EPRI report, including the revision markups in the LaSalle 50.69 LAR supplements that are incorporated by the licensee in the LAR. The licensee cited the LaSalle 10 CFR 50.69 approval as the precedent for its proposed alternative seismic approach and stated that its proposed approach followed that of this precedent without deviation. The NRC staff's review of the supplement to the LAR and the documents incorporated by reference in the LAR determined that the staff's previous evaluation documented in the LaSalle 50.69 SE is applicable to FitzPatrick.

The NRC staff's review of the focused walkdowns in the proposed alternative seismic approach described in the EPRI report, including the revision markups in the LaSalle 50.69 LAR supplements that are incorporated by the licensee in the LAR, finds that:

- The licensee's focused walkdown in the proposed alternative seismic approach: (i) includes consideration of seismically induced correlated and interaction failures that fail more than one SSC as well as single component failures, (ii) includes evaluations of the direct and indirect impacts of seismically induced correlated and interaction failures of an SSC, (iii) reflects the insights from the case studies in the EPRI report in addressing these failure modes, and (iv) confirms that the modifications to the proposed alternative seismic approach through changes to the EPRI report appropriately reflect the evaluation of such direct and indirect impacts. (These modifications are addressed in the quantitative evaluation section below.)

- The qualification of personnel performing the walkdowns and the documentation and retention of the walkdown results is acceptable for the proposed alternative seismic approach. The qualification of personnel performing the walkdowns for the proposed alternative seismic approach is consistent with the state-of-practice for the development and peer review of contemporary seismic PRAs and the documentation and retention of walkdown information for the proposed alternative seismic approach is consistent with the state-of-practice for seismic PRAs and the guidance in NEI 00-04 will result in appropriate information being presented to the IDP for categorization decisions.

- The licensee's approach for selecting the screening criterion is consistent with the state-of-practice for seismic PRAs and the SSCs screened out based on the criterion are not expected to result in HSS components within the 10 CFR 50.69 categorization process.

- The fragility approaches proposed for the development of fragility values in Step 5b of the proposed alternative seismic approach are acceptable for the proposed alternative seismic approach because (i) they represent state-of-practice approaches consistent with those used in contemporary seismic PRAs reviewed by the NRC staff, and (ii) no unreviewed methods would be used for fragility calculations.

- The personnel performing fragility evaluations for the proposed alternative seismic approach will have experience or background consistent with that used for state-of-practice seismic PRAs as well as the guidance in NEI 00-04 on personnel qualifications and the use of such personnel is, therefore, acceptable for the proposed alternative seismic approach. In addition, the NRC staff review determined that the documentation of the fragility evaluations will be consistent with documentation used for other categorization processes and is therefore, acceptable for the proposed alternative seismic approach.

- The proposed alternative seismic approach will result in consideration of relays as implicitly modeled components and of insights related to the impact of seismically induced relay-chatter for the function achieved by the SSC during the categorization.

- The focused walkdowns of SSCs undergoing categorization will identify seismic interaction and correlated failures including those resulting from potential failures of passive components as well as structural and anchorage issues. Further, the NRC staff concludes that insights from available plant-specific seismic reviews will also provide categorization related insights from a seismic failure modes perspective.

Quantitative Evaluation for the Alternative Seismic Approach

In the LAR, the licensee explained that SSCs identified as being vulnerable to correlated or interaction failure modes based on the walkdown would be subjected to a quantitative evaluation using the licensee's internal events PRA to determine the impact of seismic events on the categorization. The quantitative evaluation would be performed through a sensitivity study, termed the surrogate sensitivity, using the licensee's internal events PRA. The NRC staff notes that further details on the surrogate sensitivity are provided in Section 2.3.1 of the EPRI report, including the revision markups in the LaSalle 50.69 LAR supplements that are incorporated by the licensee in its LAR.

