UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

April 20, 2021

EA-20-138

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

SUBJECT: JAMES A. FITZPATRICK NUCLEAR POWER PLANT – FINAL SIGNIFICANCE DETERMINATION OF A WHITE FINDING WITH ASSESSMENT FOLLOW-UP AND NOTICE OF VIOLATION – NRC INSPECTION REPORT 05000333/2021090

Dear Mr. Rhoades:

This letter provides you the final significance determination for the preliminary White finding discussed in the U.S. Nuclear Regulatory Commission (NRC) letter dated January 21, 2021, which included NRC Inspection Report Number 05000333/2020012 (ML21020A108).[1] The finding, as initially described in the report, involved a failure by Exelon Generation Company, LLC (ExGen) to control defective parts at the Limerick Generating Station (Limerick) and prevent their subsequent use at the James A. FitzPatrick Nuclear Power Plant (FitzPatrick). As described in the subject inspection report, the NRC determined that this finding involved apparent violations of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components" and Criterion VII, "Control of Purchased Material, Equipment, and Services." The receipt and use of the defective part at FitzPatrick resulted in a failure of the High Pressure Coolant Injection (HPCI) system on April 10, 2020. Consequently, ExGen also violated FitzPatrick Technical Specification (TS) 3.5.1, since the HPCI system was determined to be inoperable for greater than the TS allowed outage time.

In a letter dated February 26, 2021 (ML21057A190), ExGen's Mr. Pat Navin, FitzPatrick Site Vice President, provided a written response that acknowledged the circumstances that led to the use of the defective part at FitzPatrick. However, in the response, ExGen also: (1) described Exelon's business services group (which handled the part at Limerick and FitzPatrick) as being a separate corporate entity that works only under the specific facility license at which the staff are physically located and disagreed the Criterion XV violation represented a failure that was within FitzPatrick's ability to foresee and prevent; (2) maintained that FitzPatrick's receipt inspection of the parts was performed in accordance with Criterion VII and other regulatory and self-imposed requirements; and (3) provided information and insights related to the NRC's preliminary characterization of the finding as being of low-to-moderate

[1] Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

(White) safety significance and stated that the significance of this finding could potentially be below the threshold for a White determination.

In the February 26, 2021, letter, ExGen also indicated that the NRC's description of the Criterion VII apparent violation should be analyzed as a backfit under 10 CFR Part 50.109, "Backfitting." On March 3, 2021, Mr. Daniel Collins, Director, Division of Reactor Projects and Mr. Eric D. Miller, Senior Resident Inspector, of my staff participated in a telephone call with ExGen's Mr. Navin and Ms. Adriene Smith, FitzPatrick Director of Organizational Performance and Regulatory Affairs, to obtain clarification on whether ExGen was requesting to enter the backfit appeal process described in NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests." Mr. Navin and Ms. Smith clarified during the call that ExGen was not requesting to enter the backfit appeal process at this time but may choose to formally contest the violations or seek formal review of backfit concerns after the final significance determination is issued. Therefore, the NRC evaluated the remaining items in ExGen's February 26, 2021, letter. A summary of ExGen's positions as provided in its letter, the NRC's response to the points raised by ExGen, and the details of the NRC's conclusion on the safety significance of this issue, are provided in Enclosure 1.

After careful consideration of the information developed during the inspection and the additional information provided in ExGen's February 26, 2021, letter, the NRC staff has clarified the finding and has concluded that the finding is appropriately characterized as White, a finding of low to moderate safety significance. The NRC staff has also determined that the finding involved violations of 10 CFR Part 50, Appendix B, Criterion VII, Criterion XV, and TS 3.5.1, and has revised those violations. Our considerations in reaching these determinations included that: 1) the duration of the finding and violations should be changed from 2010 to 2017 in order to more clearly focus on the time period in which Fitzpatrick had become part of the ExGen Fleet; 2) the NRC's Enforcement Policy holds licensees accountable for the actions of their employees, contractors and vendors, and, therefore, the information in ExGen's response regarding ExGen's corporate structure and internal work practices (i.e. roles and responsibilities of "buyers" and "sellers") would not impact the assignment of this regulatory and enforcement action to Fitzpatrick; and, 3) our review of the additional information provided relative to the risk for this finding did not materially impact our assessment. In fact, a more comprehensive analysis of some of the information provided may have actually resulted in an overall increase in our risk assessment. It should be noted that the violations are strictly focused on compliance with 10 CFR Part 50, Appendix B, but should not be viewed as limiting or impacting any of your internal practices as long as the applicable underlying regulatory requirements are satisfied.

The revised finding is provided in Enclosure 2. You have 30 calendar days from the date of this letter to appeal the NRC staff's determination of significance for the identified White finding. Such appeals will be considered to have merit only if they meet the criteria given in the NRC Inspection Manual Chapter 0609, Attachment 2, "Process for Appealing NRC Characterization of Inspection Findings (SDP Appeal Process)," effective January 25, 2021. An appeal must be sent in writing to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406.

The revised violations are cited in the Notice of Violation (Notice), provided as Enclosure 3. Because the violations are related, they have been categorized collectively as an enforcement problem, which is a way of documenting violations that share a common factor (i.e., cause and effect) rather than citing individually. By grouping such violations, the NRC applies appropriate focus on the underlying factors that caused the concerns, so that licensees can develop effective and comprehensive corrective actions.

In accordance with the NRC Enforcement Policy, the Notice is considered an escalated enforcement action because it is associated with a White finding. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

As a result of this White finding in the Mitigating Systems Cornerstone, the NRC has assessed FitzPatrick to be in the Regulatory Response column of the NRC's Reactor Oversight Process Action Matrix described in Inspection Manual Chapter 0305, "Operating Reactor Assessment Program," retroactive to the fourth calendar quarter of 2020. The NRC plans to conduct a supplemental inspection for this finding in accordance with Inspection Procedure 95001, "Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs," effective January 1, 2021, following Exelon's notification of readiness for this inspection. This inspection is conducted to provide assurance that the root causes and contributing causes of any performance issues are understood, the extent of condition is identified, and the corrective actions are sufficient to prevent recurrence.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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,

Raymond K. Lorson
Digitally signed by Raymond K. Lorson
Date: 2021.04.20 14:07:45 -04'00'

Raymond K. Lorson
Deputy Regional Administrator

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

Enclosures:
As stated

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ENCLOSURE 1

NRC RESPONSE TO INFORMATION PROVIDED IN THE
EXGEN LETTER DATED FEBRUARY 26, 2021, REGARDING A
HIGH PRESSURE COOLANT INJECTION FINDING

As discussed below, the NRC staff reviewed the points raised by Exelon Generation Company, LLC (ExGen) and determined that the proper characterization of the finding remains of low--to--moderate safety significance (White). The NRC staff has also determined that the finding involved violations of 10 CFR Part 50 Appendix B, Criterion VII, Criterion XV, and TS 3.5.1.

