



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

November 8, 2021

EA-20-138

Mr. David 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 – 95001
SUPPLEMENTAL INSPECTION REPORT 05000333/2021040 AND
ASSESSMENT FOLLOW-UP LETTER

Dear Mr. Rhoades:

On September 24, 2021, the U.S. Nuclear Regulatory Commission (NRC) completed a supplemental inspection in accordance with Inspection Procedure 95001, "Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs." The NRC discussed the results of this inspection and the implementation of your corrective actions with Mr. Tim Peter, Site Vice President, and other members of your staff at an exit and regulatory performance meeting on September 24, 2021. The results of this inspection are documented in the enclosed report.

The NRC performed this inspection to sufficiently challenge aspects of your station's actions in response to a White finding in the Mitigating Systems cornerstone which was documented and finalized in NRC Inspection Report 05000333/2021090 (ADAMS Accession Number ML21244A497). On September 9, 2021, you informed the NRC that your station was ready for the supplemental inspection.

The NRC determined that your staff's evaluation correctly identified the causes of the White finding. Specifically, the NRC determined your staff's evaluation identified two root causes and one contributing cause. The first root cause was that Limerick Site Supply supervisors and managers did not reinforce standards for Passport assignment closure to ensure assignments are closed with quality. The second root cause was that FitzPatrick Site Supply supervisors and managers did not reinforce standards for using level 3 procedures and training and reference materials to ensure the Site Supply personnel were performing tasks correctly and per the processes. In addition, one contributing cause identified that gaps and insufficient references between the various Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21 related procedures contributed to lack of understanding and implementation of process requirements within Supply Operations.

After sufficiently challenging aspects of James A. FitzPatrick Nuclear Power Plant performance in addressing the White finding subject of this Inspection Procedure 95001, "Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs" the NRC determined that completed or planned corrective actions were sufficient to address and preclude repetition of the performance issue that led to the White finding, and concluded your

actions met the inspection objectives. Therefore, in accordance with the guidance in Inspection Manual Chapter (IMC) 0305, "Operating Reactor Assessment Program," the NRC determined the White finding at James A. FitzPatrick Nuclear Power Plant will not be considered as an Action Matrix input after the end of the third quarter of 2021 in which the supplemental inspection exit meeting was conducted. Based on the results of this inspection and our Action Matrix assessment, the NRC has determined that James A. FitzPatrick Nuclear Power Plant transitioned to the Licensee Response Column (Column 1) of the ROP Action Matrix on October 1, 2021, considering no additional Action Matrix inputs occurred.

The NRC inspectors documented four general weaknesses in this report. General weaknesses were identified in the inspection areas of Causal Analysis and Corrective Actions. The NRC is treating these consistent with NRC Inspection Manual guidance.

The NRC inspectors documented one finding of very low safety significance (Green) in this report. This finding involved a violation of NRC requirements. We are treating this violation as a non-cited violation (NCV) consistent with Section 2.3.2 of the Enforcement Policy.

If you contest the violations or the significance or severity of the violations documented in this inspection report, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; with copies to the Regional Administrator, Region I; the Director, Office of Enforcement; and the NRC Resident Inspector at James A. FitzPatrick Nuclear Power Plant.

If you disagree with a cross-cutting aspect assignment in this report, you should provide a response within 30 days of the date of this inspection report, with the basis for your disagreement, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; with copies to the Regional Administrator, Region I; and the NRC Resident Inspector at James A. FitzPatrick Nuclear Power Plant.

This letter, its enclosure, and your response (if any) will be made available for public inspection and copying at <http://www.nrc.gov/reading-rm/adams.html> and at the NRC Public Document Room in accordance with Title 10 of the *Code of Federal Regulations* 2.390, "Public Inspections, Exemptions, Requests for Withholding."

Sincerely,

Erin E. Carfang, Chief
Projects Branch 1
Division of Operating Reactor Safety

Docket No. 05000333
License No. DPR-59

Enclosure:
As stated

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SUBJECT: JAMES A. FITZPATRICK NUCLEAR POWER PLANT – 95001
 SUPPLEMENTAL INSPECTION REPORT 05000333/2021040 AND
 ASSESSMENT FOLLOW-UP LETTER DATED NOVEMBER 8, 2021

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U.S. NUCLEAR REGULATORY COMMISSION
Inspection Report

Docket Number: 05000333

License Number: DPR-59

Report Number: 05000333/2021040

EA Number: EA-20-138

Enterprise Identifier: I-2021-040-0003

Licensee: Exelon Generation Company, LLC

Facility: James A. FitzPatrick Nuclear Power Plant

Location: Oswego, NY

Inspection Dates: September 20, 2021 to September 24, 2021

Inspectors: J. Schussler, Senior Resident Inspector (Team Leader)
M. Rossi, Resident Inspector

Approved By: Erin E. Carfang, Chief
Projects Branch 1
Division of Operating Reactor Safety

Enclosure

SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) sufficiently challenged aspects of Exelon's corrective actions to address a White finding by performing a supplemental inspection in accordance with Inspection Procedure 95001, "Supplemental Inspection Response to Action Matrix Column 2 Inputs," at James A. FitzPatrick Nuclear Power Plant, Unit 1 in accordance with the Reactor Oversight Process. The Reactor Oversight Process is the NRC's program for overseeing the safe operation of commercial nuclear power reactors. Refer to <https://www.nrc.gov/reactors/operating/oversight.html> for more information.

