



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

September 3, 2021

EA-20-138

Mr. David P. Rhoades
Senior Vice President
Exelon Generating Company LLC
President and Chief Nuclear Officer, Exelon Nuclear
4300 Winfield Road
Warrenville, IL 60555

SUBJECT: JAMES A. FITZPATRICK NUCLEAR POWER PLANT – RESPONSE TO
CONTESTED VIOLATION AND FINAL WHITE FINDING AND REVISED
NOTICE OF VIOLATION – INSPECTION REPORT 0500333/2021090

Dear Mr. Rhoades:

This letter provides you the response to your letter dated June 3, 2021, contesting the Notice of Violation (NOV) issued by Nuclear Regulatory Commission (NRC) letter dated April 20, 2021 (ML21105A543). In summary, Exelon Generation Company, LLC (ExGen) did not agree that the violation constituted a Performance Deficiency as the staff at James A. FitzPatrick Nuclear Power Plant (FitzPatrick) could not have reasonably been able to identify and prevent a nonconforming component (pressure control valve) from being installed and therefore, contested the characterization of the 10 CFR 50 Appendix B, Criterion VII and XV violations. On June 25, 2021, the NRC acknowledged receipt of this letter (ADAMS Accession ML 21176A005) and informed you that we would evaluate your response and provide the results of our evaluation.

In your letter dated February 26, 2021 (ADAMS Accession ML 21057A190), ExGen acknowledged that the failure to control a defective part and prevent its use occurred at the Limerick Generating Station (LIM) in 2010; and, as a result the staff at LIM failed to communicate the deficiency to Fitzpatrick prior to selling the defective part to FitzPatrick. ExGen further acknowledged that the sale of the defective part from Limerick to FitzPatrick in 2017, and its subsequent installation, resulted in a failure of the FitzPatrick high pressure coolant injection system (HPCI) in 2020.

The NRC conducted a detailed review of your response and the applicable regulatory requirements, in accordance with Part I, Section 2.4.4, of the NRC Enforcement Manual. The NRC team that performed the review were not involved with the original inspection effort. Based on the totality of the information, including the inspection report with referenced documents, your response to the apparent violation, and your response contesting the final violation; the review team determined that the violations referencing 10 CFR 50, Appendix B Criterion VII, "Control of Purchased Material, Equipment and Services," and Criterion XV, "Nonconforming Materials, Parts or Components," were not sufficiently supported as stated in

the issued Notice. The Criterion VII violation has been withdrawn and the Criterion XV violation has been revised.

The review team confirmed the validity of the issued Technical Specification violation and recommended a revised performance deficiency concerning FitzPatrick staff's failure to adequately follow its procurement and receipt procedures. The team determined that these failures, which substantially contributed to the installation of a defective part into the high pressure coolant injection system, was reasonably foreseeable and preventable. The circumstances of the performance deficiency were determined to constitute violations of 10 CFR 50 Appendix B, Criterion V, "Instructions, Procedures, and Drawings" (hereafter referred to as Criterion V) and Criterion XV. The noncompliance with Criterion V is newly identified, and the noncompliance with Criterion XV, with changes, is confirmed. The bases for these determinations, which include the withdrawal of the Criterion VII violation are detailed in the enclosures to this letter. The enclosed Notice (i.e., revised) supersedes the Notice issued on April 20, 2021. The revised Notice includes violations (i.e., Criterion V, Criterion XV and Technical Specification 3.5.1) that are categorized collectively as a problem associated with a finding.

Due to the change in the characterization of the performance deficiency, a review of the previously issued risk assessment was also performed (Enclosure 2). This review concluded that the underlying assumption and methodology were not altered by the revised performance deficiency and that the performance deficiency supports a finding of White significance.

You are not required to respond to this letter. If you have additional information that you believe the NRC should consider, you should follow the instructions in the Notice. The details of the NRC's evaluation of a reply to the Notice of Violation, as well as the re-stated Notice, are contained in the enclosures to this letter. In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390, "Public inspections, exemptions, requests for withholding," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC's ADAMS, accessible from the NRC Web site <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this matter, please contact Ms. Erin E. Carfang, Chief, Projects Branch 1, Division of Reactor Projects in Region I, at 610-337-5120.