The surrogate sensitivity would be performed by introducing PRA basic events, termed surrogate events, in the licensee's internal events PRA at appropriate locations to reflect seismically induced correlated failure or interaction failure of single or multiple SSCs. Subsequently, the modified internal events PRA with the surrogate events would be quantified for the loss-of-offsite power (LOOP) and small break loss-of-coolant accident (hereafter referred to as small LOCA) initiators and importance measures would be derived. The importance measures for the surrogate events derived from this sensitivity study would be used to identify the SSCs that should be HSS due to seismically correlated failures or seismic interaction related failures. The licensee further stated that the quantitative evaluation to determine the importance of SSCs on a system basis in the proposed alternative seismic approach is detailed in Section 2.3.1 of the EPRI report.

The NRC staff reviewed the quantitative evaluation for the alternative seismic approach described in the LAR, the supplement to the LAR, and the EPRI report, including the revision markups in the LaSalle 50.69 LAR supplements. Based on this review of the documents incorporated by reference by the licensee, the staff determined that its previous evaluation documented in the LaSalle 50.69 SE is applicable to FitzPatrick.

The NRC staff determined that seismically induced LOOP and small LOCA occurrence frequencies are representative for FitzPatrick based on the three seismic PRAs in the case studies in the EPRI report and the fact that the seismic hazard at the FitzPatrick site is lower than the hazard for those seismic PRAs. Therefore, the staff concludes that the proposed occurrence frequency for the seismically induced LOOP event of 1.0 per year, the proposed occurrence frequency for the seismically induced small LOCA event of 1.0×10^{-2}/year, and the proposed surrogate event failure probability of 1.0×10^{-4}/year are acceptable for use in the licensee's alternative seismic approach. Further, the staff determined that the occurrence frequency and failure probability switch in the surrogate sensitivity is acceptable for the licensee's alternative seismic approach because: (1) it is necessary for developing the importance measures for comparison against the corresponding thresholds in NEI 00-04, and (2) it does not alter the basis for the proposed values. Based on its review, the staff finds that there is reasonable assurance that the categorization outcome from the licensee's proposed alternative seismic approach will be comparable to those from seismic PRAs.

Implementation of the Alternative Seismic Approach

Based on its review of the licensee's proposed alternative seismic approach, in conjunction with the requirements in 10 CFR 50.69 and the corresponding statements of consideration, the NRC staff finds that the use of the proposed alternative seismic approach will ensure the acceptability of the evaluations required by 10 CFR 50.69(c)(1)(ii) and (iv) and will meet the intent of the rule because:

- The approach includes qualitative consideration of seismic events at several steps of the categorization process including documentation of the information for presentation to the IDP as part of the integrated, systematic process for categorization.

- The approach includes focused walkdown(s) which evaluate(s) the direct and indirect impacts of seismically induced correlated failures, interaction failures, and single component failures in a system under categorization.

- The approach includes a quantitative evaluation, with justified failure probability and initiating event frequencies, that provides reasonable assurance that the categorization results from the licensee's proposed alternative seismic approach will be similar to those from seismic PRAs.

- Personnel performing necessary walkdowns and analyses will have qualifications consistent with the state-of-practice for seismic PRAs and the guidance in NEI 00-04. The documentation of these walkdowns and analyses will be consistent with the state-of-practice for seismic PRAs and the guidance in NEI 00-04.

- The quantitative and qualitative insights presented to the IDP include potentially important seismically induced failure modes as well as mitigation capabilities of SSCs during seismically induced design basis and severe accident events, consistent with the conclusions on the determination of unique HSS SSCs from seismic PRAs in the EPRI report and with the markups provided in the LaSalle 50.69 LAR supplements, which were incorporated by reference by the licensee in the LAR. The quantification will use the licensee's internal events PRA and the insights will use prior plant-specific seismic evaluations. Therefore, in conjunction with performance monitoring for the proposed alternative seismic approach, the proposed alternative seismic approach will reasonably reflect the current plant configuration.

- The approach presents system-specific insights and categorization results from a seismic risk perspective to the IDP for consideration as part of the IDP review process, thereby providing the IDP with a means to consider potential impacts of seismic events in the categorization process.

