Exelon Generation®

**James A. FitzPatrick NPP**
P.O. Box 110
Lycoming, NY 13093

**Pat Navin**
Site Vice President

EA-20-138

JAFP-21-0013
February 26, 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: 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)

Reference 1: James A. FitzPatrick Nuclear Power Plant – Problem Identification and Resolution Report 05000333/2020012 and Preliminary White Finding and Apparent Violation (ML21020A108 Dated January 21, 2021)

Exelon Generation Company, LLC (ExGen) appreciates the opportunity to communicate our position on the facts and assumptions associated with a preliminary white finding and apparent violation documented in Reference 1. ExGen shares the concern for operational safety and the impact on the operability of the High Pressure Coolant Injection System (HPCI) which resulted from installing a defective part. ExGen has thoroughly reviewed this event and has taken extensive corrective actions to prevent recurrence at the James A. FitzPatrick Nuclear Power Plant (JAF) and all individually licensed ExGen facilities as discussed in Attachment 1 of this letter.

Reference 1 documents a finding with associated apparent violations that the NRC has preliminarily determined to be White with low-to-moderate safety significance. The finding is associated with apparent 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 Exelon failed to control defective parts and prevent their use. The subsequent receipt and use of defective parts at JAF resulted in a failure of the HPCI system on April 10, 2020 during monthly surveillance testing.

A Performance Deficiency was documented as follows: 1) “The inspectors determined that Exelon failed to control defective parts and prevent their use as required by 10 CFR 50, Appendix B, Criteria XV, ‘Non-conforming Materials, Parts, and Components’ which was in their ability to foresee and prevent” and 2) “The inspectors also determined that Exelon failed to control defective parts and prevent their use as required by 10 CFR Part 50, Appendix B, Criteria VII, “Control of Purchased Material, Equipment, and Services,” which was within their ability to foresee and prevent.”

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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)
February 26, 2021

ExGen acknowledges that a failure to control a defective part and prevent its use occurred at the Limerick Generating Station (LIM) in 2010. ExGen further acknowledges that the sale to JAF in 2017 and subsequent installation resulted in a failure of the HPCI system in 2020.

The JAF licensed facility and the LIM licensed facility are legally independent entities with separate NRC issued operating licenses that are supported by common resources as part of the larger ExGen fleet. As such, no performance deficiency applicable to the JAF licensed facility exists because the installation of non-conforming material into the JAF HPCI system was not reasonably foreseeable or preventable by the staff working in direct support of the JAF licensed facility.

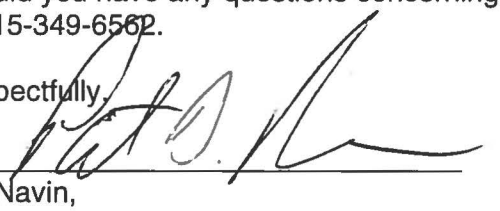
The receipt inspection completed at JAF in 2017 was performed consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and the JAF Quality Assurance Program requirements and therefore does not constitute a failure to follow a regulatory or self-imposed standard. NRC Guidance on 10 CFR Part 21 provides the basis for ExGen's position that it is the seller's obligation to inform the purchaser of non-conforming material including material that was subject to a previous 10 CFR Part 21 notification. The regulation does not require additional verification by the purchaser.

ExGen is concerned that the position reflected in the Inspection Report constitutes a new interpretation of the requirements of 10 CFR 50, Appendix B, Criterion VII that would require ExGen, as well as the industry, to add requirements to the currently approved Quality Assurance Program implementing documents and should be evaluated under the Backfit Rule pursuant to 10 CFR 50.109.

ExGen is providing new information and additional insights which reduce some of the calculational uncertainties that weigh into the Significance Determination.

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 Apparent Violation EA-20-138

2) Uncertainties Input in Response to Apparent Violation EA-20-138

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

**Attachment 1:**

Detailed Response to Apparent Violation EA-20-138

# Attachment 1
# Detailed Response to Apparent Violation EA-20-138

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# Attachment 1
# Detailed Response to Apparent Violation EA-20-138

## I. Introduction:

Inspection Report 05000333/2020012 documents a finding with associated apparent violations that have been preliminarily determined to be White with low-to-moderate safety significance. The finding is associated with apparent 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 is documented as follows: 1) “The inspectors determined that Exelon failed to control defective parts and prevent their use as required by 10 CFR 50, Appendix B, Criteria XV, ‘Non-conforming Materials, Parts, and Components’ which was in their ability to foresee and prevent.” A 2) “The inspectors also determined that Exelon failed to control defective parts and prevent their use as required by 10 CFR Part 50, Appendix B, Criteria VII, “Control of Purchased Material, Equipment, and Services,” which was within their ability to foresee and prevent.”

Exelon Generation Company, LLC (ExGen) acknowledges that a failure to control a defective part and prevent its use occurred at the Limerick Generating Station (LIM) in 2010 and as a result LIM failed to communicate the deficiency to JAF prior to selling the defective part to JAF. ExGen further acknowledges that the sale of the defective part from LIM to JAF in 2017 and subsequent installation resulted in a failure of the JAF HPCI system in 2020.

ExGen recognizes the significance and impact of installing non-conforming material into safety related systems and further recognizes that 10 CFR 50, Appendix B along with 10 CFR Part 21 provide adequate guidance to control non-conforming material to prevent installation. A Root Cause Analysis has been initiated to investigate the failure to properly resolve or communicate the 10 CFR Part 21 non-conformance prior to installation at JAF.