Sincerely,

David C. Lew  Digitally signed by David C. Lew
Date: 2021.09.03 08:37:46 -04'00'

David C. Lew
Regional Administrator

Docket No. 50-333
License No. DPR-59

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CONTESTED VIOLATION AND FINAL WHITE FINDING AND REVISED NOTICE OF
VIOLATION – INSPECTION REPORT 0500333/2021090 DATED SEPTEMBER 3, 2021

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ENCLOSURE 1

NRC RESPONSE TO INFORMATION PROVIDED IN THE EXELON LETTER DATED JUNE 3, 2021

As discussed below, the NRC Independent Review Team (IRT) reviewed the information provided by Exelon Generation Company, LLC (ExGen) and determined that the characterization of the finding remains of low-to-moderate safety significance (White). The IRT determined that the violations of 10 CFR 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment and Services," and Criterion XV, "Nonconforming Materials, Parts or Components," were not sufficiently supported as written. As a result, the Criterion VII violation has been withdrawn and the Criterion XV violation has been revised. The violation of TS 3.5.1 remains unchanged. However, the IRT determined that a violation of 10 CFR Part 50 Appendix B, Criterion V, is warranted.

Regarding the contested 10 CFR Part 50 Appendix B, Criteria VII and XV violations, the IRT determined that neither 10 CFR Part 21, nor any associated NRC guidance, requires a licensee to evaluate an incoming component for the existence of a Part 21 notification. FitzPatrick, as required by 10 CFR 21.31¹, appropriately invoked the requirements of Part 21 by its inclusion in the purchase order. Part 21 does not represent a receipt inspection characteristic for the procurement of a structure, system, component, or service. Rather, its inclusion in the purchase order places the supplier on notice that the requirements of Part 21 must be met. Accordingly, given that no additional information was presented in the inspection report regarding a failure to comply with procurement documents (i.e., the purchase order), the IRT determined the assertion, that Fitzpatrick failed to ensure "purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents," was not supported as stated in the subject inspection report. In reviewing the licensee's response and the body of information available to support the inspection outcome, the staff determined that FitzPatrick failed to comply with its procurement and receipt procedures which resulted in ExGen's failure to adequately identify and control items to prevent the use of a defective item as specified in Section 6, "Identification and Control of Items," of FitzPatrick's Quality Assurance Program Manual (QAPM). Thus, the staff determined that FitzPatrick's failure to accomplish procurement activities as prescribed by ExGen's quality assurance procedures resulted in a noncompliance with 10 CFR 50, Appendix B, Criteria V and XV. The revised finding and Notice of Violation (NOV) are described in Enclosures 2 and 3.

SUMMARY OF EXGEN COMMENT – Ability to Identify Part 21 Information

ExGen disputed NRC's basis for determining that the violations were reasonably foreseeable and preventable because the act of clearing an unrelated shelf-life hold did not provide an opportunity for either the Limerick Generation Station (Limerick) material handler, or the FitzPatrick qualified receipt inspector (QRI), to identify the Part 21 information. The Part 21 information was documented in an Issue Report (IR) located in the component database and was also documented in ExGen's Corrective Action Program (CAP) database.

¹ 10 CFR 21.31, "Procurement documents," states, "Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply."

NRC RESPONSE

The IRT considered the violation in the context of 10 CFR 21 (i.e., Part 21) as used (or implied) in the 'contrary to' statements for the issued 10 CFR 50 Appendix B, Criterion VII and Criterion XV violations. The IRT concluded that this aspect of the violations should be withdrawn.

SUMMARY OF EXGEN COMMENT – Archived, Descriptive and Readily Available

With respect to the shelf life hold, ExGen contends the NRC has mischaracterized this “archived” and “descriptive” information as “readily available” to both the Limerick material handler and the FitzPatrick quality receipt inspection quality receipt inspection.

NRC RESPONSE

As a point of clarification, the hold that was presented was a user-hold. In order to identify the reason for a user-hold, the licensee’s staff would need to further review and disposition the concern as appropriate. As described in ExGen’s June 3, 2021 response, the manipulation of the Passport system requires some degree of user familiarity and skill of the craft. As the licensee states in their response, descriptive information in the component tracking database can be provided in several panels. After a review of the information and steps to manipulate the Passport system, the NRC maintains that this information was readily available, and as a result represented a reasonable opportunity to foresee and prevent the installation of the nonconforming PCV.