However, the NRC staff has revised the finding and violations as described in Enclosures 2 and 3. Specifically, the NRC staff determined that: 1) the duration of the finding and violations should be changed from 2010 to 2017 in order to more clearly focus on the time period in which Fitzpatrick had become part of the ExGen Fleet; 2) the NRC's Enforcement Policy holds licensees accountable for the actions of their employees, contractors and vendors , and, therefore, the information in ExGen's response regarding ExGen's corporate structure and internal work practices (i.e. roles and responsibilities of "buyers" and "sellers") would not impact the assignment of this regulatory and enforcement action to Fitzpatrick; and, 3) our review of the additional information provided relative to the risk for this finding did not materially impact our assessment. In fact, a more comprehensive analysis of some of the information provided may have actually resulted in an overall increase in our risk assessment. It should be noted that the violations are strictly focused on compliance with 10 CFR Part 50, Appendix B, but should not be viewed as limiting or impacting any of your internal practices as long as the applicable underlying regulatory requirements are satisfied.

SUMMARY OF EXGEN COMMENT – Independence of Licensed Facilities

ExGen stated that the James A. FitzPatrick Nuclear Power Plant (JAF) licensed facility and the Limerick Generating Station (LIM) licensed facility are legally independent entities with separate NRC-issued operating licenses that are supported by common resources as part of the larger ExGen fleet. Support resources provided by the Exelon Business Services Company (BSC) and which are assigned to individual licensed facilities are subject to the specific operating license(s) of the facility to which they are assigned. Therefore, the ability to foresee and prevent the deficiency at LIM (seller) in 2010 should not be a basis for the deficiency being foreseeable and preventable by JAF (buyer) in 2017.

NRC RESPONSE

Although each facility maintains separate NRC operating licenses, the JAF License No. DPR-59 and the LIM License Nos. NPF-39 and NPF-85 each specify Exelon Generation Company, LLC as the licensee. However, more salient to this issue is that, upon joining the ExGen fleet in 2017, JAF began to utilize and have access to many of the same processes and programs as LIM and other ExGen sites, including the corrective action program and component tracking database. The NRC identified that both of these programs contained information pertaining to the defective high pressure coolant injection (HPCI) system oil pressure control valve (PCV).

The performance deficiency and apparent violations as originally presented in NRC inspection report number 05000333/2020012 described in full the circumstances that led to the installation of the defective PCV at JAF. This included describing the failures that occurred in 2010 at LIM in response to a Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 notification when staff at that site did not segregate or place an electronic hold on the PCV, contrary to Exelon procedures. The NRC staff considered the comments in ExGen's February 26, 2021, letter pertaining to the finding and acknowledges that in 2017, ExGen staff could not have prevented the process breakdown that occurred at LIM in 2010. However, the NRC staff maintains that it was reasonable in 2017 for ExGen staff to have identified the information about the defective component that was readily available in the component tracking database and corrective action database; common ExGen programs utilized by both sites. For example, when receiving the part, ExGen staff at JAF accessed the component tracking database and removed a 'hold' due to a shelf life concern. The 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'. Additional detail about the NRC staff's conclusions related to the finding is provided in the NRC response to ExGen's comment below related to the Criterion VII violation.

In light of these considerations, the NRC staff revised the finding and violations to properly focus on the events that occurred in 2017. The circumstances of the 2010 failures are still included in the Description Section of the finding as background information. The revised finding and violations are provided as Enclosures 2 and 3 to this final determination report.

SUMMARY OF EXGEN COMMENT - 10 CFR Part 50, Appendix B, Criterion XV

The 10 CFR Part 50, Appendix B, Criterion XV violation and associated performance deficiency occurred at the LIM licensed facility in 2010 by support resources working in direct support of the LIM operating licenses. The Inspection Report identified an apparent violation of 10 CFR Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components" based on the failure to properly identify and segregate non-conforming material that was identified and communicated to LIM by a General Electric-Hitachi (GEH) 10 CFR Part 21 notification. The JAF Causal Analysis to address the HPCI failure determined that as part of LIM's response to the 2010 GEH 10 CFR Part 21 notification, LIM personnel failed to follow procedure requirements to place an electronic hold and segregate the defective part. This allowed the defective part to be sold to JAF in 2017 without being notified of the deficiency.

NRC RESPONSE

As described above, the NRC staff acknowledges that prior to 2017, ExGen staff at JAF could not have prevented the 2010 failures at LIM related to identifying and segregating the non-conforming PCV since JAF was not transferred to ExGen until March 2017. Therefore, the finding and the related Criterion XV violation have been revised accordingly. However, the NRC staff maintains that the remaining aspect of the finding and Criterion XV violation is attributable to JAF. Specifically, the regulation requires that licensees establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation and to accept, reject, repair, or rework nonconforming items. Regardless of the past failures to identify and segregate the nonconforming PCV, in 2017 ExGen again did not control and reject the nonconforming component, resulting in its acceptance and installation at JAF. The NRC staff maintains that JAF is responsible for this failure.

In particular, the activities performed in 2017 to transfer the part between LIM and JAF and to accept and use the part at JAF were performed in support of ExGen and the JAF license. As noted in Section 1.2 of the NRC Enforcement Policy, it is NRC policy to hold licensees responsible for the acts of their employees, contractors, or vendors and their employees, and the NRC may cite the licensee for violations committed by its employees, contractors, or vendors and their employees. Therefore, regardless of the physical locations of the involved staff, their reporting authority under the greater Exelon Corporation structure, or the typical responsibilities of these individuals to support the licensed facilities at which they are located, when individuals are directed by a licensee to perform activities that affect that NRC licensee, that licensee assumes the responsibility for violations caused by the individuals' actions or inactions.

