

EA-20-138

JAFP-21-0042
June 3, 2021

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555

James A. FitzPatrick Nuclear Power Plant
Renewed Facility Operating License No. DPR-59
NRC Docket No. 50-333

Subject: Reply to a Notice of Violation; EA-20-138

References: (1) NRC Letter: "James A. FitzPatrick Nuclear Power Plant – Final Significance Determination of a White Finding with assessment Follow-Up and Notice of Violation – NRC Inspection Report 0500035405000333/2021090" Dated April 20, 2021 (ML21105A543)

(2) Exelon Letter: "Response to James A. FitzPatrick Nuclear Power Plant – Problem Identification and Resolution Report 05000333/2020012 and Preliminary White Finding and Apparent Violation (EA-20-138)" Dated February 26, 2021 (ML21057A190)

(3) NRC Letter: "James A. FitzPatrick Nuclear Power Plant – Problem Identification and Resolution Report 5000333/2020012 and Preliminary White Finding and Apparent Violation" Dated January 21, 2021 (ML2120A108)

Exelon Generation Company, LLC (ExGen) is respectfully contesting the Notice of Violation (NOV) contained in Reference 1. The White NOV (NOV 05000333/2021090) documents a finding with associated violations of Title 10 of the Code of Federal Regulations (CFR) Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion VII, "Control of Purchased Material, Equipment, and Services," because ExGen failed to control defective parts and prevent their use. The subsequent receipt and use of defective parts at James A. FitzPatrick (FitzPatrick) resulted in a failure of the High Pressure Coolant Injection (HPCI) system on April 10, 2020, during monthly surveillance testing.

A Performance Deficiency was documented as follows: "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, "Nonconforming Materials, Parts, and Components," which was within their ability to foresee and prevent."

ExGen provided Reference 2 in response to the Apparent Violation, which informed the NRC that ExGen did not agree that the violations constituted a Performance Deficiency as the FitzPatrick staff could not have reasonably been able to identify and prevent the non-conforming material from being installed.

In the Final NOV (Reference 1), the NRC provided responses to some of the issues raised by ExGen in Reference 2 and recharacterized the violation. However, the NRC response suggests a continuing misunderstanding regarding the roles and responsibilities of the individuals involved in the activities that resulted in non-conforming material from the Limerick Generating Station (Limerick) warehouse being installed in the FitzPatrick HPCI system. ExGen maintains that if these roles and responsibilities were more accurately understood, no Performance Deficiency would have been identified at FitzPatrick and the violation would be appropriately characterized as a Severity Level III Traditional Enforcement Violation.

As required by the Notice of Violation, ExGen is providing the following in response to the four questions posed in Reference 1:

- The reason for the violation, or, if contested, the basis for disputing the violation or severity level:
 - **Response:** As stated above, ExGen is contesting this violation. The basis for the contestation is provided in Attachment 1. A detailed discussion of the Root Cause of the component failure was provided to the NRC in Reference 2.
- The corrective steps that have been taken and the results achieved:
 - **Response:** A detailed description of the corrective actions taken to address the cause, as determined through the ExGen Root Cause analysis was provided to the NRC in Reference 2.
- The corrective steps that will be taken:
 - **Response:** Additional corrective actions will be considered and implemented as necessary based on the NRC response to this letter. Additional actions necessary will be formally communicated to the NRC.
- The date when full compliance will be achieved:
 - **Response:** Full compliance was restored on 04/24/2021 following completion of corrective maintenance to the HPCI System and the corrective action to address the 2010 Human Performance error at Limerick as discussed in Reference 2.

A detailed discussion of ExGen's basis for the contestation is documented in Attachment 1 of this letter. Furthermore, as discussed on the May 17, 2021 phone call between ExGen and NRC Region 1, ExGen preserves its right to file a formal backfit appeal pursuant to Management Directive 8.4 on the issues underlying the NOV at a future date.

The priority for ExGen, with this letter, is to reach a common understanding of the appropriate characterization of the violations such that effective corrective actions are implemented.

Should you have any questions concerning this response, please contact Rich Sullivan at 315-349-6562.