SUMMARY OF EXGEN COMMENT- Requirements to Research

Although ExGen provided information in the response to the AV - demonstrating that there was no regulatory requirement to research information unrelated to the shelf life hold, as well as explaining why the non-conformance would not have reasonably been identified by the Exelon Business Services Corporation (BSC) staff in 2017 - there is no indication in the issued NOV that this information was considered.

NRC RESPONSE

The IRT assessed this information during its deliberations. This information, in part, is addressed in the NRC Response to EXGEN Comments pertaining to 10 CFR Part 50 Appendix B, Criterion VII. The NRC agrees that there was no regulatory requirement to research information unrelated to the user hold. Accordingly, the revised NOV does not cite a failure to perform this level of research. Instead, the IRT recommended a performance deficiency (PD) and violation associated with failures to follow ExGen’s procedural provisions and the availability of the subject information. Ultimately, the staff determined that it was reasonable for ExGen to foresee and prevent the installation of the nonconforming PCV during receipt inspection; however, the failure of personnel to adhere to procedural requirements resulted in a failure to identify that the diaphragm in the PCV required replacement.

SUMMARY OF EXGEN COMMENT- Limerick Criterion XV

The NRC staff acknowledged that the Criterion XV violation that occurred at Limerick in 2010 could not have been prevented by the ExGen staff in 2017. However, when recharacterizing the

Criterion XV violation as having occurred in 2017, the NRC did not explain how Criterion XV was violated that year.

NRC RESPONSE

NRC staff identified that information about the Part 21 notification was readily available in the database and could reasonably be identified by a qualified procurement engineer when performing a review of available information to address the 'hold'. As determined by the IRT, the basis for the issued Criterion XV violation was underpinned by the Criterion VII violation. As described above, the IRT found Criterion VII to be unsupported. As a result of the IRT review of this matter, NRC determined that the Criterion XV violation was not sufficiently supported as stated in the issued Notice; the IRT documented a revised Criterion XV violation that was based on a procedural deficiency in lieu of a Part 21 procurement deficiency.

SUMMARY OF EXGEN COMMENT- Clearing the User Hold

The licensee stated that the shelf-life hold was actually cleared by the Limerick MH after the existence of the hold had been communicated to the FitzPatrick buyer; and, that the FitzPatrick buyer engaged the FitzPatrick Procurement Engineer (PE) who appropriately reviewed the original vendor documentation and determined that the shelf-life could be extended - which was subsequently communicated to the FitzPatrick buyer and the FitzPatrick QRI. Per the licensee, at no time did the FitzPatrick buyer, the FitzPatrick QRI, or the FitzPatrick PE have any reason – nor was there any regulatory requirement – to access the component tracking database or the ExGen CAP system to investigate the reason for the shelf-life hold. ExGen stated that clearing the hold was the responsibility of the Limerick warehouse staff as the custodian of the component.

NRC RESPONSE

The NRC recognizes that the specific facts of the procurement incident are impacted by the amount of time that has elapsed since the 2017 transfer, personnel retirements, and the lack of documentation. However, in response to the comments above, the NRC reviewed action request (AR) 04348906 - originated on June 6, 2020, by FitzPatrick - to inform our decision on the sequence of events and the actions of the involved individuals. Specifically, per the AR, (1) the PCV was put on user hold at Limerick on October 20, 2017, due to the self-life expiring within 5 days, (2) the valve was transferred to Fitzpatrick on December 15, 2017, with the shelf-life indicating 'expired' in Passport, and (3) the Fitzpatrick quality receipt package inspection identified, reviewed and dispositioned the shelf-life issue with FitzPatrick's Procurement Engineering prior to releasing the PCV for installation in the HPCI system.

Procedure SM-AA-102, Warehouse Operations, Rev 23, Attachment 1, step 1.10.6, specifies, in part, that for items on hold to be released to another facility, the receiving facility must create an action item to track the resolution before the transfer occurs. FitzPatrick, the receiving facility, did not create an action item to track the dispositioning of the hold which should have resulted in the component being returned to user-hold status and tagged until dispositioning had occurred. Based on the IRT assessment of the supporting information, the team concluded that there were a number of procedural adherence issues at both the Limerick and FitzPatrick stations with respect to procurement practices. Similar conclusions were arrived by ExGen as documented in the Corrective Action Program Evaluation (CAPE) Charter for Condition Report Number 04334315, dated June 24, 2020, when addressing both Limerick's and FitzPatrick's shortcomings in the total chain of events.

