

ENCLOSURE 1

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

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 As a result, the Criterion VII violation has been withdrawn and the Criterion XV violation has been revised.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

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

SUMMARY OF EXGEN COMMENT – Ability to Identify Part 21 Information

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

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT – Archived, Descriptive and Readily Available

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT- Requirements to Research

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT- Limerick Criterion XV

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

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT- Clearing the User Hold

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

NRC RESPONSE

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

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

SUMMARY OF EXGEN COMMENT- Clearing the User Hold

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT- Unresolve Part 21's

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

NRC RESPONSE

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

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

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

NRC RESPONSE

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

SUMMARY OF EXGEN COMMENT – Descriptive Information

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

NRC RESPONSE

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