ExGen is providing this attachment in support of our position that since the JAF licensed facility and the LIM licensed facility are legally independent entities, no performance deficiency applicable to the JAF licensed facility exists because the installation of non-conforming material into the JAF HPCI system was not reasonably foreseeable or preventable by the staff working in direct support of the JAF licensed facility nor did the JAF staff fail to follow a regulatory or self-imposed standard.

ExGen is also concerned that the position reflected in the Inspection Report constitutes a new interpretation of the requirements of 10 CFR 50, Appendix B, Criterion VII that would require ExGen, as well as the industry, to add requirements to the currently approved Quality Assurance Program implementing documents and should be evaluated under the Backfit Rule pursuant to 10 CFR 50.109.

**II. Immediate and Follow Up Actions Taken:**

On April 10, 2020 at approximately 0130, during monthly surveillance testing, an oil leak was identified on the HPCI trip system pressure control valve (PCV). Troubleshooting and maintenance activities were immediately commenced to investigate the cause and replace the PCV. The JAF HPCI system was restored to Operable status at approximately 2000 on April 10, 2020.

As a result of this event, a Corrective Action Program Evaluation (CAPE) was performed in accordance with the JAF Corrective Action Program (CAP). The CAPE determined that the PCV oil leak was the result of a premature failure of a diaphragm which was the subject of a 2010 10 CFR Part 21 notification while the part was still owned by LIM. The CAPE further identified that the 10 CFR Part 21 notification was not properly resolved or communicated by LIM prior to the part being sold to JAF in 2017.

Corrective actions resulting from the CAPE were taken as described below. (Actions are documented in the JAF CAP system under Issue Reports 4346516 and 4348906)

- Procurement and warehouse personnel at each individually licensed ExGen facility performed a Stand Down and Read & Sign to review the key learnings from the CAPE and to reinforce expectations and procedural requirements for proper labeling and handling of non-conforming material.

- Fleetwide extent of condition reviews were completed with no additional discrepancies in controlling inventory subject to a 10 CFR Part 21 notification.

- The following enhancements were made to Warehouse and Procurement procedures:

    - SM-AA-404: “Nuclear Material Procurement”

        - Added the following statements regarding transfer or sale between sites:

            - “If the CID being transferred has other discrepancies, such as an existing Part 21 notification that has yet to be resolved, the site transferring the item must notify the receiving site of the discrepancy so it can be evaluated as a deficient item under Attachment 4 of SM-AA-102, Warehouse Operations.”

            - “Items that are on hold at one site can be released to another site while on hold only if an action item is CREATED at the receiving site to track resolution of the item before transfer occurs, and the item is added to the receiving site’s hold tag log. The new action created must be completed before the receiving site can place the CAT ID back into a READY status.”

    - SM-AA-102: “Warehouse Operations”

        - Added the following statement regarding items impacted by 10 CFR Part 21 notifications:

- "In addition, these items must also be physically SEGREGATED from acceptable items with the same Cat ID. Refer to Attachment 5, step 1.14 for additional details."

**III. ExGen Position:**

Since the JAF licensed facility and the LIM licensed facility are legally independent entities, no performance deficiency (PD) applicable to the JAF licensed facility exists because the installation of non-conforming material into the JAF HPCI system was not reasonably foreseeable or preventable by the staff working in direct support of the JAF licensed facility nor did this staff fail to follow a regulatory or self-imposed standard.

This position is based on the following:

**A. Independence of Licensed Facilities:** The JAF licensed facility and the LIM licensed facility are legally independent entities with separate NRC issued operating licenses that are supported by common resources as part of the larger ExGen fleet. Support resources provided by the Exelon Business Services Company (BSC) and which are assigned to individual licensed facilities are subject to the specific operating license(s) of the facility to which they are assigned. Therefore, the ability to foresee and prevent the deficiency at LIM (seller) in 2010 should not be a basis for the deficiency being foreseeable and preventable by JAF (buyer) in 2017. (See section IV.A. for basis and supporting Information.)

**B. 10 CFR 50, Appendix B, Criterion XV:** The 10 CFR 50, Appendix B, Criterion XV violation and associated PD occurred at the LIM licensed facility in 2010 by support resources working in direct support of the LIM operating licenses. (See section IV.B. for basis and supporting information.)

**C. 10 CFR 50, Appendix B, Criterion VII:** The receipt inspection completed at JAF in 2017 was performed consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and the JAF Quality Assurance Program (QAP) requirements and therefore does not constitute a failure to follow a regulatory or self-imposed standard. (See section IV.C. for basis and supporting information.)

**D. Backfit Concern:** The NRC's relied-upon interpretation of 10 CFR 50, Appendix B, Criterion VII, is a new staff position that would result in a modification to ExGen's QAP and as such should be analyzed as a backfit under 10 CFR 50.109. (See section IV.D. for basis and supporting information.)

## IV. Basis and Supporting Information

### A. Independence of NRC Licensed Facilities:

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

**Exelon Corporation Structure**

The Inspection Report includes several references to Exelon Business Services Company (BSC) as well as several "shared services" that are provided by ExGen and BSC. ExGen is providing the following regarding the roles and responsibilities within Exelon Corporation and its affiliates to clarify these relationships.

The Exelon Corporation (ExCorp) is a utility services holding company incorporated under the laws of Pennsylvania. ExCorp owns a number of subsidiary companies, including Exelon Generation Company LLC (ExGen) as well as the Business Services Company LLC (BSC). ExGen and BSC are legally separate entities. ExCorp provides its subsidiaries with a variety of support services at cost, including legal, human resources, financial, information technology, and supply management services, through its business services subsidiary, BSC. BSC provides these services at cost to all companies within ExCorp, including ExGen, Constellation, BGE, ComEd, PECO, Atlantic City Electric, Delmarva Power, and Pepco. These services are provided by BSC pursuant to a General Services Agreement (GSA) and individual Service Level Agreements (SLAs) with each of these companies. BSC is reimbursed for these services pursuant to these same agreements. Neither ExCorp nor BSC possess NRC issued licenses.