SUMMARY OF EXGEN COMMENT- Clearing the User Hold

The licensee asserted that the NRC incorrectly stated that IR 1086768 had not been resolved at the time the PCV was sold to, and accepted at, FitzPatrick. ExGen had previously explained in their response to the AV, that all actions associated with IR 1086768 have been in "COMPLETE" status since 2010. However, the NRC did not acknowledge this fact in the NOV and inaccurately stated that the IR remained unresolved.

NRC RESPONSE

The NRC acknowledges that actions associated with IR 1086768 have been in "COMPLETE" status since 2010. The actions of concern were taken to COMPLETE by generating M Codes which directed the replacement of the diaphragm prior to installation. Specifically, in the component identification (CID) facility-specific section in Passport Panel D202, it stated, "Need to replace diaphragm 116-0013 prior to use in the plant refer IR 1086768". The IRT determined that if prescribed procedures were followed as described above, it would have been reasonable for the FitzPatrick procurement staff to identify that the action to replace the diaphragm was not completed. Furthermore, it was reasonable for procurement engineers to review Passport Panel D202 during the receipt process regardless of whether a hold was placed on the component.

SUMMARY OF EXGEN COMMENT- Unresolve Part 21's

ExGen specifically informed the NRC that there is no reference to the Part 21 in the component tracking database. Furthermore, if a search of the referenced IR would have been required, which ExGen continues to stress was NOT required, it would have indicated to the Limerick MH and the FitzPatrick QRI that there were no open ATIs associated with that IR and therefore, they would have concluded that the IR was dispositioned correctly and closed. In order for any BSC or ExGen staff to identify that there was an unresolved Part 21 concern associated with the PCV, the individual would have had to arbitrarily decide to audit the closures of each of the ATIs associated with IR 1086768, despite having no cause or regulatory requirement to do so.

NRC RESPONSE

As stated above, Part 21 does not represent a receipt inspection characteristic for the procurement of structures, systems and components (SSC).

SUMMARY OF EXGEN COMMENT- Part 21 and Closed Action Tracking Items (ATIs)

Assuming the BSC staff had reason to look for any open ATIs associated with older Part 21 notifications in 2017, which they did not, the BSC staff would have determined that appropriate actions were put in place and subsequently completed to address the 2010 Part 21 notification.

NRC RESPONSE

As stated above, Part 21 does not represent a receipt inspection characteristic for the procurement of a SSC.

SUMMARY OF EXGEN COMMENT – Descriptive Information

The issue report (IR) number associated with the 2010 Part 21 response was not documented in the status field, but instead was documented in a hidden “descriptive information” field along with 63 other line items of descriptive information.

NRC RESPONSE

The IRT disagreed with ExGen’s characterization that the relevant descriptive information concerning the deficient PCV diaphragm was not readily available. Specifically, information was clearly available in Passport panel D202. Procurement Engineers operate in accordance with procedure SM-AA-300-1001, “Procurement Engineering Process,” and other procedures. Section 4.29 describes how additional comments and basis for site applicability may be entered using CID specific panel D202. The IRT determined that, when clearing the user-hold for the PCV, it would have been reasonable for procurement engineers to access this descriptive information, which was readily available and required no more than a few minutes to review. From this descriptive information, it would have been reasonable for the licensee to identify that the defective diaphragm in the PCV required replacement. Furthermore, it was reasonable for procurement engineers to review Passport Panel D202 during the receipt process regardless of whether a hold was placed on the component.