Furthermore, the NRC staff maintains that, in consideration of the common procedures and processes shared between LIM and JAF, it was reasonable for ExGen staff at JAF to have foreseen and prevented the acceptance and use of the nonconforming PCV and that ExGen staff at JAF should have identified and rejected the defective item during receipt inspection activities conducted in December 2017. Additional information about the finding is provided in the NRC response to ExGen's comment below related to the Criterion VII violation.

SUMMARY OF EXGEN COMMENT - 10 CFR Part 50, Appendix B, Criterion VII

The receipt inspection completed at JAF in 2017 was performed consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion VII and the JAF Quality Assurance Program (QAP) requirements and, therefore, does not constitute a failure to follow a regulatory or self-imposed standard. The Inspection Report identified a Violation of 10 CFR Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services" based on the failure to identify, during receipt inspection, that the purchased valve was the subject of a 2010 10 CFR Part 21 notification. ExGen has confirmed that the JAF receipt inspection was performed consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion VII and the JAF QAP and, therefore, was not a failure to follow a regulatory or self-imposed standard. Additionally, without further actions beyond these requirements, the receipt inspector could not reasonably have been expected to identify that the valve was the subject of the 2010 10 CFR Part 21 notification based on the documentation provided by the seller (LIM).

NRC RESPONSE

Title 10 CFR Part 50, Appendix B, Criterion VII requires that licensees establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to procurement documents. However, the measures implemented by ExGen in 2017 did not identify the nonconformance of the PCV. A licensee's QAP and the processes developed to implement that program provide the mechanism for the licensee to comply with 10 CFR Part 50, Appendix B; they do not serve as replacements or alternatives to these regulatory requirements. Therefore, if a licensee's QAP, or implementation of the QAP, fails to ensure that the licensee meets an Appendix B requirement, the licensee is in violation of that requirement.

The NRC staff maintains that, in this case, the receipt inspection performed at JAF (the intended measure to assure purchased material conformed to procurement documents) was not sufficient to meet this Appendix B requirement. Specifically, as noted in the finding description in Enclosure 2, the ExGen Quality Assurance Program Manual (QAPM), Revision 0, Section A, "Management," stated, "the requirements and commitments contained in the QAPM are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations." Section 5, "Procurement Verification," required a program to be established and implemented to verify the quality of purchased items and services. Section 6, “Identification and Control of Items,” required a program to be established and implemented to identify and control items to prevent the use of incorrect or defective items. The receipt inspection, conducted using ExGen Procedure SM-AA-102, Revision 23, “Warehouse Operations,” implemented these procurement verification requirements. This receipt inspection did not identify that the PCV contained a defective diaphragm.

The NRC staff maintains that it was reasonably within ExGen’s ability to foresee and prevent the use of the nonconforming PCV at JAF. In particular, information about the defective diaphragm was located in both the ExGen component tracking database and corrective action database. The inspectors reviewed the component tracking database and determined that the issue report (IR) associated with the 10 CFR Part 21 report should have been reasonably identified by a qualified procurement engineer. Notably, when receiving the part, ExGen staff at JAF accessed the component tracking database and removed a 'hold' due to a shelf life concern. The 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.' The staff also noted that the information was available to staff involved with the transfer of the component to JAF through the ExGen corrective action program, because the issue report was noted in the component tracking database and had not been resolved at the time the part was moved to and accepted at JAF. As such, it was reasonable for ExGen staff responsible for, and in control of, both sides of the internal transaction that occurred in order to effect the movement of the PCV from LIM to JAF in 2017 to have identified the Part 21 information related to the PCV.

SUMMARY OF EXGEN COMMENT – Uncertainties Input for Significance Determination

ExGen provided new information and additional insights which the licensee stated reduce some of the calculational uncertainties that weigh into the Significance Determination (SDP). ExGen indicated that the uncertainties are smaller than characterized in the NRC inspection report and could potentially result in a significance below the threshold for a White determination.

1. The JAF Engineering staff has performed additional engineering reviews related to the maximum oil leak rate from the HPCI system PCV which provide information supporting the leak rate used in the JAF SDP analysis.

2. JAF Operations staff have gathered and documented additional timeline and performance data which better characterizes the uncertainty in the analysis of operator credit for identification and restoration of HPCI oil.

3. JAF Operations and Engineering staff have validated information regarding Main Control Room (MCR) staff operation of HPCI during transient conditions.

4. JAF Engineering and Probabilistic Risk Assessment (PRA) Staff provided information regarding incorporation of Electric Power Research Institute (EPRI) fire realisms and the associated reduction in fire ignition frequencies (FIFs) for areas that are risk important relative to HPCI operation.

NRC RESPONSE

The NRC staff reviewed the information in ExGen’s written response and determined that the proper characterization of this finding overall remains of low-to-moderate safety significance

(White). The NRC staff agreed that ExGen's use of revised fire ignition frequencies from those used in the NRC risk determination was appropriate. However, the slight reduction in the calculated increase in core damage frequency (CDF) due to a lower fire risk estimate did not impact the overall NRC risk assessment and significance determination process conclusion. The following details the NRC's assessment regarding the four areas of input provided by ExGen for consideration in the SDP:

1. <u>Calculated Maximum Oil Leak</u>

   <u>NRC Response</u>

ExGen utilized a slightly lower minimum leak rate of 0.19 gallons per minute (gpm) with a maximum leak rate of 2.8 gpm, which considered higher operating oil temperatures when the system would be in service. The NRC SDP analysis utilized a minimum leak rate of 0.28 gpm with a maximum leak rate of 3.65 gpm to arrive at a weighted leak rate estimate which would account for the probability of an early re-positioning of the degraded, nonconforming Part 21 pressure control valve (PCV). As stated in the detailed risk evaluation (DRE), the NRC used industry data to estimate a probability that an early HPCI system trip would lead to a large leak from the PCV. The early probabilistic trip of the HPCI system was determined to be 0.15 through several different methodologies as described within the DRE. However, the DRE described how this number may be an underestimation of the actual data, even though used in the development of the weighted leak rate estimation. It is not uncommon for the HPCI system to be tripped early for level control during postulated events and a sample of industry data reviewed, reflected that an early HPCI trip could occur up to 50 percent of the time based on a review of a sample of Licensee Event Reports. This illustrates in part, the uncertainty with evaluating what leak rate would have existed within this degraded part during a postulated event where HPCI would have responded. The NRC noted in the DRE that the initial leak rate subsequently identified by ExGen was reported as one pint in two minutes, although computer information provided to the analysts indicated the pump was run with the PCV at normal pressure for only one minute. Of further concern related to the accuracy of ExGen's estimated leak rate was the inconsistency between the leak rate assumed in the analysis and the initial leak of 0.25 gpm leak rate that was verbally reported to the resident inspector staff. As a result, the analyst determined that the leak rate values provided in the ExGen analysis and follow-up letter were uncertain, underestimated the actual leak rate, and are not viewed as credible.

When ExGen attempted to quantify the leak rate through a second start of the auxiliary oil pump, the pump was secured after 30 seconds based on a much larger leak rate that overwhelmed the collection apparatus used to measure the oil quantity. The 1.3 gpm was based on the captured oil for the 30 second run. The analysts noted that the second run was once again performed with the auxiliary oil pump (AOP), which develops a lower pressure (85-95 psig) than if the shaft driven oil pump (SDOP) was started (105-110 psig) during an actual run. The output of the controlling pump pressure is controlled by a main oil system PCV, which will control downstream pressure to 38 psig. However, there is some response time by the main PCV resulting in a slightly higher pressure pulse (i.e. stress) that was expected to have been absorbed by the downstream nonconforming PCV diaphragm. This further adds to the uncertainty, and validity of any measured oil leak when it was performed under non-operating conditions. Actual turbine operating conditions result in different dynamics relative to the oil system, with the potential for an even larger tear on the weakened nonconforming pressure control valve diaphragm.

Notwithstanding the multitude of uncertainties mentioned above, if the NRC were to adjust their weighted leak rate estimate by using a maximum leakage capped at 2.8 gpm or even slightly lower as suggested by ExGen, this would have an inconsequential effect on the amount of time assumed and calculated within the NRC DRE before the SDOP and AOP would lose suction due to the loss of oil inventory. The NRC determined the information provided by ExGen would have no substantive impact in this area, as the uncertainties overwhelm the ExGen's engineering analysis, including the inputs used in that analysis, for the calculated maximum oil leak rate.

2. Oil Leak Mitigation/Credited Operator Actions

ExGen's position is that giving no credit for operators to recover the HPCI system in the event of an oil leak does not recognize proceduralized actions that the operators would take and be capable of executing. ExGen contends that operating procedure, OP-15, Revision 68, Section G.10, "Adding Oil to HPCI Sump with HPCI in Service," provides explicit guidance to maintain oil in the running level band. ExGen states that operators performed a timed walkdown for recovery actions to maintain adequate oil level in the HPCI sump in the event the HPCI PCV diaphragm had a tear. The walkdown was reported to result in operators successfully restoring oil in approximately 27.5 minutes. ExGen stated that with regards to the time until the leak is located, there are several considerations. OP-AA-103-102, "Watch-Standing Practices" outlines expectations for non-licensed operators to monitor all equipment they are responsible for. This procedure also establishes post-start and post-shutdown system walk down requirements to ensure expected system and components response. Lastly, ExGen stated that if the control room received the HPCI Turbine Bearing Oil Pressure Low annunciator and HPCI operation is required, the main control room (MCR) operators would respond as follows:

1. If the HPCI Auxiliary Oil Pump did not auto-start, then attempt to manually start the pump from the control room.

2. If the annunciator does not clear, then send an operator locally to investigate the reason for the loss of oil pressure.

3. The field operator would observe a large amount of oil at the HPCI skid and check HPCI oil sump level.

4. Operations would perform actions per OP-15, Section F "Shutdown" to secure the AOP when the HPCI turbine is not rotating.

5. The control room would direct the field operator to add oil to the HPCI sump.

ExGen's position is that the oil leak can be effectively managed with readily available equipment and procedurally directed operator actions.

NRC Response

ExGen procured a Vendor Report, EC-631895, "Technical Evaluation to Support Availability of HPCI System Due to Oil Leak in PCV-12," dated June 18, 2020, which was developed regarding the oil leak and determined that there is a nominal 1-inch drop in the oil sump for every 13 gallons of oil. During the postulated events evaluated in an SDP such as this, there are multiple assumed failures of various equipment that lead to a path of core damage. For these events, various equipment may be automatically started from emergency diesel generators to the reactor core isolation cooling system (RCIC), HPCI, and a multitude of other equipment. Thus, there can be a multitude of potential response areas required for plant operators, which directly affects their response time. As noted in the calculation of the maximum oil leak section above, a probabilistic leak rate could be in the area of 0.7 gpm to an assumed maximum leakrate in the area of 2.8 gpm or higher, depending on the heatup rate of the oil and any other factors which would have contributed to the PCV diaphragm tear. As noted above, a plant operator may enter the HPCI cubicle and check the oil standpipe and with various potential oil leak rates possible, the indicated level would likely be well within the sight glass, with zero other operational abnormalities occurring or noticeable, including HPCI turbine and pump bearing temperatures. This PCV is not located in the front of the machine and depending on when an operator would check the machine, this leak may not be identified.

The NRC noted that the design of the HPCI control oil system at FitzPatrick does not have a sump low-level alarm. Additionally, during a leak, it is apparent that other critical early cues of higher bearing temperatures, low oil pressures, and low sump level would not be available through instrumentation and would not provide ensured identification of a notable leak prior to complete failure of the system to operate. Additionally, the assumed leak rate in this SDP evaluation has unquantifiable uncertainties as mentioned above, with the potential to have been larger than measured in the relatively colder non-turbine operating condition when the tear was initially generated. The sequence of events per this design and nonconforming PCV, would be a continued leak at an uncertain rate, with a silent effect on the system, the controls, and the annunciators, as there would be no abnormalities until the system would terminate operation due to complete suction loss of the shaft-driven oil pump (SDOP). As noted above, the only alarm or cue would be the turbine bearing oil pressure, which would likely not annunciate even with a large leak, due to a controlling PCV maintaining 38 psig upstream, which would serve to compensate for the degraded PCV diaphragm leak, and continue to provide downstream flow and pressure to the bearings.