The inspectors determined that the licensee's problem identification, causal analysis, and corrective actions adequately addressed the performance issue that led to the White finding.

List of Findings and Violations

Inadequate Corrective Action to Preclude Repetition			
Cornerstone	Significance	Cross-Cutting Aspect	Report Section
Mitigating Systems	Green NCV 05000333/2021040-01 Open/Closed	[X.12] - Accountability for Decisions	95001
The NRC identified a Green, non-cited violation of Title 10 of the <i>Code of Federal Regulations</i> , (10 CFR) Part 50, Appendix B, Criterion XVI, "Corrective Action" when Exelon failed to establish measures to assure that in the case of a significant condition adverse to quality measures are established which shall assure that the cause of the condition is determined, and corrective action is taken to preclude repetition. Specifically, Exelon did not identify corrective actions to preclude repetition for a significant condition adverse to quality at James A. FitzPatrick (FitzPatrick) pertaining to a White performance issue or provide a technical basis for the omission of corrective actions to preclude repetition as applied to FitzPatrick.			

Additional Tracking Items

Type	Issue Number	Title	Report Section	Status
NOV	05000333/2020012-01 EA-20-138	Defective Part Results in High Pressure Coolant Injection System Pressure Control Valve Failure	95001	Closed
LER	05000333/2020-003-01	High Pressure Coolant Injection Inoperable due to Oil Leak	71153	Closed

INSPECTION SCOPES

Inspections were conducted in accordance with the appropriate inspection procedure in effect at the beginning of the inspection unless otherwise noted. Currently approved inspection procedures with their attached revision histories are located on the public website at <http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html>. Samples were declared complete when the IP requirements most appropriate to the inspection activity were met consistent with Inspection Manual Chapter (IMC) 2515, "Light-Water Reactor Inspection Program - Operations Phase." The inspectors reviewed selected procedures and records, observed activities, and interviewed personnel to assess licensee performance and compliance with Commission rules and regulations, license conditions, site procedures, and standards.

OTHER ACTIVITIES – SUPPLEMENTAL INSPECTION, TEMPORARY INSTRUCTIONS, INFREQUENT AND ABNORMAL

71153 - Follow Up of Events and Notices of Enforcement Discretion

Follow Up of Events and Notices of Enforcement Discretion (1 Sample)

- (1) A performance deficiency associated with licensee event report (LER) 2020-003-00 was documented in NRC Inspection Report 0500333/2021090 (ADAMS Accession Number ML21244A497). After LER 2020-003-00 was submitted to the NRC Exelon revised portions of the document which was submitted to the NRC as revision 1, LER 2020-003-01 (ADAMS Accession Number ML21251A585). The inspectors did not identify any additional performance deficiencies during the review of the LER revision 1. Previously, LER 05000333/2020-003-00, High Pressure Coolant Injection Inoperable due to Oil Leak was closed in NRC Inspection Report 05000333/2020012 (ADAMS Accession Number ML21020A108). This LER 2020-003-01 revision is closed.

95001 - Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs

The inspectors reviewed and selectively challenged aspects of Exelon's problem identification, causal analysis, and corrective actions in response to a White finding and related violation of Technical Specification (TS 3.5.1). The finding included failures to comply with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B, Criterion V, "Instructions, Procedures and Drawings" and Criterion XV, "Nonconforming Materials, Parts, or Components." The White finding and related violation of James A. FitzPatrick (FitzPatrick) Technical Specification were documented in James A. FitzPatrick Nuclear Power Plant – Response to Contested Violation and Final White Finding and Revised Notice of Violation, Inspection Report 05000333/2021090 dated September 3, 2021 (ADAMS Accession Number ML21244A497).

This performance issue was previously documented in Problem Identification and Resolution Report 05000333/2020012 and Preliminary White Finding and Apparent Violation dated January 21, 2021 (ADAMS Accession Number ML21020A108), Final Significance Determination of a White Finding with Assessment Follow-up and Notice of Violation – NRC Inspection Report 05000333/2021090 dated April 20, 2021 (ADAMS Accession Number ML21105A543), and Acknowledgement of Dispute of Violation Associated with White Finding – NRC Inspection Report 05000333/2021090 dated June 25, 2021 (ADAMS Accession Number ML21176A005).

The inspectors assessed whether Exelon's corrective actions to address the root and contributing causes were sufficient to address and preclude repetition. Additionally, as a consequence of the high pressure coolant injection (HPCI) system pressure control valve failure, Exelon violated FitzPatrick Technical Specifications. Specifically, Exelon failed to comply with FitzPatrick Technical Specification 3.5.1, "ECCS-Operating" since the HPCI system was determined to be inoperable for a period of time greater than the technical specification allowed outage time. Exelon's analysis was documented under a root cause evaluation in issue report 04397491. The FitzPatrick White performance issue review and NRC's assessment are documented below.

Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs (1 Sample)

- (1) From September 20 to September 24, 2021, the inspectors conducted an onsite inspection to sufficiently challenge and verify all objectives of the inspection procedure were met.

INSPECTION RESULTS

Problem Identification Assessment	95001
<p>1. <u>Problem Identification</u></p> <p>a. <u>Identification</u>. A nonconforming part was installed in the HPCI system leading to an oil leak. The issue was self-revealed on April 10, 2020, during performance of ST-4B, "HPCI Monthly Operability Test." When auxiliary oil pump 23P-150 was started, a leak from 23PCV-12, "HPCI Trip System Pressure Control Valve," was identified.</p> <p>The failure of the HPCI pressure control valve revealed that Exelon failed to comply with (1) instructions, procedures, and drawings and (2) handling of nonconforming materials, parts, or components. Specifically, Exelon 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.</p> <p>b. <u>Exposure Time</u>. Exelon acknowledged and appropriately captured the time frame and dates for when the condition existed. Specifically, Exelon determined that the nonconforming condition where the pressure control valve was installed in the system was present from December 16, 2017, until April 10, 2020.</p> <p>c. <u>Identification Opportunities</u>. In general, Exelon appropriately considered prior occurrences and identified opportunities.</p> <p>The nonconforming pressure control valve was accepted by Exelon using a Product Quality Certificate dated December 9, 2008. The component was received by FitzPatrick then installed on December 16, 2017 and failed on April 10, 2020.</p>	

FitzPatrick identified a missed opportunity to identify facility specific notes in Passport CatID D202 screen which stated, "Need to replace diaphragm 166-00134 prior to use in the plant refer IR 1086768." Specifically, FitzPatrick was actively using the Passport program to remove a material hold and complete other actions pertaining to a material transfer from one facility to another. The formal actions to disposition the material hold and issue a purchase order provided a reasonable opportunity for FitzPatrick to identify the nonconforming component. Descriptive information relating to the nonconforming condition was readily available in the notes section and if reviewed in its entirety, the user would have identified the issue.

- d. Risk and Compliance. The root cause evaluation documented that the HPCI system was declared inoperable and incapable of performing its safety function. The root cause evaluation also documented the qualitative consequences of the event and White performance issue with respect to nuclear, radiological, safety culture, and industrial consequences. Based on their review, the inspectors concluded the root cause evaluation demonstrated an understanding of the significant plant consequences and compliance concerns associated with the event and the White performance issue.

The root cause evaluation for this event identified two root causes, and in accordance with Exelon's process outlined in PI-AA-125-1001 "Root Cause Analysis Manual", a risk assessment was not required as part of the evaluation. Exelon noted that a risk assessment would be used as a tool when a root cause cannot be determined. The NRCs risk evaluation of FitzPatrick's White performance issue was documented in prior inspection reports most recently Inspection Report 05000333/2021090.

NRC Assessment: The inspectors' review determined that Exelon's evaluation documented who identified the performance issues and under what conditions, how long the issues existed, prior opportunities for identification, and the plant-specific consequences of the event. The inspectors had the following observations:

Observation - Problem Identification, Section 1.a: The inspectors observed that Exelon's root cause evaluation utilized a corporate supply-centric approach. Exelon's problem statement stated, in part, that "a nonconforming part was installed in the high pressure coolant system leading to an oil leak and inoperability of the HPCI system." The inspectors observed that this problem statement was not linked to the FitzPatrick White performance issue. Specifically, Exelon's approach and problem statement lacked details relating to the FitzPatrick plant specific conditions of the FitzPatrick White performance issue. Furthermore, this problem statement approach led to Exelon's causal analysis identifying root causes and corrective actions which did not fully address the FitzPatrick White performance issue. As a result, Exelon revised the root cause twice, where the first revision was made during the inspection preparation week and the second revision was made during the onsite week of the supplemental inspection. Observations and weaknesses associated with document revisions and other aspects of the root cause evaluation are documented as results within this report.

This inspection observation was independently evaluated in accordance with the guidance in IMC 0612, Appendix B, "Issue Screening," and Appendix E, "Examples of

Minor Issues.” The inspectors determined that none of the conditions were deficiencies greater than minor significance and therefore are not subject to enforcement action in accordance with the NRC’s enforcement policy.

Causal Analysis Assessment

95001

2. Causal Analysis

- a. Methodology. The root cause evaluation employed systematic, evidence-based methodologies including Barrier Analysis, Task Analysis, Error Precursor and Flawed Defenses, TapRoot Analysis, Management Oversight and Risk Tree, Safety Culture Review and Event and Causal Factors Charting to gather data, identify the problem, and determine the root and contributing causes of the White Performance issue.

Exelon revised the root cause evaluation two separate times during the inspection period. The final revision captured two root causes and one contributing cause.

- (1) Root cause 1 (RC1): Limerick Site Supply supervisors and managers did not reinforce standards for Passport assignment closure to ensure assignments are closed with quality. Specifically, the direct cause was a human performance error made in 2010 where a Limerick procurement specialist improperly closed actions addressing a 10 CFR Part 21 nonconformance.

