



Department of Energy

Washington, DC 20585

January 13, 2021

Mr. Jonathan Dowell
Program Manager
Fluor-BWXT Portsmouth LLC
3930 US-23
Piketon, Ohio 45661

NEA-2021-01

Dear Mr. Dowell:

This letter refers to the Office of Enterprise Assessments' Office of Enforcement investigation into the facts and circumstances associated with deficiencies in radiation protection program implementation at the Portsmouth Site. The Office of Enforcement provided the results of the investigation to Fluor-BWXT Portsmouth LLC (FBP) in an investigation report dated May 6, 2020. An enforcement conference was convened on July 9, 2020, with you and members of your staff to discuss the report's findings and FBP's response. A summary of the enforcement conference and list of attendees are enclosed.

In November 2018, an FBP employee expressed concern to FBP dosimetry personnel that the employee had not been asked to provide a routine bioassay sample at the expected frequency. FBP determined that the worker had been omitted from the bioassay list due to a query error in a non-quality-controlled database. This query error had gone undetected due to FBP's lack of compliance with software quality assurance (SQA) program requirements for the control of software. In March 2019, after performing two extent-of-condition reviews, FBP determined that as a result of this error, it had not performed required bioassays for a total of 193 workers.

Separately, in May 2019, in response to media reporting on FBP's environmental monitoring data, FBP identified a calculation error in a spreadsheet that had resulted in underreporting of both onsite and offsite environmental radiological monitoring information in its annual site environmental reports (ASERs) for 8 years. It too had gone undetected due to FBP's lack of compliance with SQA program requirements.

Through an enforcement investigation, the Office of Enforcement determined that both issues had resulted, at least in part, from FBP's failure to implement an effective SQA program. The Department of Energy (DOE) considers these SQA program implementation deficiencies to be of high safety significance. Though the deficiencies resulted in no unexpected worker exposures and no public or environmental impacts above regulatory limits, if left uncorrected they could have resulted in significant adverse



impacts on the safety of workers and the public. FBP's failure to provide a compliant SQA program could have resulted in the failure of multiple pieces of safety software that provide hazard control functions throughout the project. That FBP was aware of some of these deficiencies in the implementation of the SQA program since at least 2015 and failed to take appropriate corrective actions is of particular concern to DOE. The investigation of these events revealed deficiencies in quality assurance requirements, including (1) work processes, (2) personnel training and qualification, (3) quality improvement, and (4) documents and records.

Based on the evaluation of the evidence in this matter, including information presented at the enforcement conference, DOE concludes that FBP violated requirements enforceable under 10 C.F.R. Part 820, *Procedural Rules for DOE Nuclear Activities*, including 10 C.F.R. Part 830, *Nuclear Safety Management*, Subpart A, *Quality Assurance Requirements*.

Accordingly, DOE hereby issues the enclosed Preliminary Notice of Violation (PNOV), which cites two Severity Level I violations, two Severity Level II violations, and one Severity Level III violation. One of the Severity Level I violations, in the area of work processes, was escalated from Severity Level II due to the duration of the problem, which was clearly identifiable through assessment activities and through recurrent examples of the violation.

DOE's statutory authority permits it to cite violations on a per day basis. DOE determined that for one of these Severity Level I violations, in the area of quality improvement, FBP had sufficient prior notice on at least three occasions to have identified and corrected this violation before it was revealed through these events. These corrections would have enhanced the program designed to identify and correct problems such as those that resulted in the other violations. Consequently, this PNOV cites FBP for two additional days for the quality improvement violation. The five violations result in a total base civil penalty, before mitigation, of \$1,070,000.

FBP did not identify these quality assurance program deficiencies through rigorous and routine self-assessment activities, but instead the deficiencies were revealed by the events and subsequent extent-of-condition reviews. DOE therefore considers these deficiencies to be self-disclosing and grants no mitigation for timely self-identification, consistent with DOE's nuclear safety enforcement policy.