The first absolute automatic cue for the operators would be this alarm, but it appears, per the design, that it would come in after the SDOP would lose its suction prime due to low oil level, resulting in a loss of discharge pressure. This would drop pressure to the control valve actuator rotating gear pump and result in closure of the control steam valves as well as the turbine stop valve. The SDOP will then spin down, with the main auxiliary oil pump (AOP) starting on low oil pressure at around 35 psig. A further uncertainty is the AOP will start and run with no suction head, likely cavitating as it continues to run without an adequate oil supply. As noted above, the operators would actually be instructed to start the AOP if it didn't auto start even with an inadequate suction pressure. When an operator would arrive in the area, there would be 60 to 65 gallons or more of hot oil within the skid area. There would be no leak visible or identifiable, because the nonconforming PCV would have closed on loss of pressure and there would be no pressure to drive any further leakage.

In this condition, it would not be obvious if there had been a pipe crack, a severe crack in the various control oil piping and fittings, or complete failure of the oil system, and it's likely operators would be challenged to identify where the oil came from with 120 degree oil potentially scattered within the skid area. Furthermore, there is another uncertainty with how long the AOP would have been running, as it does not automatically receive a trip signal, resulting in cavitation without any oil supply and/or if it would have damaged itself. ExGen states they would enter section G.10, "Adding Oil to HPCI Oil Sump with HPCI in Service." With this scenario, however, HPCI would not be in-service as it would be secured automatically (steam valves closed) due to the failure, contrary to the procedure entry definition/description.

OP-15, G.10, as written is intended to gather pre-filtered oil and if not prefiltered, to obtain an oil filtration device and extension cord and fill an oil transfer container from labeled oil barrels in the lube oil storage room per engineering direction. Again, it should be noted, it is very likely the leak source would be difficult to determine at this point. Additionally, hooking up a funnel to a leak source appears to not be proceduralized and the placement would not even be recognized in this scenario, not to mention the effects of running the oil system below the AOP suction capability, with air entrainment or other kinds of potential adverse effects on the AOP and motor.

Lastly, if recovery of HPCI in this situation became a priority as suggested in ExGen's response, an operator would have to fill the sump by finding a portable pump along with electricity for "said" pump (i.e. for LOOP scenarios there likely isn't normal outlet power), then keep-up with the potential large leak rate while looking for the leak point. Then, once the leak point is identified, the operator needs to build the apparatus to route the leak to the sump. Additionally, a recovery event such as this includes a human error probability (HEP) assessment which would need to be analyzed on how it may affect the most dominating basic event in this risk analysis (failure to depressurize event). This scenario will take cognitive ability to detect what happened, make decisions and to understand the success path to restore the high pressure system, including its recovery feasibility. In core damage scenarios or cutsets, this HPCI recovery event would be accompanied by the SPAR model depressurization basic event (ADS-XHE-XM-MDEPR). This event would now likely justify including a diagnosis as well as an action assessment due to the cognitive nature of understanding and deciding if the operator could restore a high pressure injection source in time while reactor vessel level is lowering, while waiting until EOPs direct depressurization with the potential thought that HPCI is close to being brought back to service. Adding this diagnostic piece to the normal depressurization event in the SPAR model raises the potential for a higher failure probability by almost an order of magnitude even considering extra time for diagnosis and action to depressurize in the SPAR-H calculation. Therefore, by including a HPCI recovery event, the failure to depressurize event could now be considered for increased failure probability due to the diagnosis needed in this situation. A rough calculation has shown that this can increase one of the dominating postulated core damage event scenarios such as a loss-of-condenser-heat sink for a 38-day exposure (DRE risk of 4E-7/yr) to an increased risk of 2E-6/yr for this one event.

In summary, recovery credit including the challenges accompanying this condition, should likely be considered for an increased failure in the ADS-XHE-XM-MDEPR basic event, which may have a significant increase in the end result of the previous risk determination and make the effects of recovery credit a non-substantive issue relative to lowering the calculated increase in CDF/yr for this event.

Notwithstanding this, based on the above uncertainties, the lack of cues within the system design, the uncertainties with the leak rate, the uncertainty with the timing and ability to detect the leak through a walkdown post event for many systems, operator recovery was determined not to be a feasible action in the primary base case evaluation of the condition, and the information provided has no substantive effect on that conclusion. However, as is always prudent, the NRC analysts performed a sensitivity study using appropriate considerations of recovery difficulty in the DRE (Cases 3 and 4, used 1 out of 5 recovery) within the report giving some credit for recovery. This sensitivity did not account for an evaluation of increasing the failure to depressurize (basic event) through the model. If this became a base assumption the SRA believes it would be appropriate to re-analyze for the above consideration which would likely result in a notable overall increase of the calculated CDF for the HPCI PCV failure.

3. HPCI Operations During Transient Conditions

ExGen has stated that while operating HPCI with drywell pressure greater than 2.7 psig, the full flow path test return valves close to divert all flow to the Reactor Pressure Vessel (RPV). To control RPV water level, the main control room (MCR) operators would dial the flow controller back as needed to control the injection rate and maintain level within the required bands established in the station Emergency Operating Procedures (EOPs).

ExGen also acknowledged that running the HPCI pump on minimum flow with the full-flow test return valves closed, is not preferred for long term reliability. However, in response to transient and accident conditions, operations in this manner is consistent with guidance in station EOPs by ensuring the HPCI system remains available as a high-pressure water source. As such, MCR operators would not secure HPCI if it was running on minimum flow nor would the pump be damaged during a transient or accident response to the point that sufficient flow could not be developed.