Respectfully,

Pat Navin,
Site Vice President

Attachment: 1) Detailed Response to Notice of Violation EA-20-138

U.S. Nuclear Regulatory Commission
Reply to Notice of Violation; EA-20-138
June 3, 2021

cc: Director, Office of Enforcement
Regional Administrator - NRC Region I
NRC Senior Resident Inspector James A. FitzPatrick Nuclear Power Plant

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I. Introduction:

Inspection Report 05000333/2021090 documents a finding with associated violations that has been determined to be White with low-to-moderate safety significance. The finding is associated with violations of Title 10 of the Code of Federal Regulations (CFR) Part 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion VII, "Control of Purchased Material, Equipment, and Services."

The Performance Deficiency (PD) is documented as follows: "The inspectors determined that [Exelon Generation Co. LLC (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, "Nonconforming Materials, Parts, and Components," which was within their ability to foresee and prevent."

ExGen communicated in our response to the Apparent Violation (AV) that: (1) there is no regulatory requirement underlying the violation, and (2) the violations were not within James A. FitzPatrick's (FitzPatrick's) ability to foresee and prevent and therefore did not meet the NRC's definition of a PD. The NRC maintained their position in the final Notice of Violation (NOV) that Criterion VII and XV are the basis for the violation, and installation of the non-conforming material was foreseeable and preventable. In both the AV and the NOV, the NRC's basis for determining that the violations were reasonably foreseeable and preventable is that the act of clearing an unrelated shelf life hold provided the opportunity for the Limerick Generation Station (Limerick) material handler (MH) and the FitzPatrick qualified receipt inspector (QRI) to identify the Part 21 information and associated Issue Report (IR) in the component database and the ExGen Corrective Action Program (CAP) database. However, the NRC has mischaracterized this "archived" and "descriptive" information as "readily available" to both the Limerick MH and the FitzPatrick QRI.

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

This NOV response letter will address information that ExGen provided to the NRC in the AV response that the NRC did not address in the NOV. The specific information that was not addressed by the NRC established that there is no regulatory or procedural requirement to research hidden¹ fields in the component tracking database that were unrelated to the shelf life hold and therefore, the information regarding the 2010 Part 21 non-conformance that was located in an unrelated hidden field was not "readily available" to the BSC staff supporting the 2017 sale and transfer. Thus, the installation of non-conforming material was not

¹ Throughout this document, the word "hidden" is used in the context that when looking at a screen or window in the component tracking database, the user would be required to click on a button or icon to bring up or make visible additional information.

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reasonably foreseeable or preventable.

II. NOV Assessment:

A. 10 CFR Part 50, Appendix B, Criterion XV

ExGen is contesting the NOV characterization of the violation of 10 CFR Part 50, Appendix B, Criterion XV.

The NRC staff acknowledged that the Criterion XV violation that occurred at Limerick in 2010 could not have been prevented by the ExGen staff in 2017. However, when recharacterizing the Criterion XV violation as having occurred in 2017, the NRC did not explain how Criterion XV was violated that year.

ExGen maintains that no Criterion XV violation occurred in 2017, as the measures that had been established to identify and segregate the non-conformance were not followed in 2010 while processing the Part 21 notification at Limerick. Information that would have informed the Limerick MH of the non-conformance in 2017 was effectively archived in 2010 when action tracking items (ATIs) to resolve the Part 21 notification were inappropriately taken to "COMPLETE" status by Limerick station personnel.

The NRC indicated that the act of clearing an unrelated shelf life hold provided the opportunity, in 2017, for the Limerick MH to identify the Part 21 "archived" and "hidden" information, which the NRC characterized as "readily available". In the response to the AV, ExGen justified why the information was not readily available to the BSC staff at either site and informed the NRC that researching this "archived" and "hidden" information is not required by 10 CFR Part 50, Appendix B or the applicable procedures, SM-AA-102 or SM-AA-404. However, the NRC did not respond to ExGen's explanation in the final NOV. A detailed discussion of the activities associated with clearing this hold as well as the nature of the archived Part 21 information and applicable regulatory requirements is provided in Section III, below.

B. 10 CFR Part 50, Appendix B, Criterion VII

ExGen is contesting the violation of 10 CFR Part 50, Appendix B, Criterion VII.