The inspectors acknowledge that Exelon’s causal analysis identified RC1, however, it did not address the FitzPatrick White performance issue. Consequently, RC1 was not subject to in-depth inspection as part of the Inspection Procedure 95001, “Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs.”

- (2) Root cause 2 (RC2): FitzPatrick Site Supply supervisors and managers did not reinforce standards for using level 3 procedures and training and reference materials (T&RM) to ensure the Site Supply personnel were performing tasks correctly and per the processes.

- (3) Contributing cause: Gaps and insufficient references between the various 10 CFR Part 21 related procedures contributed to lack of understanding and implementation of process requirements within Supply Operations.

- b. Level of Detail. The inspectors determined the initial root cause evaluation did not contain an adequate level of detail to identify the root and contributing causes. In response, Exelon revised the root cause evaluation two separate times. The inspectors determined the evaluation in its final revision was generally commensurate with the safety significance and complexity of the White performance issue and was of sufficient detail to identify the root and contributing causes, extent of conditions and extent of causes. The revised root cause evaluation investigation team utilized a formal cause analysis process to identify the problems and determine corrective actions. The revised root cause evaluation was performed by individuals in Exelon’s organization with varying levels of experience and background.

- c. Operating Experience. The inspectors determined that Exelon appropriately considered prior occurrences and operating experience to identify and prevent similar occurrences. The inspectors noted that Exelon searched industry databases using key words, used internal operating experience, and reviewed the corrective action program for similar instances. Lastly, Exelon used an external website to search for other occurrences of the specific finding and violation.
- d. Extent of Condition and Cause. The inspectors determined that Exelon appropriately identified the extent of condition and extent of cause. The extent of condition and cause evaluations contained actions for FitzPatrick and across Exelon's fleet.

Two extent of condition reviews were completed by Exelon.

- (1) The first extent of condition review was assigned to stations across Exelon's fleet. This required that each site, including FitzPatrick, validate whether any 10 CFR Part 21 items were currently in inventory. In this case, if FitzPatrick had an item in inventory the station ensured it was electronically and physically segregated and had a Hold tag per SM-AA-102 "Warehouse Operations". Additionally, 642 applicable part category identifications were identified by Exelon and reviewed to determine if the part category identification number was issued for use and subsequently installed at each site including FitzPatrick. Exelon determined no deficient components associated with the category identifications were issued or installed in safety-related or other applications at FitzPatrick or other stations.
- (2) The second extent of condition review utilized an approach known as "same-same, same-similar, similar-same and similar-similar" methodology. In this instance the object was "10 CFR Part 21 report identified nonconforming parts" and the defect was "Nonconforming parts were installed causing HPCI inoperability." FitzPatrick used this methodology to establish and evaluate circumstances where same and similar objects and defects could exist.

In general, to accomplish the extent of cause review, FitzPatrick completed a review of corrective action program condition issue reports, assignments and closure activities coded to supply from January 1, 2020, to September 3, 2021. Additionally, specific to RC2, FitzPatrick reviewed their corrective action program documents and observation database for entries related to procedure use.

Exelon did complete an extent of cause review relating to RC1, however it was not pertinent to the FitzPatrick White performance issue, and therefore not subject to the supplemental inspection objectives.

- e. Safety Culture. The inspectors determined the safety culture components referenced in NUREG-2165, "Safety Culture Common Language," were appropriately considered during the licensee's evaluations of the root cause, extent of condition, and extent of cause.

NRC Assessment: The inspectors' initial review concluded Exelon's initial root cause evaluation contained a potential significant weakness. Two revisions to the root cause evaluation were required to ensure the evaluation contained the appropriate level of detail, relevant operating experience, root causes, contributing causes, extent of conditions, and extent of causes of the White performance issue. The inspectors identified the following general weaknesses and observations:

General Weakness - Methodology, Section 2.a: The inspectors determined the initial revision of the root cause evaluation was not conducted using an adequate application of cause analysis methodology. Specifically, the inspectors determined that given the same recurrence of events, the barrier which failed to prevent a White performance issue at FitzPatrick would fail again in the same way. The inspectors shared this with the station during the onsite inspection week as a significant weakness. Exelon determined a revision to the root cause evaluation was required to further detail the barrier analysis methodology, which resulted in the addition of a new robust barrier. The inspectors determined that Exelon was able to correct the significant weakness during the inspection period and consequently characterized the issue as a general weakness.

General Weakness - Level of Detail, Section 2.b: The inspectors determined that the initial root cause evaluation level of detail was inadequate. The root cause evaluation was revised twice by Exelon to fully encompass the details pertaining to the FitzPatrick White performance issue. The inspectors informed Exelon of a potential significant weaknesses in the root cause evaluation during the inspection preparation week, which resulted in a document revision prior to the onsite inspection. Specifically, the initial root cause evaluation contained one root cause (RC1) which was not linked to the FitzPatrick White performance issue, consequently Exelon did not identify a corrective action to preclude repetition of the FitzPatrick White performance issue or provide a detailed basis for this decision. During the onsite inspection week, the inspectors informed Exelon of a significant weakness, which resulted in the second root cause evaluation document revision. The second revision added the following: details to the barrier analysis, a new barrier, corrective actions and effectiveness review criteria.