ExGen possesses 27 distinct NRC issued licenses to own and/or operate nuclear power reactors in accordance with 10 CFR Part 50. As stated in the respective licenses, ExGen is the licensed operator and Exelon FitzPatrick LLC (Exelon FitzPatrick) is the licensed owner for FitzPatrick (JAF) (License No. DPR-59) and ExGen alone is the licensed owner and operator of the two reactor licenses for the Limerick Generating Station (LIM) (License Nos: NPF-39 and NPF-85). The 10 CFR Part 50 NRC licenses possessed in whole or in part by ExGen all contain separate requirements unique to that individual license and each individual licensee must comply with the unique terms of the applicable license. For purposes of compliance, ExGen is 27 independent NRC issued licensees and the relationship between those licenses is no different than it is between ExGen and the NRC issued licenses possessed by non-ExGen entities. ExGen does not possess a "global" 10 CFR Part 50 license that applies equally to all of ExGen's nuclear facilities. And while ExGen may be held responsible for non-compliances at LIM as the license holder for that licensed facility, responsibility for those non-compliances under that specific license does not carry over to the other licenses merely through ExGen's collective possession of 27 separate licenses.

Finally, to further illustrate this concern, examples are provided here with clarifying information to better characterize the ExGen and BSC relationship and the

independence of the JAF and LIM licensed facilities.

*Example (From Inspection Report):*

*"Contrary to the above [10 CFR Part 50, Appendix B and SM-AA-102], from July 1, 2010 to April 10, 2020, Exelon [Generation Company LLC] did not ensure that measures were established to control materials, parts, or components which do not conform to requirements in order to segregate and prevent their inadvertent use or installation, in that a nonconforming item was not reviewed and rejected in accordance with documented procedures. Specifically, Exelon [Generation Company LLC] did not take required actions for an applicable 10 CFR Part 21 report issued on July 1, 2010 that identified a material defect in HPCI system turbine overspeed reset control valve diaphragms. Exelon [Generation Company LLC] did not place an electronic hold, physically segregate, or use conspicuous signage for a subject defective diaphragm, allowing the defective diaphragm to be installed. As a result, on December 16, 2017, a valve containing the defective diaphragm was installed at FitzPatrick."*

Of critical concern is that this description of the apparent violations does not distinguish between ExGen as the license holder for LIM's two licenses (License Nos: NPF-39 and NPF-85) from ExGen as the licensed operator for JAF (License No: DPR-59). This paragraph from the Inspection Report largely describes actions that were taken in 2010 under the LIM operating licenses that ExGen concedes were in violation of NRC requirements. ExGen and Exelon FitzPatrick as the license holders for JAF, however, had no role in the 2010 non-compliances and had no reasonable way to know that they existed. The fact that these separate actions were performed by one entity (BSC) is not applicable to the determination of whether there was a non-compliance under the JAF license. As noted above, BSC provides supply services for all of ExGen's licensed facilities, but those services are specific to the NRC issued license under which they are performed.

**ExGen Shared Services**

The fact that the actions cited by the NRC involved several ExGen and ExCorp shared services is also not material to whether a PD or violation under the JAF license occurred. To promote fleet excellence and as a strong business practice, ExGen develops and institutes corporate-wide procedures and practices that are individually implemented at each licensed facility as applicable to the unique licenses. To name a few, these areas include the Quality Assurance Program, Corrective Action Program, licensing and regulatory assurance, engineering, security, and fuel management.

Among other benefits, this establishes uniform "best practices" and reduces financial and resource burden on individual licensed facilities in not having to separately develop procedures and policies to comply with regulatory requirements. While the employees who perform these shared functions at the corporate level of ExGen are not employees of any individual licensee, the licensees are ultimately responsible for the work performed in support of the individual license.

ExGen is concerned that the Inspection Report contains assumptions about these shared services that are erroneously interpreted to combine accountability for the 2017 non-conformance at the JAF licensed facility with a non-compliance at the LIM licensed facility in 2010.

Example (From Inspection Report)

*"Exelon [Generation Company LLC] operates a central supply organization that provides support for day-to-day nuclear station (site) operations with a dual reporting relationship to the centralized supply organization and the site organization."*

It is inaccurate to say that ExGen "operates a central supply organization." As already noted, Supply personnel administratively report to BSC but perform services that are controlled under the JAF license and subject to the BSC-ExGen General Services Agreement (GSA), the specific Service Level Agreement (SLA) between BSC and ExGen, as well as the Nuclear Operating Services Agreement (NOSA) between ExGen and Exelon FitzPatrick. Nonetheless, Supply services performed at a licensed facility by BSC are specific to that licensed facility and that license. The BSC Supply reporting relationship at the licensed facility is also clarified in the ExGen QA Topical Report (QATR) which states that licensed facility Supply personnel are dedicated to the licensed facility they are assigned. Specifically, "Site supply….coordinates parts requirements, specifies and evaluates parts, procures all materials for the site, ships and receives material, and controls the onsite inventory."

The ExGen QA Program (QAP) description is also a function that ExGen collectively manages for each individual NRC licensee in the fleet, but accountability to properly implement the QAP is with each individual licensed facility on a license-by-license basis.