ExGen maintains that the Receipt Inspection conducted by FitzPatrick in 2017 was performed in accordance with the ExGen Quality Assurance Program (QAP) and 10 CFR Part 50, Appendix B, Criterion VII, and could not have reasonably identified the non-conforming condition since the procurement documents provided by Limerick failed to include information that would have indicated the non-conformance. There was no reason for the FitzPatrick QRI to question the validity of those documents. Furthermore, absent any indication of an issue with the component, Criterion VII does not require the QRI to conduct research (beyond the scope of the procurement documents) to determine if there is additional information that may be relevant to the component. Any such interpretation of the regulation would unnecessarily duplicate the NRC's requirement that the seller assure in procurement documents that a safety-related component satisfies quality assurance requirements and the requirements of 10 CFR Part 21.

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The NRC stated that in 2017, BSC staff at FitzPatrick accessed the component tracking database and removed a hold due to a shelf life concern and that this presented an opportunity to identify the Part 21 information. This statement inaccurately presumes that the act of clearing this hold was conducted at FitzPatrick as part of the receipt inspection. However, this unrelated shelf life hold was actually cleared by the Limerick MH after communicating to the FitzPatrick buyer that the hold was due to the shelf life expiring. The FitzPatrick buyer engaged the FitzPatrick Procurement Engineer (PE) who appropriately reviewed the original vendor documentation to determine that the shelf life could be extended and communicated this to the FitzPatrick buyer and FitzPatrick QRI. At no time did the FitzPatrick buyer, FitzPatrick QRI, or the FitzPatrick PE have any reason – nor was there any regulatory requirement – to access the component tracking database or the ExGen CAP system to investigate the reason for the shelf life hold. Clearing the hold was the responsibility of the Limerick warehouse staff as the custodians of the material. As discussed in detail below, the Limerick MH correctly identified and communicated the reason for the hold to FitzPatrick.

To summarize, the act of clearing a hold, in and of itself, does not require a review above or beyond the information necessary to address the hold.

C. Final Significance Determination

ExGen is not contesting the Final Significance Determination per IMC 0609 Attachment 2.

ExGen appreciates the opportunity to provide additional information regarding the final significance determination and accepts that the NRC executed the Significance Determination Process consistent with NRC guidance. No additional information will be provided regarding the Risk Significance of this event.

III. Shelf Life HOLD Detail

A. Unresolved Issues:

There is no indication in the final NOV that the information regarding the Criterion VII violation provided by ExGen in response to the AV, as discussed above, was considered or addressed.

ExGen provided a significant amount of information associated with the sale of the Pressure Control Valve (PCV) from Limerick to FitzPatrick, including a detailed discussion about a hold that was applied by the Limerick staff to the PCV on October 20, 2017, due to a pending shelf life concern. In the Final NOV, the NRC maintained that when clearing this unrelated shelf life hold, the BSC staff had a reasonable opportunity to identify the non-conforming component, but the NRC did not address the clarifying information provided by ExGen.

The NRC stated in the AV, and again in the NOV, that the Part 21 information was readily available to the BSC staff through the ExGen CAP database, as IR 1086768 (written in 2010 to document the Part 21 notification) was noted in the component tracking database. The NRC went on to state that the IR had not been resolved at the time the part was sold to and accepted at FitzPatrick. This is not

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correct. As ExGen explained in the response to the AV, all actions associated with IR 1086768 have been in "COMPLETE" status since 2010. However, the NRC did not acknowledge this fact in the NOV and inaccurately stated that the IR remained unresolved.

The NRC's characterization of the information as "readily available" suggests that the information would have presented itself to the Limerick MH during the normal course of activities to clear the shelf life hold and sell the component to FitzPatrick. As discussed below, the Part 21 IR in the component tracking database is documented in a hidden field. The Limerick MH would not, during the normal course of clearing the hold, be required or expected to open this hidden field.

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

This expectation to open and review hidden fields and then audit the closure of archived ATIs listed in the hidden fields, without cause, expands of the requirements of both 10 CFR Part 50, Appendix B, Criterion VII and Criterion XV. ExGen further maintains that if the actual mechanics of clearing this hold, as well as the sequence of events necessary to seek out and locate the 2010 Part 21 IR number in the hidden fields of the component tracking database, were accurately understood, the NRC would not have characterized the Part 21 information as "readily available".