ENCLOSURE 2

REVISED FINDING IN RESPONSE TO CONTESTED VIOLATION

Defective Part Results in High Pressure Coolant Injection System Pressure Control Valve Failure			
Cornerstone	Significance	Cross-cutting Aspect	Report Section
Mitigating Systems	White NOV 05000333/2020012-01 Open EA-20-138	[H.1] - Resources	71153
<p>The inspectors documented a self-revealed White finding and related violation of FitzPatrick Technical Specifications (TS 3.5.1). The finding included failures to comply with Title 10 of the <i>Code of Federal Regulations</i> (10 CFR) Part 50, Appendix B, Criterion V, "Instructions, Procedures and Drawings" and Criterion XV, "Nonconforming Materials, Parts, or Components." Exelon Generation, LLC (ExGen) did not adequately implement quality-related procedures which contributed to FitzPatrick's failure to identify a nonconforming component, which was verified as acceptable for use. Subsequently, FitzPatrick's maintenance staff installed the nonconforming component which caused the inoperability of the HPCI system on April 10, 2020.</p>			
<p><u>Description:</u></p> <p>The HPCI system at FitzPatrick provides an emergency source of water following a transient or accident. This high pressure source of coolant is delivered from two water sources using steam generated from the reactor to drive the associated turbine and pump. The HPCI system pump can deliver up to 4,250 gallons per minute and may be operated across a wide range of reactor pressures. The HPCI system pump and turbine are supported by an oil system designed to lubricate bearings and provide adequate pressure to control the steam turbine stop and control valves.</p> <p>During a HPCI maintenance window in December 2017, an emergent need arose for a replacement pressure control valve (PCV). ExGen did not have a replacement PCV on site at the time, and subsequently located a replacement PCV at Limerick. On December 16, 2017, ExGen issued purchase order (P.O.) 637326 to move the HPCI system PCV from the Limerick warehouse to FitzPatrick during a planned HPCI system maintenance window. Due to the emergent demand, the purchase order was issued in parallel with a document review by FitzPatrick. Per issue report (IR) 04348906, originated on June 6, 2020, the PCV was put on user hold at Limerick on October 20, 2017, due to the shelf-life expiring within 5 days. This IR states the valve was transferred to FitzPatrick on December 15, 2017, with an expired shelf-life annotated in Passport (the licensee's component tracking database). Additionally, the IR states that prior to releasing the PCV for installation, Fitzpatrick's quality receipt inspection identified, reviewed, and dispositioned the shelf-life issue with FitzPatrick Procurement Engineering.</p> <p>Procedure SM-AA-300-1001, Section 4.10.2, specified that when the requesting facility (FitzPatrick) is not a specific user of the procured component that the existing Catalogue Identification (CID) at the target site (Limerick) shall be reviewed by the requesting site. The purpose of this review is to ensure that quality and technical requirements of the component are adequate for the requesting facility's need; and, that the review shall be performed by a procurement engineer (PE) for a safety-related component. The CID was not in a ready state</p>			

at the time of request, as a 'user hold' existed in Passport for a shelf-life concern. The document package associated with P.O. No. 011466532 included electronic correspondence documenting that appropriate Fitzpatrick staff reviewed the document package for P.O. No. 0011466532 and found it to be acceptable. FitzPatrick's review did not identify discrepant information located within Exelon's equipment database (e.g., the CID facility-specific section in Passport panel D202).

The FitzPatrick procurement staff authorized Limerick to transfer a component in 'hold' status in the Passport system without initiating a new 'hold' upon receipt of the component at the destination site (FitzPatrick). These actions were not in accordance with the requirements of procedure SM-AA-102, Warehouse Operations, Rev. 23. Procedure SM-AA-102, specified that items released on hold shall be tracked by a respective Action Request (AR) assignment, Work Order task or Issue report with respective assignments to track the released material. Specifically, the licensee failed to ensure that a component released on hold was adequately tracked by a respective AR assignment, work order task or issue report with respective assignments to ensure requisite component quality, and the Catalogue ID (CID) for this component was set to "READY." Additionally, a hold tag was required to be attached to the component upon receipt of the transfer at the receiving site and entered into the site's hold tag log. These actions were not performed. The failure to initiate a hold upon receipt of the PCV or initiate tracking documents resulted in opportunities for FitzPatrick to identify the discrepant information located within the equipment database. The formal actions to disposition the hold, as required per SM-AA-102, provided a reasonable opportunity, under these specific circumstances, for FitzPatrick to identify that the PCV was nonconforming. Descriptive information relating to the nonconforming condition was readily available in several panels in the licensee's component tracking data base. For example, panel D202 included a readily available note which stated "need to replace diaphragm 116-00134 prior to use in plant."