Example: (From Inspection Report)

*"Exelon [Generation Company LLC] implements a fleet-wide quality assurance program, along with procurement and warehouse procedures for all its associated nuclear stations to verify, store, and move components between stations using Business Services Company personnel."*

As with the Inspection Report's description of the Supply function, this statement is not entirely accurate. Each 10 CFR Part 50 licensee is independently responsible to establish, implement and maintain an approved QAP consistent with the requirements of 10 CFR 50, Appendix B, as required by 10 CFR 50.34(a)(7) and 10 CFR 50.54(a). While ExGen obtains NRC approval for a uniform QAP through the Quality Assurance Topical Report (QATR), the QATR makes it clear that each individual licensee in the ExGen fleet must implement the program on a licensee-by-licensee basis. After receiving NRC approval, ExGen sends the QATR Revisions to "all site document control centers" and "implementation" by the licensed facilities is required by a certain date.

As such, the QAP for JAF is unique to JAF and the QAP for LIM is unique to LIM. This was observed most recently in the NRC's approval of the ExGen QATR on November 5, 2020. The Safety Evaluation Report (SER) stated that "[t]he QAP descriptions and commitments to quality standards differ on a plant-specific basis" and that "[e]ach licensee is still responsible for determining whether changes to their plant-specific QAPs…."

**Section IV.A. Conclusion:**

While the purpose of referencing various corporate organizations and functions in the Inspection Report is unclear, it is ExGen's position that the Inspection Report

erroneously interpreted the ExGen and BSC relationship which resulted in combining accountability for the 2017 non-conformance at JAF with a 2010 non-compliance at LIM. The Inspection Report does not appear to recognize that the JAF licensed facility and the LIM licensed facility are legally independent entities that share common support resources as part of the larger ExGen fleet.

**B. 10 CFR 50, Appendix B, Criterion XV**

The 10 CFR 50, Appendix B, Criterion XV violation and associated PD occurred at the LIM licensed facility in 2010 by support resources working in direct support of the LIM operating licenses.

The Inspection Report identified an apparent violation of 10 CFR 50, Appendix B, Criterion XV, "Nonconforming Materials, Parts, or Components" based on the failure to properly identify and segregate non-conforming material that was identified and communicated to LIM by a General Electric-Hitachi (GEH) 10 CFR Part 21 notification.

The JAF Causal Analysis to address the HPCI failure determined that as part of LIM's response to the 2010 GEH 10 CFR Part 21 notification, LIM personnel failed to follow procedure requirements to place an electronic hold and segregate the defective part. This allowed the defective part to be sold to JAF in 2017 without being notified of the deficiency.

10 CFR Part 21 Responsibilities:

Both JAF and LIM procedures require the specific licensed facilities to individually evaluate the impact of a 10 CFR Part 21 notification at the affected licensed facility. The requirement applies to both installed as well as warehoused material. These procedures are adequate to ensure that any warehoused material impacted by a 10 CFR Part 21 notification is identified and segregated, corrected or discarded prior to use, transfer, or sale.

10 CFR 50 Appendix B Responsibilities:

As discussed in section IV.A. of this attachment, the support resources assigned to LIM are responsible to ensure LIM complies with the conditions of the LIM operating license including compliance with 10 CFR 50, Appendix B. Specifically, a support resource assigned to evaluate or respond to a 10 CFR Part 21 notification is responsible to ensure that the requirements of 10 CFR 50, Appendix B, Criterion XV are met if a 10 CFR Part 21 review determines that warehoused material is defective or non-conforming. This responsibility applies to both support resources assigned to LIM as well as staff directly employed by LIM. The following timeline illustrates the key steps applicable to the non-conforming PCV.

- **07/01/2010**: GEH issued report MFN 10-192 (10 CFR Part 21 Reportable Condition Notification) applicable to BWR HPCI system pressure control valves (PCV) which specifically identified LIM as an affected station but not JAF.

- **07/01/2010**: Assignment 1086768-02 was created for the LIM HPCI system engineer to perform a formal review of the GEH notification in accordance with station procedures.

- **08/19/2010:** Assignment 1086768-02 was completed and as part of the closeout, assignment 1086768-06 was created to a LIM procurement specialist to restrict use of the affected PCVs and reconcile replacement of deficient parts with GEH.

- **10/28/2010:** LIM procurement specialist completed assignment 1086768-06 with closure comments identifying that replacement diaphragms were ordered however the closure did not address the required action to restrict use of the affected PCV.

    - The inappropriate closeout of this action, without following procedure requirements to segregate and place on electronic hold (or the required action to restrict the use of) non-conforming material, resulted in the non-conforming part being available for sale or transfer to another licensed facility with no further notification or controls required.

- **03/31/2017:** Exelon Generation Company, LLC (ExGen) became the licensed owner and operator of JAF.

- **12/15/2017:** JAF purchased the non-conforming PCV from LIM.

- **12/16/2017:** JAF installed the non-conforming PCV into the JAF HPCI system.

- **04/10/2020 (approximately 0130):** JAF HPCI PCV leakage identified during monthly surveillance testing.

- **04/10/2020 (approximately 2000):** JAF HPCI PCV Valve replacement complete, HPCI system restored to OPERABLE status.

Section IV.B. Conclusion:

As demonstrated above, a PD did occur while addressing the 2010 10 CFR Part 21 notification however this PD is limited to the actions of the support individuals working in direct support of the LIM operating license.

**C. 10 CFR 50, Appendix 50, Criterion VII**

The receipt inspection completed at JAF in 2017 was performed consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and the JAF QAP requirements and therefore does not constitute a failure to follow a regulatory or self-imposed standard.