ExGen acknowledges that the IR number associated with the 2010 Part 21 notification was documented in the component tracking database. However, during the required normal course of clearing the shelf life hold, releasing the PCV to FitzPatrick, and then completing the receipt inspection in accordance with station procedures, this "hidden" information would not have been presented to the individuals nor did any event or condition occur that would have driven the BSC staff to seek out this information.

This clarifying information regarding the 2017 shelf life hold, the location of the Part 21 IR in a "hidden" field and the "COMPLETE" status of the 2010 Part 21 ATIs are the most relevant information regarding whether the installation of non-conforming material was foreseeable and preventable to the BSC or ExGen staff supporting the sale and transfer in 2017. Nevertheless, this does not appear to have been considered by the NRC when characterizing this Finding.

In summary, there was no indication of an unresolved Part 21 issue and therefore, there was no procedural or regulatory requirement to conduct additional searches of the component tracking database or the CAP system as the NRC suggests should have been done in 2017.

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B. Readily Available VS Available Through Research

The availability of the 2010 Part 21 information must be accurately characterized to fully understand ExGen's concern with the NRC's position that this information was "readily available".

From the NOV:

"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 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."

Based on these statements, the NRC appears to misunderstand the historic and hidden nature of the 10 CFR Part 21 information that was found in the referenced systems. For clarification, both the ExGen Corrective Action Program system (database) and the component tracking database include archived and historic information that is separate and apart from current and active information. As stated earlier, contrary to NRC statements in the AV and the NOV, all ATIs associated with the 2010 Part 21 in the ExGen CAP system have been in "COMPLETE" status since 2010, and the IR is considered "COMPLETE" in the ExGen CAP system. Assuming the BSC staff in 2017 had reason to look for any open ATIs associated with older Part 21 notifications (which they did not), this would have informed the BSC staff in 2017 that appropriate actions were put in place and subsequently completed to address the 2010 Part 21 notification.

The component tracking database also includes functionality that allows users to enter descriptive information. However, the descriptive information is not used for controlling component availability. Component availability is specifically controlled under the "Status" column of the component tracking database. This is not a hidden field but is visible to the user once the Catalog Identification number (CatID) is entered. The IR number associated with the 2010 Part 21 response was not documented in the status field, but instead was documented in a hidden "descriptive information" field along with 63 other line items of descriptive information.

Descriptive information in the component tracking database can be provided in several panels. The highest level panel that is visible to the user when accessing the component tracking database using the CatID includes a general description of

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the component as well as the status of the component (Ready / HUSER (hold) / etc.). Additional hidden panels may be accessed through a series of drop down menus to identify or add more descriptive information if necessary. Unless specifically accessed, these lower level descriptive information panels are not visible to the MH, QRI, or PE, nor do any procedures or regulations require accessing these panels unless a question or concern arises that results in the need for additional research to resolve the concern. Then, and only then, would the user be expected to expand the applicable drop down option and review the available information to determine the answer to whatever question or concern arises. To reiterate, this information is NOT presented to the MH, QRI, or PE but would only be identified through research if a specific concern indicated the need for such research.

The Part 21 IR number was entered into this lowest level descriptive information field and identified Limerick as the site to which the information applied.

The NRC has suggested that the fact that the PCV was in "H/USER" or a hold status would have given the MH, QRI, and PE the necessary concern or question to require the additional research. This is not accurate. As described below, the reason for the hold status was indeed readily available and visible to the Limerick MH in the topmost CatID panel near the "Status" column in the form of a highlighted electronic note. This note clearly informed the user of the need to resolve a shelf life issue and made no mention of or reference to the 2010 Part 21 notification or the associated IR. The review of the procurement documents in 2017 during the sale of the PCV did not require entry into the component tracking database or the CAP database. Again, during the receipt inspection process, there was no information readily available that would have indicated an unresolved Part 21 concern.

This historic information in both the CAP system and the descriptive information in the component tracking database are not procedurally used to actively manage the availability of warehoused equipment, but instead are available as reference when needed. Importantly, the IR 1086768 entry in the component tracking database is date-stamped 2010, yet the date stamp for the shelf life hold in the active status field is 2017. ExGen maintains that this fact, alone, would have correctly informed a qualified PE that IR 1086768 did not provide relevant information regarding the hold added in 2017.