As evident by multiple root cause evaluation revisions that changed or edited root causes, contributing causes, corrective actions to preclude repetition, and effectiveness reviews, the inspectors determined the inadequate level of detail documented in Exelon's initial root cause evaluation was a significant weakness. Two root cause evaluation revisions subsequently captured additional technical rigor, further basis for Exelon's decisions, additional root causes, and additional corrective actions to preclude repetition. Upon review of the final root cause evaluation revision, the inspectors determined the lack of detail significant weakness was resolved to be a general weakness.

Observation - Extent of Condition, Section 2.d: The inspectors observed that the extent of condition review methodology was narrowly focused. Specifically, Exelon's application of the same-similar method defined the "defect" as installed nonconforming parts causing other systems' inoperability. The inspectors identified that a 10 CFR Part 21 deficient component could be installed that did not cause other systems' inoperability, which would more accurately reflect the intention of an extent of condition review. Whereas if the system was rendered inoperable the extent of condition would be evident, consequently resulting in the structure, system, or component being inoperable. The inspectors determined that generally Exelon completed a review of which was

sufficient to capture a failure precursor event. FitzPatrick reviewed all 10 CFR Part 21 items installed in the plant for deficiencies, of which none were found.

These weaknesses and observations were independently evaluated in accordance with the guidance in IMC 0612, Appendix B, "Issue Screening," and Appendix E, "Examples of Minor Issues." The inspectors determined that none of the conditions were deficiencies of greater than minor significance and therefore are not subject to enforcement action in accordance with the NRC's enforcement policy.

Corrective Action Assessment

95001

3. Corrective Actions

- a. Corrective Actions to Preclude Repetition. The inspectors concluded that Exelon failed to identify corrective actions to preclude repetition of the FitzPatrick White performance issue that were appropriate, timely or commensurate with the safety significance prior to the inspection period. This conclusion is documented within this report as a Green, Non-Cited Violation of 10 CFR Part 50 Appendix B, Criterion XVI. The inspectors noted that the following corrective actions represent Exelon's final root cause evaluation.

(1) Completed

- (a) Exelon identified the following corrective actions to preclude repetition for the second identified root cause (RC2) associated with FitzPatrick Site Supply personnel failing to use procedures.
 1. Interim corrective action to preclude repetition for FitzPatrick Site Supply to perform a briefing, along with a read and sign associated with the applicable procedures SM-AA-102 and SM-AA-300-1001 requirements as they relate to material transfer requirements and reinforce the expectations for Level 3 and T&RM procedure use and adherence. Discussion of procedure use and adherence issues identified during the extent of cause evaluation will all occur. (CAPR 04397491-67)
 2. Interim corrective action to preclude repetition for FitzPatrick site supply leadership to implement eight specific bulleted actions. These actions included in part to institute a checklist, increased frequency of briefings, increase frequency of observations, and a monthly review of observations. (CAPR 04397491-64)
- (b) Exelon identified the following corrective actions to preclude repetition for the first identified root cause (RC1) pertaining to Limerick Site Supply.

The inspectors acknowledge that Exelon's causal analysis identified RC1, however it is not applicable to the FitzPatrick White performance issue. Consequently, RC1 and the associated corrective actions documented below were not subject to in-depth inspection as part of the Inspection Procedure 95001, "Supplemental Inspection Response to Action Matrix Column 2 (Regulatory Response) Inputs."

1. Interim corrective action to preclude repetition was that Limerick Supply completed a read and sign for compliance on applicable procedures, SM-AA-102 and PI-AA-115-1003 requirements as they related to 10 CFR Part 21 and reinforce Procedure Use and Adherence. (CAPR 04397491-21)
 2. Interim corrective action to preclude repetition was that Limerick Site Supply Leadership were to create and implement a plan to provide direct oversight and approval of all Passport assignment closures. Senior Manager of Supply Operations was to approve this plan. Corporate Supply to independently assess Passport action item closure quality improvement. (CAPR 04397491-33)
 3. Exelon identified a corrective action to preclude repetition which was previously completed in January 2014. Procedure PI-AA-115-1003, formally LS-AA-115-1003 was revised (Revision 1) to incorporate a mandatory Manager/Supervisor review prior to closing out Attachment 5, Guidance for Supply/Procurement Engineering Applicability Review of NRC and/or Vendor Part 21 notifications.
- (c) Effectiveness Review. The inspectors determined that effectiveness reviews were not completed for the corresponding completed corrective actions to preclude repetition at the time of the supplemental inspection. The inspectors determined the documented effectiveness review actions contained quantitative and qualitative measures of effectiveness. Additionally, the inspectors concluded the documented actions, owners, and due dates were appropriate and commensurate with the corresponding corrective action to preclude repetition.