The Inspection Report identified a Violation of 10 CFR 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services" based on the failure to identify, during receipt inspection, that the purchased valve was the subject of a 2010 10 CFR Part 21 notification.

ExGen has confirmed that the JAF receipt inspection was performed consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and the JAF QAP and therefore was not a failure to follow a regulatory or self-imposed standard. Additionally, without further actions beyond these requirements, the receipt inspector could not reasonably have been expected to identify that the valve was the subject of the 2010 10 CFR Part 21 notification based on the documentation provided by the seller (LIM).

10 CFR Part 21 Procurement Clause:

As stated in the Inspection Report, the Purchase Order (PO) from JAF informed LIM that the sale was subject to the requirements of 10 CFR Part 21. This statement is informing the seller (LIM) of its independent obligation to comply with 10 CFR Part 21 to include notifying the buyer (JAF) of any defects associated with the purchased component. This statement should not be interpreted to mean that the buyer (JAF) has the responsibility to determine if a 10 CFR Part 21 notification has ever been issued for the basic component.

Inspection Requirements for Material Purchases between Licensed Facilities:

The requirement for JAF to perform a receipt inspection of components purchased from another ExGen licensed facility is the same requirement as if the component was purchased directly from a qualified vendor or another utility. This is required by the JAF QAP and is relied upon for meeting the requirements of 10 CFR 50, Appendix B, Criterion VII.

Opportunities to identify the 10 CFR Part 21 Notification:

The Inspection Report states that the staff working in direct support of the JAF licensed facility had three (3) opportunities to identify that the valve was the subject of a 2010 10 CFR Part 21 notification. However, neither 10 CFR 50, Appendix B, Criterion VII, 10 CFR Part 21 or JAF procedures require the buyer (JAF) to conduct additional inquiries, without evidence that further information is required, to verify that purchased material conforms to the procurement documents. Therefore, without actions beyond the regulatory and procedural requirements, the receipt inspector at JAF could not reasonably have been expected to identify that the valve was subject to a 10 CFR Part 21 notification.

*First Opportunity (From Inspection Report):*

*"First, to receive the part at Fitzpatrick, Business Services Company staff removed a 'hold' due to a shelf-life concern. The inspectors reviewed the component tracking*

*database and identified that information on IR 1086768, the IR associated with the 10 CFR Part 21 notification, was present in the database and could reasonably be identified by a qualified procurement engineer when performing a review of available information to address the 'hold'."*

ExGen Response:

It should be noted that this hold was not applied because of the 10 CFR Part 21 notification, but because the diaphragm was approaching the shelf life.

ExGen has confirmed that the correct hold information regarding shelf life was readily available to both LIM and JAF personnel in an expected field and therefore there was no reason for LIM or JAF personnel to conduct additional research into other fields of the component database prior to removing the shelf life hold.

The field in the component database where IR 1086768 was entered is not used for controlling hold status. This field is used for capturing historic information. It is beyond the requirements of 10 CFR 50, Appendix B, Criterion VII and JAF procedures for the JAF staff to review, without reason, in this case, six (6) pages of more than 100 lines of historic information to determine if information affecting material certification was incorrectly entered into this field. This field is not used to convey part status or hold information and would not be accessed while removing a hold or performing a receipt inspection.

*Second Opportunity (From Inspection Report):*

*"Second, the [10 CFR] Part 21 information was available to the Business Services Company staff through the Exelon corrective action program, as IR 1086768 was noted in the component tracking database. The IR had not been resolved at the time the part was moved to and accepted at FitzPatrick."*

ExGen Response:

Clarification: Issue Report 1086768 and all associated actions were in COMPLETE status in the LIM Corrective Action Program (CAP) system since 2010.

Although information in the LIM CAP system is accessible to all ExGen CAP users at any individually licensed ExGen facility, a review of another licensed facility's CAP system to determine any open concerns with a warehoused component is not a requirement of 10 CFR 50, Appendix B, Criterion VII, 10 CFR Part 21, or JAF procedures when sourcing material or performing a receipt inspection. The ExGen QAP requires non-conforming material to be segregated and placed on electronic hold to prevent use. The program does not require nor rely on the buyer (JAF) to conduct a CAP search when sourcing material or as a part of receipt inspection.

*Third Opportunity (From Inspection Report):*

*"Finally, the NRC provided a public list of all 10 CFR Part 21 notifications which was not reviewed by Business Services Company staff."*

ExGen Response:

As discussed above, there is no regulatory or self-imposed standard which requires the

buyer (JAF) to conduct additional research for issues which may affect a certified component unless the buyer (JAF) has reason to question the material certification. It is beyond the requirements of 10 CFR 50, Appendix B, Criterion VII, 10 CFR Part 21, and the JAF procedures for a receipt inspector to perform a search of the NRC database to determine if the seller (LIM) failed to follow any 10 CFR 50, Appendix B or 10 CFR Part 21 requirements.

**Section IV.C. Conclusion:**

As evidenced by the discussion above, since there was no regulatory or procedure requirement or any other reason to look for the 10 CFR Part 21 information, the JAF receipt inspection could not reasonably have been expected to identify that the valve was the subject of the 10 CFR Part 21 notification based on the documentation provided by the seller (LIM). Furthermore, as the receipt inspection was conducted consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and JAF procedures, there was no failure to follow a regulatory or self-imposed standard.

Assigning this PD to JAF would not result in the implementation of additional measures that would improve safety or performance at JAF since the actions taken were fully compliant with 10 CFR 50, Appendix B, Criterion VII requirements.