The review of P.O. No. 011466532 did not identify the discrepant information located within the CID facility specific section in Passport panel D202. The document package associated with the P.O. included electronic correspondence (i.e., a one-line email) documenting that a senior procurement engineer reviewed the document package for the P.O. and found it to be acceptable. The use of panel D202 is described in Section 4.29 of SM-AA-300-1001, "Procurement Engineering Process and Responsibility," Rev 24. Specifically, the procedure states "Additional comments and the basis for site applicability may be added under the CID facility specific section in Passport panel D202, AAA route list, D201 panel OLE field, or BOM NOTES, as appropriate." The guidance in Procedure SM-AA-300-1001, combined with the failures to follow procedural requirements for applying hold tags and initiating tracking documentation further inform the agency's conclusion that reasonable opportunities existed to foresee and prevent the installation of the nonconforming PCV.

Consequently, without identifying adverse information concerning the PCV, procurement staff verified a nonconforming component as acceptable for use. As a result of the nonconforming part installation, on April 10, 2020, at 1:15 AM, while conducting monthly technical specification surveillance testing of the HPCI auxiliary oil system, operators identified an oil leak on 23PCV-12 as a result of a tear in the subject diaphragm. Ultimately, the HPCI system was declared inoperable and placed the station into a higher licensee-established risk category (Yellow). ExGen notified the NRC of the inoperability per 10 CFR Part 50.72(b)(3)(v)(D) via Event Notification 54647. The 23PCV-12 valve was replaced and the HPCI system restored to operable status on April 10, 2020, at 8:02 PM.

Corrective Actions: ExGen performed immediate corrective actions to replace the nonconforming HPCI system PCV. ExGen also performed a fleet-wide stand down for procurement staff to conduct additional training. Additionally, ExGen created a separate action for each ExGen site to validate that a similar condition does not exist regarding other of nonconforming materials, parts, or components within their inventory tracking database. Furthermore, ExGen revised its warehouse and procurement procedures, adding steps pertaining to items subject to 10 CFR Part 21 notifications and items with holds.

Corrective Action References: IR 4334315, IR 4348906

Performance Assessment:

Performance Deficiency: The inspectors determined that FitzPatrick's did not comply with the requirements and guidance of quality-related procurement procedures, which contributed to ExGen's failure to adequately identify and control a nonconforming item.

Procedure SM-AA-102, Warehouse Operations, Rev 23, states items that are on hold at one site can be released to another site while on hold only if an action item is created at the receiving site to track resolution of the item before the transfer occurs, and the item is added to the receiving site's hold tag log. Additionally, a hold tag shall be attached to the item upon receipt of the transfer at the receiving site.

On December 16, 2017, FitzPatrick failed to follow SM-AA-102. Adherence to the requirements of this procedure, as well as using guidance provided in SM-AA-300-1001, would have presented a reasonable opportunity for FitzPatrick to identify and assess readily available information that was within the licensee's Catalogue ID database and also linked to the ExGen corrective action program. Consequently, without reviewing readily available adverse information concerning the PCV, procurement staff verified a nonconforming component as acceptable for use. Subsequently, FitzPatrick's maintenance staff installed the nonconforming component which caused the inoperability of the HPCI system.

Screening: The inspectors determined the performance deficiency was more than minor because it was associated with the Equipment Performance attribute of the Mitigating Systems cornerstone and adversely affected the cornerstone objective to ensure the availability, reliability, and capability of systems that respond to initiating events to prevent undesirable consequences. Specifically, the HPCI system was unavailable to perform its safety function as a result of the failed PCV.

Significance: The performance deficiency was assessed by a Region I Senior Reactor Analyst (SRA) and NRR Senior Risk Analysis and determined that prior risk assessment was still valid for the failed HPCI system. The finding was determined to be of low to moderate safety significance (White). The risk important core damage sequences were dominated by internal events, primarily loss of condenser heat sink and loss of main feedwater. The dominant core damage sequence is loss of condenser heat sink, failure of high-pressure injection (HPI), and failure to manually depressurize the reactor. See Enclosure 1 to this final determination report and the Attachment, "HPCI Oil PCV Failure Detailed Risk Evaluation," to the preliminary determination report (ADAMS Accession Number: ML21020A108) for a detailed review of the quantitative and qualitative criteria considered in the final risk determination.