Fitzpatrick was under no regulatory or procedural obligation to data-mine the historical information in the CAP system or the hidden descriptive information in the component tracking database to find and then audit "COMPLETE" Part 21 information, especially where that information bore no relation to the 2017 active hold.

C. Processing a HOLD

The NRC response to the ExGen concern states:

"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

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address the 'hold'."

Based on this statement, the NRC again appears to misunderstand how ExGen applies and manages the hold statuses associated with warehoused material. Additionally, as previously stated, the NRC incorrectly attributed the function of clearing a hold to the receipt inspection.

ExGen procedures allow that a hold may be applied for any one of several reasons. ExGen processes and practices used to manage holds include a status log that indicates, via a date stamp, when a hold is applied as well as when the hold is removed. Per the date stamp, the shelf life hold referenced in the NOV was applied to the component tracking database on October 20, 2017, after it was identified, by a monthly report, that the shelf life was due to expire. At this time, there were no other holds applied to the component. The individual that applied this hold stated that an electronic note was added in the status log window of the component tracking database to indicate that the hold was due to the shelf life concern. Per skill of the craft practices, it is common practice to add an electronic note to the panel for which the note applies. This electronic note appears in the topmost CatID panel of the component tracking database such that it ensures the reason for the hold is readily identifiable and the next user is not required to research the reason for the hold. When the hold was identified in December of 2017, the electronic note in the status window correctly informed the Limerick MH that the shelf life needed to be addressed prior to releasing the component for use or sale. The shelf life concern was subsequently communicated to the FitzPatrick buyer and PE who reconciled the shelf life concern using the original manufacturer's certified documentation. The hold was removed by the Limerick MH while the PCV was still in the custody of the Limerick warehouse and only after the FitzPatrick staff was made aware of the reason for the hold and confirmed the shelf life was acceptable.

The NRC statement above further suggests that the NRC believes that the reason for the hold was not readily apparent to the Limerick MH and that some level of investigation at both Limerick and FitzPatrick was necessary to determine why the hold was applied. This is not the case. The hold field is an active field in this database and, as discussed above, the notes that explain the reason for the hold are also applied in this active field such that the reason for the hold is clearly communicated. The MHs are not required nor expected to research and interpret unrelated archived information to clear a hold. ExGen expects that if the reason for a hold on safety-related material is not readily apparent to the material handler, the hold would NOT be cleared until the cause of the hold is determined with certainty. Again, that did not occur in this case because the reason for the hold was appropriately documented in the expected window and therefore readily available and self-evident. No regulation or procedure required BSC staff at FitzPatrick or Limerick to conduct additional inquiries to discover the entirely unrelated Part 21 information prior to clearing the hold.

III. Conclusion:

With the issuance of the Final Notice of Violation, the NRC has taken the position that both the FitzPatrick Receipt Inspector and the Limerick Material Handler, despite already correctly identifying and resolving a shelf life hold, would be

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expected to review a separate and unrelated hidden list of historic line items and research each individual line item from that list to confirm that there is no information that would negate or contradict existing certified procurement documents. That research, in this case, would require a review of 63 line items dating back to the late 1990s, a detailed audit of actions completed in 2010, and would require the individual to have access to and proficiency with the now retired PIMS work management database. Moreover, corrective actions necessary to address the Finding(s) as currently characterized would require this chain of events for every ExGen site-to-site purchase or transfer and would detract from the focus on the necessary corrective actions to ensure properly addressing the non-conformance at the time of discovery. In addition, this interpretation of Appendix B requirements would set industry-wide precedent and significantly affect supply chain activities.

Based on the clarifying details above, the NRC should now recognize that the installation was not reasonably foreseeable or preventable, and therefore, no Performance Deficiency exists. ExGen further maintains that as there is no PD associated with this violation, it would be more appropriate to characterize the NOV as a Traditional Enforcement Violation of 10 CFR Part 50, Appendix B, Criterion XV. Corrective actions have already been developed and implemented to address the Criterion XV failure that occurred at Limerick in 2010.