Prior to the Office of Enforcement's investigation, FBP had developed a causal analysis addressing the missed bioassay samples. The Office of Enforcement notes that, while the initial root cause analysis did identify underlying causes within the dosimetry and radiation protection groups, it did not adequately address broader problems in sitewide implementation of SQA program requirements. Further, FBP did not identify the common causes of the bioassay and ASER reporting deficiencies, both of which resulted, at least in part, from FBP's failure to fully implement all required SQA program elements.

FBP did not perform a separate cause analysis for the ASER reporting issues; corrective actions were limited to issuing errata to correct the misreported data.

After the scope of the deficiencies was identified by DOE in an Office of Environmental Management assessment and the early phases of this investigation, FBP initiated a root cause analysis for SQA program deficiencies. This cause analysis was thorough and comprehensive.

Once FBP fully understood the extent of the SQA program deficiencies following the root cause analysis, FBP took aggressive corrective action, rebuilding the site's SQA program. This action included creation of a new organization to oversee the program, new procedures, and new training modules for all site personnel, including additional training for software owners. FBP also implemented organizational changes and culture-change strategies, and initiated a contractor assurance improvement initiative. Together, these actions, if implemented as planned, appear adequate to correct the underlying SQA programmatic deficiencies and prevent future similar violations. As a result, DOE has granted 25 percent mitigation of the civil penalties for corrective actions addressing deficiencies in quality assurance requirements in the areas of work processes, personnel training and qualification, and documents and records. The remaining violation is associated with quality improvement; historically, DOE has not granted mitigation for corrective actions taken for such violations because these conditions indicate either a failure to take effective corrective action for a precursor event that should have led to earlier recognition of the problem, or that prior corrective actions for a recurring problem were not effective.

In consideration of the mitigating factors, DOE calculated a mitigated civil penalty (prior to adjustment for fee reduction) of \$963,000. However, partially in response to the violations associated with this event, DOE withheld all available environment, safety, health, and quality (ESH&Q) and regulatory contract award fee (approximately \$2.6M) from FBP in fiscal year 2019. In consideration of the mitigating factors and fee previously withheld, DOE has elected to exercise enforcement discretion and proposes no civil penalty for the violations cited in this PNOV.

Pursuant to 10 C.F.R. § 820.24, *Preliminary Notice of Violation*, you are obligated to file a written reply within 30 calendar days after the date of filing of the enclosed PNOV and to follow the instructions specified in the PNOV when preparing your response. If you fail to submit a reply within 30 calendar days, then in accordance with 10 C.F.R. § 820.33, *Default order*, subsection (a), DOE may pursue a Default Order.

After reviewing your reply to the PNOV, including any proposed additional corrective actions entered into DOE's Noncompliance Tracking System, DOE will determine

whether any further activity is necessary to ensure compliance with DOE nuclear safety requirements. DOE will continue to monitor the completion of corrective actions until this matter is fully resolved.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin L. Dressman", with a long, sweeping horizontal flourish extending to the right.

Kevin L. Dressman
Director
Office of Enforcement
Office of Enterprise Assessments

Enclosures: Preliminary Notice of Violation (NEA-2021-01)
Enforcement Conference Summary
Enforcement Conference List of Attendees

cc: Robert Edwards, III, PPPO
Doug Fogel, FBP

Preliminary Notice of Violation

Fluor-BWXT Portsmouth LLC
Portsmouth Site

NEA-2021-01

A U.S. Department of Energy (DOE) investigation into the facts and circumstances associated with radiation protection (RP) program implementation deficiencies at the Portsmouth Site revealed multiple violations of DOE nuclear safety requirements by Fluor-BWXT Portsmouth LLC (FBP). In late 2018 and early 2019, FBP identified that required internal exposure monitoring had not been performed for 193 radiological workers. Separately, FBP identified that from 2011 to 2018, it had incorrectly reported radiological environmental data.

DOE provided FBP with an investigation report dated May 6, 2020, and convened an enforcement conference on July 9, 2020, with FBP representatives to discuss the report's findings and FBP's response.