**D. Backfit Concern:**

The relied-upon interpretation of 10 CFR 50, Appendix B, Criterion VII, as indicated in the inspection report, is a new staff position that would result in a modification to ExGen's QAP and as such should be analyzed as a backfit under 10 CFR 50.109.

Backfitting is defined by the regulations at 10 CFR 50.109 as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position…." The Commission has explained in Management Directive 8.4 the following:

*"Backfitting normally occurs when the agency imposes a new or changed regulation or requirement upon a facility or facilities through rulemaking or order. Backfitting concerns also arise when the agency communicates a new or changed staff position interpreting applicable requirements imposed on facilities.* ***A new or changed staff position may arise in several regulatory contexts, including facility inspections,*** *license amendment reviews, or issuance of guidance documents."* (emphasis added)

Contrary to 10 CFR 50.109 and Commission direction in Management Directive 8.4, the position taken by the staff in the Inspection Report constitutes a "imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position" and it will result in a "modification of or addition to … the procedures or organization required to … operate a facility." Specifically, the Inspection Report states that "[t]he inspectors determined that Business Services Company staff did not adequately review the purchase order requirements. As a result, Business Services Company staff failed to identify the open Part 21 during the Quality Receipt Inspection." The Inspection Report goes on to state that "Exelon [Generation Company LLC] failed to verify that the PCV met all purchase

order requirements as required by SM-AA-102 and accepted the defective part upon receipt of purchase order 637326 at FitzPatrick. The purchase order included, 'the requirements of Federal Regulation 10 CFR 21 apply to all items identified in this P.O.' The verification of the PCV did not include a review for Part 21 notifications." However, by misstating the clear requirements of 10 CFR Part 50, Appendix B, Criterion VII, the Inspection Report attempts to establish a "regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position". Criterion VII states that "Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery." Nowhere does Criterion VII require that a licensee's "measures" established to comply with Criterion VII must "include a review for Part 21 notifications" and, to ExGen's knowledge, never has such an expectation been articulated by the NRC in generically applicable guidance. ExGen's NRC-approved QATR implemented at each licensed facility also does not describe such a requirement as part of a receipt inspection.

Rather, it is long understood that under 10 CFR Part 50, Appendix B Criterion VII the purchaser may rely on the seller's 10 CFR 50 Appendix B program to identify any potential Part 21 applicability to the component. NRC guidance on Part 21 found in NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," provides some insights into the purchaser's obligations with respect to procuring a safety-related component. In NUREG-0302, the NRC stated unequivocally that "The licensee's responsibility for ensuring compliance with the provisions of Part 21 by its contractors, suppliers, and consultants is limited to the requirement that each procurement document for a facility or basic component specifies that the provisions of 10 CFR Part 21 apply, when applicable.… Organizations, which are subject to Part 21, are not required to perform quality assurance-type audits on suppliers specifically for the purpose of ensuring compliance with Part 21."

NEI 14-09, "Guidelines for Implementation of 10 CFR part 21 Reporting of Defects and Noncompliance", (Rev. 1) provides additional insights regarding the current NRC position with respect to the obligation of suppliers in identifying Part 21-related issues. As endorsed by the NRC, NEI 14-09 further expands on the obligations of purchasers with respect to transactions involving safety-related components. NEI 14-09 states, for instance, that "[e]ach entity subject to 10 CFR Part 21 is responsible and must assure itself that appropriate procedures are established. Normal management controls are an acceptable means to verify conformance to 10 CFR Part 21. Quality assurance type audits are not required to verify that appropriate procedures are in effect, and 10 CFR Part 21 procedures do not need to be covered in QA Manuals, for either Purchasers or Suppliers."

NEI 14-09, Rev. 1, also supports ExGen's position stated above that it is the seller's obligation to inform the purchaser of Part 21-related issues. In section 8.2.1, Transfer of Parts by Purchasers, NEI 14-09 states that:

"There may be instances when a purchaser of a basic component may in turn sell that basic component to another utility or transfer it between plants that it owns. When a

licensee sells a 'Basic Component' to another utility (whether for $0.00 or for an established value) the utility acts as a 10 CFR 50, Appendix B supplier and as such carries the responsibility of 'Reporting Defects and Noncompliances' per the requirements of 10 CFR Part 21, whether or not the purchase documents indicate those requirements. The sale of that 'Basic Component' to another utility does not relieve the original Seller of the 'Basic Component' of its responsibilities to 'Report Defects or Noncompliances' for the original delivery of the 'Basic Component.'"

**Backfit Conclusion:**

ExGen is concerned that the Inspection Report represents a new or changed interpretation of 10 CFR Part 50, Appendix B, Criterion VII, departing from the clear language of the regulation and the NRC's positions regarding the obligations of purchasers and vendors as established in guidance. The position in the Inspection Report also essentially establishes a new, generically applicable position that would have industry-wide implications if each purchaser of basic components were expected to conduct an undefined, and open-ended search for potential 10 CFR Part 21 implications. Further, if a Notice of Violation is issued, JAF, and likely the entire ExGen fleet, would be required to modify existing 10 CFR 50, Appendix B procedures as well as procurement procedures to include additional steps to evaluate unknown 10 CFR Part 21 issues.

## V. Overall Conclusion:

Neither the LIM response to the 10 CFR Part 21 notification in 2010 nor the JAF receipt inspection in 2017 represent a JAF PD as described in Inspection Manual Chapter 0612 as evidenced by the information provided.

Specifically:

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

B. The 10 CFR 50, Appendix B, Criterion XV violation and associated PD occurred at LIM in 2010 by support resources working in direct support of the LIM operating license.