(2) Planned

- (a) To address both root causes Exelon identified the following corrective actions to preclude repetition which are planned to be completed.
1. Revision to procedure SM-AA-2009, Nuclear Supply Regulatory and Job Specific Training, to include a line item specific to presenting and reinforcing procedures SM-AA-102 and PI-AA-115-1003 requirements as they relate to 10 CFR Part 21 notification affected material. Reinforce the lessons learned from this event for new Exelon employees and all employees every three years. (CAPR 04397491-48)
 2. Interim corrective action to preclude repetition identified that FitzPatrick Site Supply will perform a briefing, along with a read and sign, on applicable procedure SM-AA-102, SM-AA-404 and SM-AA-300-1001 requirements as they related to material transfer requirements. Reinforce expectations for Level 3 and T&RM procedure use and adherence. Additionally, FitzPatrick will present the root causes, contributing causes and additional corrective actions from the final version of the Root Cause Evaluation. Lastly FitzPatrick will conduct briefings to reinforce how the procedure changes are providing defense in depth to preclude repetition. (CAPR 04397491-71)

3. New procedure step in procedure SM-AA-404, "Nuclear Material Procurement," to require that on-hold material transfer between sites, using Passport or Purchase Order, shall be approved by the requesting site Supply Manger, Firstline Supervisor, or designee. The approving person shall be independent of the personnel performing the transfer and shall document that all the Supply procedure requirements have been met. An attachment shall be added to the procedure SM-AA-404 to provide a checklist and signature block to meet this requirement. The completed checklist shall be in Passport D201 notes chicklet for future reference. (CAPR 04397491-74)

(b) Effectiveness Review. The inspectors determined that after a second root cause evaluation revision, the effectiveness review actions established by Exelon were appropriate. In general, each planned corrective action to preclude repetition identified a corresponding effectiveness review which contained quantitative and qualitative measures of effectiveness. Additionally, the inspectors concluded the actions, owners, and due dates were appropriate and commensurate with the corresponding corrective action to preclude repetition.

b. Other Corrective Actions

(1) Completed

(a) Exelon completed the following corrective actions which are associated with the contributing cause.

1. Revise procedure SM-AA-102 to require that parts identified as deficient or potentially deficient as part of a 10 CFR Part 21 notification be treated in a prescribed manner including hold tag identifier and logged appropriately. (CA 04397491-24)
2. Revise PI-AA-115-1003, "Processing of Level 3 OPEX Evaluations," to incorporate markups and lessons learned from the root cause evaluation. This markup adds clear guidance to Attachment 5, Guidance for Supply/Procurement Engineering for review of NRC and or Vendor 10 CFR Part 21 notifications. (CA 04397491-37)

(2) Planned

The inspectors concluded that Exelon did not identify any planned corrective actions, aside from previously documented corrective actions to preclude repetition.

NRC Assessment: The inspectors determined Exelon's root cause evaluation failed to identify a corrective action to preclude repetition for a significant condition adverse to quality associated with the FitzPatrick White performance issue prior to the supplemental inspection period. This is captured within this report as a Green, Non-Cited Violation of 10 CFR Part 50, Appendix B, Criterion XVI.

Upon the completion of two root cause evaluation revisions the inspectors concluded that, in general, the dates for implementation and completion of the planned root and contributing cause corrective actions were reasonable, effective, and prioritized with consideration for risk significance and regulatory compliance. The inspectors also concluded the licensee established reasonable measures of success to evaluate the effectiveness of the corrective actions.

Additionally, the inspectors informed Exelon that the NRC has plans to inspect and assess the planned corrective action to preclude repetitions upon their completion. These planned corrective actions are annotated below and summarized previously in the planned corrective actions to preclude repetition, section 3.a.(2) of this report. The NRC is tracking these as open items in an NRC internal reactor program system database which is used for inspections, inspection scheduling and reporting:

- CAPR 04397491-48
- CAPR 04397491-71
- CAPR 04397491-74

Lastly, the inspectors identified the following weaknesses:

General Weakness - Planned Corrective Actions to Preclude Repetition

Section 3.a.(2)(a): The inspectors concluded that the lack of a corrective action to preclude repetition for a significant condition adverse to quality of the White performance issue was a potential significant weakness. The inspectors shared this potential significant weakness with FitzPatrick during the inspection preparation week. As a result, Exelon revised the root cause evaluation prior to onsite inspection. This revision added corrective actions to preclude repetition specifically related to FitzPatrick's White performance issue. The inspectors reviewed the second root cause evaluation revision document and determined the identified corrective actions to preclude repetition to be appropriate with respect to the FitzPatrick White performance issue. As a result of the root cause evaluation revisions and additional corrective actions to preclude repetition, this issue is characterized as a general weakness and is documented within this report as a Green, NCV of 10 CFR Part 50, Appendix B, Criterion XVI.

General Weakness - Planned Corrective Actions to Preclude Repetition

Effectiveness Review Section 3.a.(2)(b): The inspectors identified a general weakness regarding the effectiveness review of a corrective action to preclude repetition pertaining to employee training. A corrective action to preclude repetition, to revise SM-AA-209, "Nuclear Supply Regulatory and Job Specific Training", included a line item to present and reinforce SM-AA-102 and PI-AA-115-1003 requirements as they relate to 10 CFR Part 21. The effectiveness review for that corrective action to preclude repetition was defined to verify completion of initial or periodic training for all supply staff. The inspectors determined this action lacked measurable effectiveness criteria. Upon identification by the inspectors, Exelon revised the effectiveness review to also include an evaluation of the staff's knowledge following the training to demonstrate effectiveness. As a result, the effectiveness review went from completion of a training task to a measurable comprehension of the required training. The inspectors determined this issue to be a significant weakness which was resolved during the inspection and as such is captured as a general weakness.