Pursuant to Section 234A of the Atomic Energy Act of 1954, as amended, and DOE regulations set forth at 10 C.F.R. Part 820, *Procedural Rules for DOE Nuclear Activities*, DOE hereby issues this Preliminary Notice of Violation (PNOV) to FBP. The violations included deficiencies in implementation of quality assurance (QA) requirements related to (1) work processes, (2) personnel training and qualification, (3) quality improvement, and (4) documents and records. DOE has categorized the violations as two Severity Level I violations, two Severity Level II violations, and one Severity Level III violation. DOE determined that the violations were ongoing for an extended period of time and that FBP had sufficient prior notice to have identified and corrected the violations before they were revealed through these events. On three occasions, FBP failed to take effective corrective actions for documented deficiencies in its software quality assurance (SQA) program. These SQA program deficiencies included failure to implement aspects of the program designed to identify and correct problems such as those that resulted in the other violations. As a result, this PNOV cites FBP for two additional days for the quality improvement violation. Accordingly, the base civil penalty for these violations is \$1,070,000.

Severity Levels are explained in Part 820, Appendix A, *General Statement of Enforcement Policy*. Paragraph VI(b) states that "Severity Level I is reserved for violations of DOE Nuclear Safety Requirements which involve actual or high potential for adverse impact on the safety of the public or workers at DOE facilities."

Paragraph VI(b) also states that "Severity Level II violations represent a significant lack of attention or carelessness toward responsibilities of DOE contractors for the protection of public or worker safety which could, if uncorrected, potentially lead to an adverse impact on public or worker safety at DOE facilities."

Additionally, paragraph VI(b) states that “Severity Level III violations are less serious but are of more than minor concern: i.e., if left uncorrected, they could lead to a more serious concern.”

In consideration of the mitigating factors, DOE calculated a civil penalty (prior to adjustment for contract fee reduction) of \$963,000. However, DOE withheld all available environment, safety, health, and quality (ESH&Q) and regulatory contract award fee (approximately \$2.6M) from FBP in fiscal year 2019, partially in response to the violations associated with this event. As a result, DOE elects to exercise enforcement discretion and proposes no civil penalty for the violations cited in this PNOV.

As required by 10 C.F.R. § 820.24(a) and consistent with Part 820, Appendix A, the violations are listed below. Citations specifically referencing the QA criteria of 10 C.F.R. § 830.122 constitute a violation of § 830.121(a), which requires compliance with those QA criteria.

I. VIOLATIONS

Title 10 C.F.R. § 830.121, *Quality Assurance Program (QAP)*, subsection (b), states that “[t]he contractor responsible for a DOE nuclear facility must:...(4) conduct work in accordance with the QAP.”

FBP implements this and other QA criteria in FBP-QA-PDD-00001, *Quality Assurance Program Description (QAPD)*, Revision 9, dated December 4, 2018.

A. Work Processes

Title 10 C.F.R. § 830.122(e), *Criterion 5—Performance/Work Processes*, requires contractors to “(1) [p]erform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.”

FBP implements this requirement in Section 5 of its QAPD. Paragraph 5.1.1 provides that “[w]ork is controlled through the use of approved procedures or work control documents.”

Section 11 of FBP’s QAPD documents FBP’s SQA program, which includes the following provisions:

- Paragraph 11.1.B of FBP’s QAPD provides that “[t]he requirements of this Section [which describes the SQA program] and FBP-BS-PRO-00091¹, *Information Technology Software Quality Assurance*, apply to all Safety Software...applicable to FBP operations.”

¹ Revision 12 of FBP-BS-PRO-0091 was current at the time of the investigation. Based on the Office of Enforcement’s review of Revisions 8 through 12 of the procedure, and the change log for prior revisions, the requirements cited in this PNOV have been in place without substantive change since the procedure was initially issued on March 29, 2011.

- Paragraph 11.1.2.D.1 of FBP’s QAPD provides examples of what types of software must be controlled as Safety Software. Among these is, “[s]oftware [that] determines or monitors personnel, facility, or environmental radiation exposure or contamination.” FBP-BS-PRO-00091, which implements QAPD Section 11, defines the same population as “Safety-Related Software” and includes the same examples as the QAPD, including the one above. In Section 5.2, the procedure assigns the owners of software the responsibility to “[p]erform Verification and Validation testing.” Appendix F, *Software Testing Requirements*, requires that “verification testing...be sufficient to establish test requirements are satisfied and the computer program produces a valid result for its intended function.”