C. The receipt inspection completed at JAF in 2017 was performed consistent with the requirements of 10 CFR 50, Appendix B, Criterion VII and the JAF QAP requirements and therefore does not constitute a failure to follow a regulatory or self-imposed standard.

D. The NRC's relied-upon interpretation of 10 CFR 50, Appendix B, Criterion VII, is a new staff position that would result in a modification to ExGen's QAP and as such should be analyzed as a backfit under 10 CFR 50.109.

**Attachment 2:**

Uncertainties Input in Response to Apparent Violation EA-20-138

ExGen is providing new information and additional insights which reduce some of the calculational uncertainties that weigh into the Significance Determination (SDP) as follows:

1. The James A. FitzPatrick Nuclear Power Plant (JAF) Engineering staff has performed additional engineering reviews related to the maximum oil leak rate from the High Pressure Coolant Injection (HPCI) system Pressure Control Valve (PCV) which provide information supporting the leak rate used in the JAF SDP analysis.
2. JAF Operations staff have gathered and documented additional timeline and performance data which better characterizes the uncertainty in the analysis of operator credit for identification and restoration of HPCI oil.
3. JAF Operations and Engineering staff have validated information regarding Main Control Room (MCR) staff operation of HPCI during transient conditions.
4. JAF Engineering and PRA Staff provided information regarding incorporation of EPRI fire realisms and the associated reduction in fire ignition frequencies (FIFs) for areas that are risk important relative to HPCI operation.

Items 1 thru 3 have been determined to have a non-proportional impact on credited operator reliability and overall SDP results.

<u>Calculated Maximum Oil Leak</u>

JAF utilizes a minimum leak rate of 0.19 gallons per minute (gpm) with a maximum leak rate of 2.8 gpm as determined in the MPR analysis (Ref. 1). The NRC SDP analysis utilizes a minimum leak rate of 0.28 gpm with a maximum leak rate of 3.65 gpm. The MPR analysis concluded that 2.8 gpm was a conservative value (high) based on removal of the following influential inputs that would reduce the maximum leakage [Section 5.2.2 of Ref. 1]:

- No hydraulic resistance from the diaphragm tear
- Neglect pressure losses from upstream tubing and fittings (including upstream restricting orifice [23RO-24])
- Assume the needle valve (23CV-20) is at its maximum open position

In reviewing the pertinent JAF maintenance procedures, MP-023.01 (Ref. 2) and MP-023.14 (Ref. 3), it was determined that the position of 23CV-20 is throttled to achieve a HPCI auto reset time of the mechanical overspeed trip of 4 to 6 seconds. As such, the actual leak rate through 23PCV-12 would be less than the conservative maximum leak rate of 2.8 gpm calculated in the MPR analysis.

<u>Oil Leak Mitigation / Credited Operator Actions:</u>

The NRC applies a 1.0 failure rate for responding to the oil leak based on the following conclusions:

> *"The analysts reviewed HPCI operating procedure (OP-15) and special procedure section (G.10) that monitors oil level and provides guidance to add oil during turbine operations. Based on this review, the analysts concluded that the oil addition procedure gives appropriate guidance for low volume 'topping-off' to account for some variation in level during HPCI operations. However, it is not written to support rapid high-volume*

*makeup, as there is no direction for local high volume oil pump setup. During subsequent discussions, the licensee provided insights into available resources, operator / crew ingenuity, and skill of the craft to make-up or direct leakage flow back to the sump. However, the analysts noted that neither the severe leak rate or probabilistic analytical leak rates would allow adequate time to identify and respond."*

ExGen's position is that giving no credit for operators to recover the HPCI system in the event of an oil leak does not recognize proceduralized actions that the operators would take and be capable of executing. OP-15 (Ref. 5) Section G.10, "Adding Oil to HPCI Sump with HPCI In Service", is not a "topping off procedure" and it provides explicit guidance to maintain oil in the "running level" band. Further, Step G.10.4 states:

*"Using a funnel with an attached tygon hose, add oil until oil level is in the middle of the red (running level) band."*

Operators performed a timed walkdown for recovery actions to maintain adequate oil level in the HPCI sump in the event the HPCI pressure control valve (23PCV-12) diaphragm had a tear. The walkdown confirmed that the actions in OP-15 (Ref. 5) Section G.10 to add oil to the HPCI oil sump with the system in service are adequate to perform more than just "topping off" of the oil sump. The walkdown resulted in operators successfully restoring oil in approximately 27.5 minutes. It should be noted that the leak from the PCV diaphragm would be more easily routed to the sump for continuous makeup than adding oil from an external source, as was done in the timed walk down. Additionally, JAF Operations has performed a test to demonstrate that 2.8 gpm can adequately flow through the readily available catch containment and tygon tube equipment to support continuous makeup to the oil sump.

With regards to the time until the leak is located, there are several considerations. OP-AA-103-102 "Watch-Standing Practices" (Ref. 6) outlines expectations for non-licensed operators to monitor all equipment they are responsible for "which would include starting and stopping equipment, swapping trains or components, altering system lineups, etc." This procedure also establishes post start and post shutdown system walk-down requirements to ensure expected system and components response. JAF simulator training reinforces the need for the MCR staff to dispatch non-licensed operators to validate that there is a normal start for equipment.

If the control room received the HPCI Turbine Bearing Oil Pressure Low annunciator (Ref. 11) and HPCI operation is required, the MCR operators would respond as follows:

1. If the HPCI Auxiliary Oil Pump did not auto start, then attempt to manually start the pump from the control room panel 09-3.
2. If the annunciator does not clear, then send an operator to locally investigate the reason for the loss of oil pressure.
3. The field operator would observe a large amount of oil at the HPCI skid and check HPCI oil sump level.
4. Operations would perform actions per OP-15 (Ref. 5) Section F "Shutdown" to secure the AOP when the HPCI turbine is not rotating.
5. The control room would direct the field operator to add oil to the HPCI sump. Walkdowns confirmed that oil would be added within approximately 27.5 minutes.