- The approach presents the IDP with the basis for using the proposed alternative seismic approach including the moderate seismic hazard for the plant and the criteria for use of the proposed alternative seismic approach.

Evaluation for Performance Monitoring for the Alternative Seismic Approach

In its LAR, the licensee stated that its configuration control process ensures that changes to the plant, including a physical change and changes to documents, are evaluated to determine the impact on design bases, licensing documents, programs, procedures, and training.

The NRC staff evaluated the licensee's discussion of its performance monitoring program for the proposed alternative seismic approach to ensure: (1) the continued validity of the plant-specific information that was developed for each SSC that is categorized, (2) that any changes to the plant, including the seismic hazard, are captured and appropriately addressed as part of the 10 CFR 50.69 program, and (3) that the requirements in 10 CFR 50.69(e) are met for the proposed alternative seismic approach.

In its LAR, the licensee stated that its performance monitoring process requires periodic review to assess changes that could impact the categorization results and to provide the IDP with an opportunity to recommend categorization and treatment adjustments due to such changes. The licensee explained that its configuration control program had been updated to have a checklist related to the impact of seismic events on categorization. The licensee identified some of the items in the checklist in its LAR.

The licensee stated that its performance monitoring program requires that SCDs cannot be approved by the IDP until the IDP's comments on issues, including system-specific seismic insights, have been resolved to the satisfaction of the IDP.

The licensee explained that its scheduled periodic reviews would occur no longer than once every two refueling outages and would evaluate new insights resulting from available risk information (i.e., PRA model or other analysis used in the categorization) changes, design changes, operational changes, and SSC performance. If it was determined that these changes have affected the risk information or other elements of the categorization process such that the categorization results are more than minimally affected, then the risk information and the categorization process would be updated. The licensee explained that if a PRA model or other risk information is updated, a review of the SSC categorization would be performed in addition to the periodic review.

The NRC staff recognizes that the seismic hazard at any site could potentially increase such that the categorization process may be impacted from a seismic risk perspective, either solely due to the seismic risk or via the integrated importance measure determination. In its LAR, the licensee stated that if the FitzPatrick seismic hazard changed at some future time and if the licensee's feedback process determined that a process different than the proposed alternative seismic approach is warranted for seismic risk consideration under 10 CFR 50.69, it will seek prior NRC approval for the use of such an approach. The NRC staff notes that seeking prior NRC approval for the use of a process different from the proposed alternative seismic approach and the previously approved seismic margin assessment is consistent with the new license condition proposed by the licensee. The licensee further stated that after receiving NRC approval, it would follow its categorization review and adjustment process procedures and would update, as appropriate, the SSC categorization in accordance with 10 CFR 50.69(e).

Based on its review, the NRC staff finds that the licensee's configuration control program includes consideration of seismic issues as well as failure modes such as interaction between components and review of seismic loading and seismic dynamic qualification. Further, the licensee's performance monitoring program assesses changes that impact the categorization results and provides the IDP with an opportunity to recommend categorization and treatment adjustments due to such changes. Therefore, the NRC staff finds that the licensee's performance monitoring and configuration control process addresses plant-specific seismic evaluation, thereby ensuring that the corresponding impacts on SSC categorization continues to remain valid and if necessary, are presented to the IDP for consideration of categorization changes.

During its review, the NRC staff noted that the licensee's performance monitoring program for 10 CFR 50.69 has the capability to identify significant changes to the plant risk profile as well as instances in which a RISC–3 or RISC–4 SSC may fail to perform a safety significant function, resulting in an immediate evaluation and review of such instances. Based on its review, the staff finds that the requirements in 10 CFR 50.69(e) are met for the proposed alternative seismic approach.

Conclusion for Proposed Alternative Seismic Approach

Based on its review, the NRC staff concludes that the licensee's proposed alternative seismic approach is acceptable for considering seismic risk in the licensee's categorization process under 10 CFR 50.69.

3.3.1.3 Key Principle 4 Conclusions

Based on its review of the acceptability of the internal events and fire PRAs, as well as evaluation of the use of non-PRA methods, the NRC staff concludes that the proposed change satisfies the fourth key principle for risk-informed decision making prescribed in RG 1.174.