The inspectors assessed the significance of the finding using Appendix A, "The Significance Determination Process (SDP) for Findings At-Power." The inspectors reviewed Inspection Manual Chapter (IMC) 0609, Attachment 4, "Initial Characterization of Findings," and determined the finding affects the mitigating system cornerstone. The inspectors evaluated the significance of this finding using Inspection Manual Chapter (IMC) 0609, Appendix A, "The Significance Determination Process (SDP) for Findings at Power," Exhibit 2 – Mitigating Systems Screening Questions. The inspectors determined that the finding represented a loss of the PRA function of a single train, the HPCI system, for greater than its technical specification (TS) allowed outage time and required a detailed risk evaluation (DRE).

A Region I Senior Reactor Analyst (SRA) performed a detailed risk evaluation. The finding was determined to be of low to moderate safety significance (White). The risk important core damage sequences were dominated by internal events, primarily loss of condenser heat sink and loss of main feedwater. The dominant core damage sequence is loss of condenser heat sink, failure of high-pressure injection (HPI), and failure to manually depressurize the reactor. This final determination report and the Attachment, "HPCI Oil PCV Failure Detailed Risk Evaluation," to the preliminary determination report provide a detailed review of the quantitative and qualitative criteria considered in the final risk determination (ADAMS Accession Number: ML21020A108).

Cross-Cutting Aspect: H.1 - Resources: Leaders ensure that personnel, equipment, procedures, and other resources are available and adequate to support nuclear safety. The cause of the finding was determined to be associated with a cross-cutting aspect of Resources in the Human Performance area because ExGen staff failed to identify and address a nonconformance during verification of the quality of the HPCI system PCV. Specifically, the inspectors determined there were multiple ways for ExGen to reasonably identify a nonconformance associated with the PCV diaphragm which had not been addressed. Furthermore, procurement implementing procedures did not provide adequate guidance to ensure that procedure users would identify and resolve this issue. Having comprehensive steps within the relevant procedure would likely have prevented installation of the defective part at FitzPatrick.

ENCLOSURE 3

NOTICE OF VIOLATION

Exelon Generation Company, LLC
James A. FitzPatrick Nuclear Power Plant

Docket No. 50-333
License No. DPR-59 EA-20-138

During an NRC review in response to a contested violation conducted from June 3, 2021, through September 3, 2021, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

Title 10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.

Title 10 CFR Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components," states, in part, that measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

Exelon Procedure SM-AA-102, Warehouse Operations, Revision 23, prescribes activities affecting quality and measures to control nonconforming components. Procedure SM-AA-102, Attachment 1, step 1.10.6, states "Items that are on hold at one site can be released to another site while on hold only if an action item is created at the receiving site to track resolution of the item before the transfer occurs, and the item is added to the receiving site's hold tag log. A hold tag shall be attached to the item upon receipt of the transfer at the receiving site."

FitzPatrick Technical Specification (TS 3.5.1) requires, in part, that the HPCI system be operable in Modes 1, 2 and 3 with reactor steam dome pressure >150 psig. If the HPCI system is determined to be inoperable, it shall be returned to an operable status within 14 days. If not restored to an operable status, the unit shall be shut down and in Mode 3 within 12 hours.

Contrary to the above, from December 16, 2017, to April 10, 2020, activities affecting quality were not accomplished in accordance with procedures for controlling a nonconforming component and a nonconforming component was not controlled in accordance with documented procedures. Specifically, Exelon failed to initiate an action item at FitzPatrick to track resolution of a nonconforming Pressure Control Valve (PCV) before its transfer occurred, did not add it to the receiving site's hold tag log, and did not attach a hold tag upon receipt. As a result, on December 16, 2017, Exelon did not identify that the PCV's diaphragm required replacement and installed the nonconforming PCV in the High Pressure Coolant Injection (HPCI) system. Consequently, the HPCI system was rendered inoperable prior to April 10, 2020, for a period longer than its TS allowed outage time, and the unit was not shut down and placed in Mode 3 within 12 hours in accordance with requirements.

These violations are categorized collectively as a problem and are associated with a White Significance Determination Process finding.

No response to this Notice of Violation is required since the NRC previously received adequate responses as documented in a letter dated February 26, 2021 (ML21057A190). If you wish to provide additional information for the NRC to consider, you should notify the Region I Regional Administrator verbally within 10 days of receipt of this Notice of Violation, followed by a written response submitted within 30 days of the date of the verbal notification to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region I, and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice. This reply should be clearly marked as a "Reply to a Notice of Violation; EA-20-138".

Your response, if made, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, the licensee may be required to post this Notice within two working days of receipt.

Dated this 3rd day of September 2021.