NRC response

The NRC acknowledges that the station EOPs direct level control within the proper bands, using any systems that may be available. The NRC also recognizes the difficulty with controlling level using HPCI for various events. This is illustrated in the Fitzpatrick RCIC System, B 3.5.3, technical specification basis document referring to Actions A.1 and A.2. The Bases states for transients and certain abnormal events (i.e. which drive the NRC's risk SDP evaluation), with no loss-of-coolant-accident, RCIC (as opposed to HPCI) is the preferred source of makeup coolant because of its relatively small capacity, which allows easier control of the RPV water level. Thus, there is a limited time allowed to restore RCIC to an operable status. This simply confirms the challenge of operating HPCI under conditions where there may be lower makeup requirements.

OP-15, Revision 68, "High Pressure Coolant Injection," System Description, describes the design operating conditions for when pump discharge water flows through the feedwater line into the RPV, that HPCI will continue to inject 4250 gpm until RPV water level reaches 222.5 inches, then HPCI will trip on high RPV water level. If RPV water level lowers to 126.5 inches, HPCI will auto-initiate following a high RPV water level trip. This simply explains the automatic design of the system where it is designed to continually, with no operator action, inject, trip and reset as required. However, the NRC understands that this is not the preferred operation or response as operators are trained and instructed to control RPV level within the proper station EOP designated band without allowing HPCI trips; this description from OP-15 simply illustrates the design of the system.

As documented in the NRC SDP evaluation, while we have found no restriction within the Fitzpatrick operating procedures specific to HPCI operating in the minimum flow mode taking water from the condensate storage tank and depleting it to the torus, there are some uncertainties with this operating mode (i.e., low flow only available). Specifically, there are Terry Turbine Maintenance guides and technical reports/industry guidance applicable to HPCI, which recognize that the design basis is to deliver constant flowrate to the RPV over a wide range of reactor pressures. If reduced vessel injection flowrate (i.e., match decay heat for non-LOCA transients), is required to control level, this is an off-design operation and is time-consuming and requires operator attention to control. The pump head versus flow characteristics are relatively flat as flowrate decreases below rated volume and it is recognized that reduced flowrates below a nominal 75 percent below design, will likely cause system instability within the control system.

Additionally, typical Terry turbine guidance cautions that the pump/turbine controls should not be operated less than 50 percent of rated flow for a sustained period of time. Further guidance states that operating at 10 to 20 percent minimum flow is intended for startup and shutdown only and severe internal cavitation at high head conditions can result in pump damage.

According to ExGen's above statement, operators would not secure HPCI in the minimum flow mode and therefore may have run the pump in this off-normal condition for long periods of time in postulated events. There are several uncertainties with the definitive nature of this statement. First, OP-15, Attachment 4, HPCI AUTO INITIATION VERIFICATION and SUBSEQUENT ACTIONS, recognizes appropriately, that when operation of HPCI below 3000 gpm is required, monitoring of the system operation frequently is required to ensure proper operation and if oscillations occur then the system is to be operated with the controller in manual. The NRC recognizes that if oscillations occur, the flow controller will result in increasing and decreasing speed changes. This by itself would create the need for the main PCV within the oil system to respond to control to 38 psig with changes in the SDOP speed. Any small delays in PCV response could result in pressure changes and or small stress changes to the downstream degraded PCV diaphragm. Additionally, OP-15, Attachment 6, "HPCI Operation Flowchart," requires verifying HPCI parameters per Section D of OP-15. These parameters include monitoring outboard-end and pump-end vibration levels to ensure less than 0.385 inches per second.

Because this operation may occur for extensive time periods through a mission time up to 15 hours, long periods of HPCI operation can be expected in this condition. The HPCI system is not normally run for long periods on minimum flow and hence there likely is no data available on system effects. Therefore, an additional uncertainty would be if this mode of operation (long term minimum flow operation) would challenge the procedure's acceptable pump vibration levels with the expected cavitation with the pump internals. If vibration levels would be exceeded, this would be a decision point with regard to operation of the system (i.e. should the system be used to fill to the EOP level zone at higher rates, then secured and restarted when boil-off reduced level back to the lower end of the control zone). It is also unknown how internal pump cavitation may affect the HPCI skid itself and if there could be any adverse effects on resonance vibration on the nonconforming degraded PCV diaphragm condition through the mission time, while running in this off-normal condition. It should be noted if there would be an adverse effect on the nonconforming PCV; this could extend the exposure time going backwards, factoring in all of the uncertainties mentioned above.

In addition, the DRE documented the basis for the 0.15 trip rate of the turbine based on industry operating data, which is relevant to the expected operator responses for operation of the HPCI turbine.

In summary, the statement concluding the operators would stay on minimum flow has uncertainty with the ability to do that, considering the system is designed for much higher flowrates per its design. Lastly, extended operation on minimum flow will deplete the preferred condensate storage tank (CST) suction source to the torus, resulting in additional challenges of CST source availability for the longer- term mission and also on control rod drive pump capability as the CST is depleted for certain events. Because of the above uncertainties, the NRC SDP used an exposure time above 38 days (i.e., 59 days) for only a very few applicable events.

Notwithstanding the many uncertainties identified above with the definitive statements of not securing HPCI if operating on extended minimum flow conditions, the NRC in response to this letter and statement of expected operations, revised the 59-day exposure times for the events to 38 days to determine its impact on the SDP. The result was there was an inconsequential difference for the few events where the longer exposure time was used and the final determination of a low to moderate risk significant issue remained unchanged.

4. Fire Analysis

The JAF PRA staff developed and used updated fire modeling ignition frequencies for the fire areas reviewed in the NRC SDP analysis. The NRC analysis had used fire scenario frequencies listed in the Fitzpatrick Fire PRA notebook at the time of the evaluation (JF-PRA-021.11 “James A. FitzPatrick - Fire Probabilistic Risk Analysis Summary & Quantitative Notebook,” Revision 2). ExGen’s position is that the fire ignition frequencies in the JAF analysis should be used because they are based on more realistic fire modeling frequencies.

NRC response

The NRC concurs that the JAF updated fire frequencies would result in smaller frequencies and reduction in the NRC fire model risk assessment. The SPAR Delta CDF increase was calculated to be 9.9E-7/yr. Using the revised frequencies, the Delta CDF in Table 2 of ExGen’s letter resulted in a total of 5.6E-7/yr risk increase. It should be noted fire risk was not a dominant contributor to this risk assessment.