3.3.2 Key Principle 5: Monitor the impact of the Proposed Licensing Basis Change

NEI 00-04 provides guidance that includes programmatic configuration control and a periodic review to ensure that all aspects of the 10 CFR 50.69 program (i.e., includes traditional engineering analyses) and PRA models used to perform the risk assessment continue to reflect the as-built, as-operated plant and that plant modifications and updates to the PRA over time are continually incorporated.

Sections 11 and 12 of NEI 00-04 include discussion on periodic review as well as program documentation and change control. Maintaining change control and periodic review will also maintain confidence that the 10 CFR 50.69 program and risk categorization for SSCs continue to reflect the as-built, as-operated plant.

Based on the above, the NRC staff finds that the risk management process described by the licensee in the LAR is consistent with Section 11 and Section 12 of NEI 00-04, as endorsed by RG 1.201, and is consistent with the requirements in 10 CFR 50.69(f) and (e). Therefore, the staff concludes that the proposed change satisfies the fifth key principle for risk-informed decisionmaking prescribed in RG 1.174.

4.0 PROPOSED REVISION TO THE OPERATING LICENSE

In the LAR, the licensee proposed the addition of the following license condition to the renewed facility operating license for FitzPatrick:

> Exelon 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 and non-Class SSCs and their associated supports; the results of the non-PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009 for other external hazards except seismic; and the alternative seismic approach as described in Exelon's submittal letter dated July 30, 2021, and all its subsequent associated supplements as specified in License Amendment No. XXX dated [DATE].
>
> 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).

The NRC staff finds that the proposed license condition is acceptable because (1) it adequately implements 10 CFR 50.69 using models, methods, and approaches consistent with the applicable guidance that has previously been endorsed by the NRC; and (2) the evaluation in Section 3.3 above finds the non-PRA methods for assessing risk for seismic, and passive components, which are deviations from NEI 00-04, to be acceptable.

On February 1, 2022, Exelon was renamed CEG. Therefore, with conforming changes to reflect this name change, the license condition will state:

> Constellation Energy Generation, LLC 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 and non-Class SSCs and their associated supports; the results of the non-PRA evaluations that are based on the IPEEE Screening Assessment for External Hazards updated using the external hazard screening significance process identified in ASME/ANS PRA Standard RA-Sa-2009 for other external hazards except seismic; and the alternative seismic approach as described in the Exelon Generation Company, LLC submittal letter dated July 30, 2021, and all its subsequent associated supplements as specified in License Amendment No. 352 dated August 23, 2022.
>
> 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).

The NRC staff notes that the guidance for implementing 10 CFR 50.69 provided by the Commission in the *Federal Register* notice dated November 22, 2004, Section III.4.10.2, "Section 50.36 Technical Specifications,"[5] states that the 10 CFR 50.69 rule does not include 10

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[5] "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors" (69 FR 68008, 68028-68029).

CFR 50.36 in the list of special treatment requirements that may be replaced by the alternative 10 CFR 50.69 requirements for RISC-3 and RISC-4 SSCs when implementing a 10 CFR 50.69 license amendment. As a result, the staff does not consider technical specifications (including Improved Technical Specifications and the associated Technical Requirements Manual) to be part of the 10 CFR 50.69 rule. Therefore, the licensee must address proposed changes to its technical specifications separately.

5.0 STATE CONSULTATION

In accordance with the Commission's regulations, the New York State official was notified of the proposed issuance of the amendment on July 20, 2022. 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 or change inspections or surveillance requirements. 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 (November 30, 2021; 86 FR 67988). 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: August 23, 2022

SUBJECT: JAMES A. FITZPATRICK NUCLEAR POWER PLANT – ISSUANCE OF AMENDMENT NO. 352 RE: ADOPTION OF 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS AND COMPONENTS FOR NUCLEAR POWER REACTORS" (EPID L-2021-LLA-0142) DATED AUGUST 23, 2022

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