Inspection Conclusion Assessment	95001
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4. Conclusion

The inspectors concluded that after two revisions to the root cause evaluation during the inspection period, which added a root cause, corrective actions to preclude repetition, and effectiveness reviews, Exelon provided suitable actions to ensure regulatory compliance and safety significant White performance issues were addressed during the inspection period. Specifically, the inspections identified significant weaknesses in four areas; (1) causal methodology, (2) corrective actions to preclude repetition, (3) level of detail, and (4) effectiveness reviews that Exelon resolved during the onsite inspection week. The inspectors concluded that multiple weaknesses in FitzPatrick's initial root cause evaluation resulted in not addressing a White performance issue and is indicative of a weakness in the site's ability to assess and correct a significant condition adverse to quality.

The inspectors determined that the corrective actions have been prioritized commensurate with the significance and regulatory compliance, and corrective actions taken were prompt and effective, and that the Notice of Violation related to the supplemental inspection is sufficiently addressed. The inspectors also determined that the final root cause evaluation produced corrective action plans which appear to effectively address and preclude repetition of significant performance issues. The station took prompt action to address the inspector's observations, address significant weaknesses, revise corrective actions, cause methodology, level of detail and effectiveness review.

Because Exelon was able to resolve each of the significant weaknesses prior to the conclusion of the inspection, each of the issues was documented within this report as a general weakness. The inspectors reviewed the weaknesses to determine if the inspection objectives could be met, upon the conclusion of multiple root cause evaluation revisions. The inspectors determined that the final root cause evaluation revision contained sufficient information such that Exelon met the objectives of the inspection procedure.

Inadequate Corrective Action to Preclude Repetition			
Cornerstone	Significance	Cross-Cutting Aspect	Report Section
Mitigating Systems	Green NCV 05000333/2021040-01 Open/Closed	[X.12] - Accountability for Decisions	95001
<p>The NRC identified a Green, non-cited violation of Title 10 of the <i>Code of Federal Regulations</i>, (10 CFR) Part 50, Appendix B, Criterion XVI, "Corrective Action" when Exelon failed to establish measures to assure that in the case of a significant condition adverse to quality measures are established which shall assure that the cause of the condition is determined, and corrective action is taken to preclude repetition. Specifically, Exelon did not identify corrective actions to preclude repetition for a significant condition adverse to quality at James A. FitzPatrick (FitzPatrick) pertaining to a White performance issue or provide a technical basis for the omission of corrective actions to preclude repetition as applied to FitzPatrick.</p>			
<p><u>Description:</u> NRC Inspection Report 05000333/2021090 dated September 3, 2021, identified a White performance issue at FitzPatrick which documented a self-revealed White finding and</p>			

related violation of FitzPatrick Technical Specifications (TS 3.5.1). The finding included failures to comply with 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. As a result, FitzPatrick's maintenance staff installed the nonconforming component which subsequently caused the inoperability of the HPCI system on April 10, 2020.

On September 9, 2021, FitzPatrick announced their readiness for the NRC to conduct Supplemental Inspection Procedure 95001 "Supplemental Inspection Response To Action Matrix Column 2 (Regulatory Response) Inputs." The inspectors reviewed a root cause evaluation which included in part the identification of root causes, contributing causes, corrective actions to preclude repetition, corrective actions, and an effectiveness review. During the inspection, the inspectors determined that Exelon did not identify a corrective action to preclude repetition of the White performance issue at FitzPatrick. Specifically, Exelon did not identify corrective actions to preclude repetition to address a significant condition adverse to quality, for FitzPatrick's failure to comply with 10 CFR Part 50, Appendix B, Criterion V and XV. Alternatively, Exelon failed to articulate a technical basis for the omission of FitzPatrick corrective actions to preclude repetition which would address the FitzPatrick White performance issue.

This violation is evident in the fact that Exelon's initial corrective action program document identified corrective actions to preclude repetition for other stations rather than FitzPatrick. Several of those corrective actions were unrelated to implementation of quality-related procedures and the acceptance and installation of the nonconforming part at FitzPatrick in 2017, and therefore insufficient to be credited as corrective actions to preclude repetition for the White performance issue at FitzPatrick.

Exelon subsequently documented a revision to the root cause to amend the evaluation. The revision included a new root cause specific to the FitzPatrick White Performance issue and an associated FitzPatrick corrective action to preclude repetition. The inspectors concluded that the planned corrective actions to preclude repetition which Exelon subsequently established were adequate measures to assure the cause of the FitzPatrick white performance issue condition was determined and precluded repetition of the significant condition adverse to quality.

Corrective Actions: Exelon's corrective actions included revisions of the root cause evaluation which added corrective actions to preclude repetition for the FitzPatrick White performance issue, a significant condition adverse to quality.