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

HPCI Operations During Transient Conditions

JAF Operations and Engineering staff have validated information regarding MCR staff operation of HPCI during transient conditions, as follows:

- When operating HPCI with drywell pressure greater than 2.7 psig (HPCI initiation signal), the test return valves close to divert all flow to the Reactor Pressure Vessel (RPV). To control RPV water level, the MCR operators would dial the flow controller back as needed to control the injection rate and maintain level within required bands established in station Emergency Operating Procedures (EOPs). Several procedures direct the MCR operators to control HPCI injection rates, including EOP-2 (Ref. 4), OP-15 (Ref 5), and OP-JF-103-102-1002 (Ref. 7). The direction for injection in each procedure covers various scenarios that the operators may encounter but are all capable of allowing adequate control of HPCI injection to the RPV.
- Operations acknowledges that running the HPCI pump on minimum flow (when a valid initiation signal is present and the full flow test valve closed) is not preferred for long term reliability. However, in response to transient and accident conditions, operation in this manner is consistent with the guidance in station EOPs by ensuring that the HPCI system remains available as a high pressure water source. As such MCR operators would not secure HPCI if it was running on min flow nor would the pump be damaged during a transient or accident response to the point that sufficient flow could not be developed.

Fire Analysis

In the JAF risk assessment, the PRA staff developed and used updated fire modeling ignition frequencies for the fire areas reviewed in the NRC SDP analysis. The revised FPRA results are documented in JF-SDP-002, Nov. 2020 (Ref. 8), and JF-MISC-015, Nov. 2020 (Ref. 9). The NRC analysis uses fire scenario frequencies listed in the Fire PRA Notebook (Ref. 10), shown in column 2 of Table 2. ExGen's position is that the FIFs in the JAF analysis should be used because they are based on more realistic fire modeling techniques.

Since the issuance of the Fire PRA notebook (Ref. 10), several improvements have been made to the Fire PRA, which include circuit analysis, HRA, and fire scenarios. Given these refinements, the risk importance measures for the 'HPCI fail to run' event have decreased by approximately a factor of 10.

The NRC evaluation using Reference 10 identifies three locations where the fire scenarios contributed the most for the HPCI event: 'A' Battery Charger Room (BR-1), Division 1 Switchgear Area (SW-1), and Turbine Building Elevation 252 (TB1E252). Two of these areas, BR-1 and TB1E252, include bounding fire scenarios with the full room FIF. The fire scenarios for BR-1 were refined in the updated documentation and are summarized in Table 2.

Fire PRA improvements for TB1E252 in the JAF analysis included updating the modeling such that the ignition sources with offsite power cables potentially damaged are limited to the switchgears and Motor Control Centers. The updated FIFs for these fires is estimated to be 5.64E-4/yr.

Table 2 provides a comparison of the NRC evaluation conditional risk and the conditional risk calculated using the revised FIFs. The FIFs noted are still considered conservative and implementation of additional EPRI fire realisms (e.g., NUREG-2230) and more detailed fire modeling refinements will result in smaller frequencies and potentially smaller Conditional Core Damage Probabilities (CCDPs).

Table 2: Fire External Event Fire Frequency and Conditional Risk Evaluation Comparison

| | FIF (per year) | SPAR Delta CCDP | Exposure | SPAR Delta CDF | Revised FIF (per year) | Delta CDF |
|---|---|---|---|---|---|---|
| BR-1 | 1.50E-03 | 2.58E-03 | 59 | 6.3E-07 | 6.30E-04 | 2.6E-07 |
| SW-1 | 1.00E-03 | 1.70E-03 | 59 | 2.7E-07 | 1.00E-03 | 2.7E-07 |
| TB1E252 | 1.89E-03 | 2.84E-04 | 59 | 8.7E-08 | 5.64E-04 | 2.6E-08 |
| Total | | | | **9.9E-07** | | **5.6E-07** |

Overall Conclusion

ExGen recognizes that there are uncertainties associated with the SDP risk analysis and some of the supporting information on which it is based, as described above. ExGen believes that the evidence and analysis presented supports our position that the uncertainties are smaller than characterized in the NRC inspection report and could potentially result in a significance below the threshold for a White determination.

References:

1. MPR Report 0284-0063-RTP-001, Rev. 0: “Independent Review of PCV-12 Oil Leak in JAF HPCI System”
2. MP-023.01: “HPCI TURBINE MAJOR INSPECTION”
3. MP-023.14: “HPCI TURBINE MINOR INSPECTION, 23TU-2”
4. EOP-2: “RPV Control”
5. OP-15: “High Pressure Coolant Injection”
6. OP-AA-103-102: “Watch-Standing Practices”
7. OP-JF-103-102-1002: “Strategies for Successful Transient Mitigation at JAF”
8. JF-SDP-002: “James A. FitzPatrick Nuclear Power Plant - Results for Significance Determination Process (SDP) Evaluation for HPCI Inoperable”
9. JF-MISC-015: “James A. FitzPatrick Power Station - Probabilistic Risk Assessment FPRA Changes for the HPCI Oil Leak SDP Evaluation”
10. JF-PRA-021.11: “James A. FitzPatrick - Fire Probabilistic Risk Analysis Summary & Quantitative Notebook”
11. ARP-09-3-3-35: “HPCI TURB BRG OIL PRESS LO”