NRC Overall Risk Determination Conclusion

The NRC does not believe the information and analysis presented by ExGen is substantive in its nature in reducing the uncertainties and/or influencing a change in the final determination of significance below the threshold for a White determination, in part, for the various reasons mentioned above.

However, the NRC analysts reviewed all the information presented by ExGen in their February 26, 2021 letter and performed a final sensitivity using all the suggested considerations provided by ExGen’s supporting information.

The NRC analyst’s final sensitivity revised the exposure times from 59 days to 38 days based on the potential for survival of HPCI remaining on minimum flow and never being tripped or secured during the course of mission times up to 24 hours. The NRC analysts used the HPCI recovery credit (0.8) as documented in the original DRE, however it should be noted this was not the base case and they did not evaluate the effect this could have or potential increase on the dominant basic event, (failure to depressurize), as mentioned above in the recovery section. Finally, the analysts used the lower fire risk increase presented by ExGen. With all these sensitivity changes, the increase in risk for internal events, flooding, fire and seismic resulted in a revised conditional increase in CDF/yr of a nominal 2E-6/yr. It should be noted these changes were only performed as a sensitivity as the NRC determined the information presented had no substantive effect on the risk outcome (i.e., 3E-6/yr) and did not change the original SRA PRA modeling assumptions, except for the fire ignition frequencies used. All other PRA modeling assumptions have been documented and justified within the existing DRE.

Although some of the information provided within this letter may suggest there could be a potential for an increase in risk over that which was originally calculated, the analysts believed the original estimate remains a valid best-estimate given the information and uncertainties relevant to this issue.

RISK SUMMARY

In summary, the NRC staff carefully reviewed the responses provided by ExGen. The NRC staff acknowledges and considered ExGen's viewpoint, but ultimately determined that the new information did not alter the NRC's original risk assessment outcome or methodology as described in Inspection Report 05000333/2020012, dated January 21, 2021 (ADAMS Accession Number: ML21020A108). Based upon the additional information provided, the NRC staff concluded that the finding remains appropriately characterized as White.

ENCLOSURE 2

REVISED FINDING

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

The inspectors documented a self-revealed White finding and related violations of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services," and Criterion XV, "Nonconforming Materials, Parts, or Components," because Exelon Generation, LLC (ExGen) did not adhere to requirements to ensure that a high pressure coolant injection (HPCI) system oil pressure control valve (PCV) conformed to all procurement requirements. Consequently, ExGen did not reject the defective PCV, as identified in a 10 CFR Part 21 notification. As a result, ExGen accepted and installed the part at FitzPatrick on December 16, 2017. The HPCI system was subsequently declared inoperable on April 10, 2020, during a planned surveillance test due to the defect identified in the Part 21 notification. This also caused the HPCI system to be inoperable for greater than its technical specification allowed outage time in accordance with NRC reportability guidelines.

<u>Description</u>: 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.

On November 7, 2017, the NRC issued Order NRC-2017-0177 establishing Exelon Generation, LLC (ExGen) as the owner, operator, and holder of the FitzPatrick Renewed Facility Operating License No. DPR-59. ExGen owns or co-owns and operates 22 nuclear reactors at 13 sites in four states. As stated, in part, in the application dated August 18, 2016 (ML16235A081), and approved by NRC Order NRC-2017-0177, ExGen provided that:

> *"…integration of the operation of FitzPatrick with Exelon Generation's current fleet of nuclear power plants, will allow consolidated operations of FitzPatrick and the other nuclear units operated by Exelon Generation. The seamless integration of FitzPatrick into Exelon Generation's operations will create a single organization with responsibility over all of the plants for which it is the licensed operator."*

Exelon Corporation, the parent company of ExGen, also operates a central supply organization (Business Services Company, LLC (BSC)) that provides support for day-to-day nuclear station (site) operations with a dual reporting relationship to the centralized supply organization and the site organization. ExGen implements a fleet-wide quality assurance program, along with procurement and warehouse procedures for all its associated nuclear stations to verify, store, and move components between stations using BSC personnel. Once accepted within the ExGen Quality Management System, a component can be installed at the site of receipt, or moved and installed at another facility.

On December 11, 2008, ExGen received, inspected, and accepted a HPCI oil pressure control valve, stock code 11466532. On July 1, 2010, ExGen was notified of a defective part when General Electric-Hitachi issued MFN 10-192 (ML101820160), “Part 21 Reportable Condition Notification: Failure of HPCI Turbine Overspeed Reset Control Valve Diaphragm.” The Part 21 identified a vulnerability associated with the HPCI system oil PCV actuator diaphragm due to a manufacturing error. This error resulted in inadequate fabric reinforcement that is critical to ensure durability and reliability of the diaphragm, preventing tearing of the diaphragm when used in the HPCI turbine lube oil system turbine trip and reset valves (PCVs). The failure of the HPCI system PCV’s diaphragm results in a loss of HPCI system turbine lubricating and control oil through the failed diaphragm. According to the Part 21 notification, “depending on the amount of oil lost and the system demands, this loss could ultimately result in a failure of the HPCI system.” ExGen engineering staff entered issue report (IR) 1086768 into their corrective action program and assigned actions including direction to BSC staff to address the Part 21.

Exelon procedure SM-AA-102, “Warehouse Operations,” Revision 14, Attachment 3, Section 1.5.2 required, “Items found to be of suspect quality or deficient (e.g., items identified externally via 10 CFR Part 21 defect reporting or items identified internally by maintenance) shall be:

1. Placed on ‘Hold’ status electronically to prevent allocation and inadvertent issue. In Passport this may require the item to be issued from stock, then returned, moved from [pending] to [hold] status.

2. Physically segregated from acceptable items with the same Catalog ID/Stock Code.”

BSC staff working for ExGen at Limerick identified a PCV subject to the Part 21 notification at the Limerick facility, but did not segregate or place an electronic ‘hold’ on the PCV in their component tracking database to prevent PCV installation with the defective diaphragm as required by internal procedures following the July 1, 2010, Part 21 notification. BSC staff documented the nonconformance in the component tracking database which referenced IR 1086768. However, procedure SM-AA-102 did not include a standard method to document Part 21 deficiencies within the component tracking database. Instead, there were several options for documenting a Part 21 notification within this system, and ExGen relied on skill of the craft for determining how to implement the procedural requirement.