Corrective Action Reference: 04448241

Performance Assessment:

Performance Deficiency: Exelon failed to establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations defective material and equipment and nonconformances are promptly corrected and in the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined, and corrective action is taken to preclude repetition.

Exelon did not establish measures to assure that conditions adverse to quality identified as a FitzPatrick White performance issue were promptly corrected and specifically the significant

condition adverse to quality detailed measures that determined that cause and corrective action to preclude repetition. Specifically, Exelon completed a root cause evaluation to determine the cause of a FitzPatrick White performance issue and failed to identify a corrective action to preclude repetition or document a technical basis to capture the reason such corrective action was not needed for FitzPatrick.

Screening: The inspectors determined the performance deficiency was more than minor because if left uncorrected, the performance deficiency would have the potential to lead to a more significant safety concern. Specifically, the lack of a corrective action to preclude repetition would allow the same procedure and non-conforming parts violation to recur, potentially resulting in the installation of a nonconforming safety-related component which could adversely impact safety system operability.

Significance: The inspectors assessed the significance of the finding using Appendix A, "The Significance Determination Process (SDP) for Findings At-Power." The inspectors performed a review of this finding using the guidance in IMC 0609, Appendix A, Exhibit 2, "Mitigating System Screening Questions." The inspectors determined the finding had a very low safety significance (Green) since the degraded condition did not represent a loss of required PRA function and the system maintained its operability.

Cross-Cutting Aspect: X.12 Accountability for Decisions: Single-point accountability is maintained for nuclear safety decisions. The inspectors determined single point accountability was not maintained for nuclear safety decision made by FitzPatrick managers. Specifically, the organization did not hold themselves accountable for the FitzPatrick White performance issue, as evidenced by a significant condition adverse to quality White performance issue where measures were not established to assure that the cause of the condition was determined and corrective action taken to preclude repetition.

Enforcement:

Violation: Title 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action" requires, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.

Contrary to the above, between September 6, 2021 and September 23, 2021, Exelon personnel did not assure that the cause of the condition was determined and take corrective action to preclude repetition. Specifically, a significant condition adverse to quality White performance issue did not have a corrective action to preclude repetition. Consequently, inadequately implemented quality-related procedures which contributed to FitzPatrick's failure to identify nonconforming components were not promptly identified, corrected, condition determined, and corrective action taken to preclude repetition.

Enforcement Action: This violation is being treated as a non-cited violation, consistent with Section 2.3.2 of the Enforcement Policy.

EXIT MEETINGS AND DEBRIEFS

The inspectors verified no proprietary information was retained or documented in this report.

- On September 24, 2021, the inspectors presented the supplemental inspection results to Mr. Tim Peter and other members of the Exelon staff.

DOCUMENTS REVIEWED

Inspection Procedure	Type	Designation	Description or Title	Revision or Date
71153	Miscellaneous	LER 2020-003-00	LER: 2020-003, High Pressure Coolant Injection Inoperable due to Oil Leak, JAFP-20-0042	06/09/2021
		LER 2020-003-01	LER: 2020-003-01, High Pressure Coolant Injection Inoperable due to Oil Leak	09/08/2021
95001	Corrective Action Documents	04334315		
		04347674		
		04397491		
	Corrective Action Documents Resulting from Inspection	04448241	Repeat Root Cause Revisions	09/23/2021
	Miscellaneous	PO 00637326	Purchase Order JAF to LIM for PCV	
		Root Cause Evaluation IR 04397491	Non-Conforming Parts Installed in High Pressure Coolant Injection (HPCI) System	Revision 2, 9/23/2021
		Root Cause Evaluation IR 04397491	Non-conforming Parts installed in High Pressure Coolant Injection (HPCI) System	Revision 0, 09/06/2021
		Root Cause Evaluation IR 04397491	Non-conforming Parts installed in High Pressure Coolant Injection (HPCI) System	Revision 1, 09/17/2021
	Procedures	CC-AA-309-1012	10 CFR Part 21 Technical Evaluations	Revision 5
		HU-AA-104-101	Procedure use and Adherence	Revision 7
		INV-KR-009	Material Transfer Process - Nuclear, Knowledge Retention Document	Revision 3
		LS-AA-115-1003	Processing of Significance Level 3 OPEX Evaluations	Revision 1
		PI-AA-115-1003	Processing of Level 3 OPEX Evaluations	Revision 1
		PI-AA-115-1004	Processing of NEW and IRIS Report	Revision 7
		PI-AA-125-1001	Root Cause Analysis	Revision 6
		SM-AA-102	Wearhouse Operations	Revisions 14, 30, 32
		SM-AA-2009	Nuclear Supply Regulatory and Job Specific Training	Revision 8

Inspection Procedure	Type	Designation	Description or Title	Revision or Date
		SM-AA-300-1001	Procurement Engineering Process and Responsibilities	Revision 24
		SM-AA-404	Nuclear Material Procurement	Revision 26 and 28
	Self-Assessments	JAF 95001 Self Assessment (PI-AA-126-1001-F-01)	Readiness Assessment – Supplemental Inspection for NRC White Finding – HPCI Valve	