10 CFR 26.719

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102-07129-MLL/JYL
November 5, 2015

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Sirs:

Subject: **Palo Verde Nuclear Generating Station (PVNGS)**
Units 1, 2, and 3
Docket Nos. STN 50-528/529/530
Unanticipated Result for a Blind Performance Test Sample

Pursuant to 10 CFR 26.719(c)(1), Arizona Public Service Company (APS) hereby provides, as an enclosure to this letter, a report of an unanticipated result for a fitness for duty (FFD) blind performance test sample.

On September 24, 2015, the PVNGS FFD department received, from a Department of Health and Human Services (HHS) certified laboratory, a blind performance test result that was not consistent with the expected result.

APS completed an evaluation of the HHS-certified laboratory investigation of this issue on October 6, 2015. Results of the investigation are provided in the enclosure to this letter.

APS makes no commitments in this letter. If you have questions regarding this submittal, please contact Mark McGhee, Nuclear Regulatory Affairs Department Leader, at (623) 393-4972.

Sincerely,

Lacal, Maria L(Z06149)

Digitally signed by Lacal, Maria L(Z06149)
DN: cn=Lacal, Maria L(Z06149)
Reason: I am approving this document
Date: 2015.11.05 10:58:02 -07'00'

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Enclosure: Summary of Investigation Results

cc: M. L. Dapas NRC Region IV Regional Administrator
M. M. Watford NRC NRR Project Manager
C. A. Peabody NRC Senior Resident Inspector PVNGS

ENCLOSURE

Summary of Investigation Results

SUMMARY OF INVESTIGATION RESULTS

Introduction

According to 10 CFR 26.168, licensees that engage Department of Health and Human Services (HHS) certified laboratories to perform fitness for duty (FFD) testing must submit blind performance test samples to the HHS-certified laboratory as part of the quality control program. A blind sampling program involves intermingling blind test samples of known composition with the population of FFD samples routinely submitted to the laboratory. The blind test samples are not identified, and are processed by the laboratory in the same manner as the routine FFD samples. The licensee is then able to test the validity of the laboratory's measurement process by comparing the laboratory's reported results with the expected results for the blind test samples. Palo Verde Nuclear Generating Station (PVNGS) uses FFD blind performance test samples that are prepared and provided by a commercial blind sample provider.

Summary of Event

On September 24, 2015, the PVNGS FFD department received an HHS-certified laboratory report indicating a "Negative/Normal" test result for a blind test sample that was expected to indicate "Adulterant." Following a review of test results by a PVNGS Medical Review Officer staff member, the laboratory was contacted and advised of the issue. The laboratory initiated an internal investigation to determine the cause of the unanticipated test result. As part of the investigation, the laboratory performed a confirmatory test on the original blind test sample using an alternate analysis technique which successfully produced the anticipated "Adulterant" result for the sample with a low pH level. An amended report was provided to PVNGS with correct results from the confirmatory test on October 1, 2015.

Reporting Requirements

This event is being reported pursuant to 10 CFR 26.719(c)(1) as an error in testing that requires notification within 30 days of completing an investigation. On October 6, 2015, the PVNGS FFD department completed an evaluation of the HHS-certified laboratory internal investigation results, and the evaluation is documented in the PVNGS Corrective Action Program as Condition Report (CR) 15-08524. Additionally, in a review conducted by the PVNGS Nuclear Assurance Department, the laboratory's internal investigation results and corrective actions were found to be acceptable.

Internal Investigation by the HHS-certified Laboratory

The HHS-certified laboratory conducted an internal investigation which reviewed the laboratory's pH screening assay, calibrators and controls, instrument function as well as possible operator error. The investigation concluded that the sample testing process had been performed in accordance with the standard operating procedures of the laboratory. The pH assay utilized for the sample testing had been thoroughly validated in the laboratory and repeatedly tested. The National Laboratory Certification Program (NLCP) has a rigorous proficiency testing program, and as a participant in it, this HHS-certified laboratory routinely receives samples with a low pH that are adulterated with acids. For the past 15 years, the HHS-certified laboratory had been using this assay to analyze specimens and had never encountered any errors. In addition, in May 2014, the NLCP issued a memo indicating that there could be an issue regarding some screening assays with low pH specimens, and directed all laboratories to conduct validation experiments. In response to the directive, this HHS-certified laboratory conducted validation studies using low pH specimens. The results of the validation studies were found to be acceptable.

However, in the event addressed by this report, the blind test sample had a low pH and produced an unanticipated result. The investigation also identified the following facts:

- The blind test sample was noted to have a significantly darker color than normal specimens.
- An alternative commercial pH assay based on different reagents did not show the same degree of interference with this particular blind specimen.
- No additional unanticipated results in the reporting of blind performance test samples were identified in reports from the laboratory.

The investigation did not identify a definite cause for the unanticipated result. The probable cause has been attributed to the specific assay which was used to measure the pH levels as it did not read the low pH.

Corrective Actions

To address this issue, the following actions were taken:

- The reporting error was corrected by the laboratory and an amended report was provided to PVNGS.
- To prevent potential pH testing issues for 10 CFR Part 26 specimens in the future, the HHS-certified laboratory implemented an alternative commercial pH assay as a corrective measure on October 1, 2015.
- The adequacy of implemented corrective actions by the laboratory was reviewed and validated by an independent toxicologist.
- This event was entered into the PVNGS Corrective Action Program as CR 15-08524.