On November 19, 2010, SM-AA-102 was revised to require, “conspicuous signage that shows these items are on hold,” in addition to the electronic hold and physical separation. However, BSC staff at Limerick did not use conspicuous signage on the PCV.

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. During a HPCI maintenance window in December 2017, ExGen replaced the HPCI PCV diaphragm and spring as part of preventive maintenance. Following maintenance, ExGen was unsuccessful at restoring HPCI due to inadequate pressures in the oil system. ExGen did not have a replacement PCV on site at the time, and subsequently located the subject PCV at Limerick.

To effect the movement of the part, BSC staff at Limerick and FitzPatrick followed the process prescribed in the ExGen Quality Assurance Program Manual (QAPM), Revision 0. QAPM Section A, “Management,” stated, “the requirements and commitments contained in the QAPM are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations.” QAPM, Section 5, “Procurement Verification,” required that, “a program is established and implemented to verify the quality of purchased items and services at intervals and to a depth consistent with the item's or service's importance to safety, complexity, and quantity and the frequency of procurement.” QAPM, Section 6, “Identification and Control of Items,” required a program to be established and implemented to identify and control items to prevent the use of incorrect or defective items.

The inspectors determined that, in spite of utilizing the above process, staff involved with transferring the HPCI PCV and inspecting and accepting it at FitzPatrick did not identify the nonconformance, even though the information was readily available in both the ExGen component tracking database and corrective action database. The defective valve was accepted using a Product Quality Certificate dated December 12, 2008. This Product Quality Certificate was invalidated by the July 1, 2010 Part 21 notification. The PCV was subsequently installed in the FitzPatrick HPCI system during the maintenance window on December 16, 2017.

Staff involved with transferring the HPCI PCV and inspecting and accepting it at FitzPatrick reasonably had access to information about the nonconformance through at least two means. First, to receive the part at FitzPatrick, BSC staff at FitzPatrick accessed the component tracking database and removed a 'hold' due to a shelf life concern. The inspectors reviewed the component tracking database and identified that information on IR 1086768, the IR associated with the 10 CFR Part 21 notification, was present in the database and could reasonably be identified by a qualified procurement engineer when performing a review of available information to address the ‘hold'. Second, the Part 21 information was available to the staff through the ExGen corrective action program, as IR 1086768 was noted in the component tracking database. The IR had not been resolved at the time the part was moved to and accepted at FitzPatrick, and this information would have been available to any staff involved with this activity.

As a result of the defective 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 pressure control valve (PCV), 23PCV-12. The auxiliary oil pump was secured and the HPCI system was still considered operable by ExGen staff. Operators were not able to definitively quantify the initial leak. At 3:00 AM, a second start of the auxiliary oil pump was attempted to quantify the leak. During the second run, operators estimated the leak to be 1.3 gpm. Thus, 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 defective 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 dispositioning Part 21 components with inaccurate codes in their parts 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
<u>Performance Assessment</u>: Performance Deficiency: The inspectors determined that ExGen failed to ensure that purchased material conformed to all procurement requirements and to reject a nonconforming item and prevent its installation and use as required by 10 CFR Part 50, Appendix B, Criterion VII, “Control of Purchased Material, Equipment, and Services,” and Criterion XV, “Non-conforming Materials, Parts, and Components,” which was within their ability to foresee and prevent. ExGen implemented the requirements of 10 CFR Part 50, Appendix B using the Quality Assurance Program Manual (QAPM), Revision 0 in 2017. Section A, “Management,” stated, “the requirements and commitments contained in the QAPM are mandatory and must be implemented, enforced, and adhered to by all individuals and organizations.” Section 5, “Procurement Verification,” required a program to be established and implemented to verify the quality of purchased items and services. Section 6, “Identification and Control of Items,” required a program to be established and implemented to identify and control items to prevent the use of incorrect or defective items. Procedure SM-AA-102 implemented these procurement verification requirements. On December 16, 2017, ExGen failed to verify that the PCV conformed to procurement documents and did not identify that the PCV was nonconforming. Consequently, the PCV containing the defective diaphragm was not rejected and was, instead, accepted using a Product Quality Certificate dated December 9, 2008, which was subsequently invalidated by the Part 21 notification issued July 1, 2010. The PCV was installed at FitzPatrick on December 16, 2017 and failed on April 10, 2020. 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 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. 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.

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 inspection conducted from April 10, 2020, through December 14, 2020, and for which an inspection exit meeting was conducted on December 14, 2020, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services," requires, in part, that measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors conform to procurement documents. Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear power plant or fuel processing plant site and shall be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material or equipment.

   Contrary to the above, on December 16, 2017, the licensee did not ensure measures were established to assure that purchased material, equipment and services conform to procurement documents. Specifically, the licensee did not ensure that a replacement high pressure coolant injection (HPCI) system oil pressure control valve (PCV) conformed to procurement documents. As a result, on December 16, 2017, the licensee accepted and installed for use a PCV at the James A. FitzPatrick Nuclear Power Plant (FitzPatrick) that had a known nonconforming material defect (i.e., defective diaphragm) that was first identified in a 10 CFR Part 21 report on July 3, 2010.

B. Title 10 CFR Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components," requires 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. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

   FitzPatrick Technical Specification (TS 3.5.1), in part, requires the HPCI system to 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, the licensee did not ensure that measures were established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation and did not ensure that nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. Specifically, staff involved with the sale, inspection, and installation of the HPCI PCV to FitzPatrick failed to ensure the PCV conformed to all procurement requirements and failed to reject the nonconforming item. As a result, the valve was accepted and installed for use at

FitzPatrick. On April 10, 2020, the HPCI system was declared inoperable during a monthly surveillance test as a result of a leak and system oil loss from the nonconforming HPCI PCV that would have prevented the system from performing its safety function. 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 NRC reportability guidelines.

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

Pursuant to the provisions of 10 CFR 2.201, Exelon Generation Company, LLC (the licensee) is hereby required to submit a written statement or explanation 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, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-20-138" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response 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 20th day of April 2021.