Contrary to the above requirements, FBP failed to control as Safety Software the software that determines or monitors personnel and environmental radiation exposure. Specific examples include the following:

1. In implementing its internal dosimetry program, FBP dosimetry personnel used a user-created database to determine when workers were procedurally required to submit bioassay samples. An undetected query error in this database resulted in FBP not notifying 193 individual workers to provide the required bioassay samples. Contrary to SQA program requirements, the database was never verified and validated, even though it was used to monitor time intervals between potential personnel internal radiation exposures and provide notification when bioassay was required. As a result, 193 workers made one or more entries into airborne radioactivity areas without receiving the required bioassay screening. For these workers, samples were collected as late as 815 days after entry.

This noncompliance constitutes a Severity Level I violation.

Base Civil Penalty – \$214,000

Mitigated Civil Penalty (prior to adjustment for fee reduction) – \$160,500

Proposed Civil Penalty (as adjusted) – \$0

2. DOE annual site environmental reports (ASERs) provide important information needed by site managers and DOE Headquarters to assess environmental program performance at DOE sites, to assess sitewide environmental monitoring and surveillance effectiveness, and to confirm compliance with environmental standards and requirements. ASERs are also the means by which DOE sites demonstrate compliance with radiological protection requirements for members of the public and for the environment.

In calculating data that supported its annual Radiological National Emissions Standard for Hazardous Air Pollutants (NESHAPS) reports and its ASERs, FBP performed dose conversions—calculations converting environmentally detected radionuclide concentrations to potential doses to members of the public—using a spreadsheet that contained an error in the conversion calculation. As a result, potential offsite doses to the public were underreported by two orders of magnitude in NESHAPS reports and ASERs submitted by FBP from 2011 to 2018. Contrary to SQA program requirements, FBP did not verify or validate this spreadsheet during that time, despite using it to demonstrate

compliance with radiological protection requirements for members of the public and the environment.

This noncompliance constitutes a Severity Level II violation.

Base Civil Penalty – \$107,000

Mitigated Civil Penalty (prior to adjustment for fee reduction) – \$80,250

Proposed Civil Penalty (as adjusted) – \$0

B. Personnel Training and Qualification

Title 10 C.F.R. § 830.122(b), *Criterion 2—Management/Personnel Training and Qualification*, requires contractors to “[t]rain and qualify personnel to be capable of performing their assigned work.”

FBP implements this requirement in Section 2 of its QAPD. Paragraph 2.1.1 of FBP’s QAPD states that “[t]raining is provided to personnel...to ensure they possess the knowledge and use the skills required to perform their job assignments.”

Contrary to the above requirements, FBP failed to train personnel responsible for the use and control of Safety Software to perform this task. FBP had identified this lack of training as early as 2015, when software owners mentioned during an independent assessment performed by FBP QA (CM-IA-FY15-1646, *Safety Software Quality Assurance Audit*, March 24, 2015) that training would be helpful for implementing FBP-BS-PRO-00091. During a subsequent independent assessment performed by FBP QA in 2018 (CM-IA-FY18-6311, *Software Quality Assurance (SQA), Quality Assurance Program Description (QAPD) Section 11.0*, May 16, 2018), FBP identified that “there is no formalized training for SQA.” FBP was unable to produce any SQA training documentation in response to a request by the Office of Enforcement, and multiple interviews confirmed that personnel had not received training on SQA requirements.

This noncompliance constitutes a Severity Level II violation.

Base Civil Penalty – \$107,000

Mitigated Civil Penalty (prior to adjustment for fee reduction) – \$80,250

Proposed Civil Penalty (as adjusted) – \$0

C. Quality Improvement

Title 10 C.F.R. § 830.122(c), *Criterion 3—Management/Quality Improvement*, requires contractors to “(3) [i]dentify the causes of problems and work to prevent recurrence as part of correcting the problem.”

FBP implements this requirement in its QAPD, which includes the following provisions:

- Paragraph 3.3 of FBP’s QAPD states that “[t]he extent and rigor of causal analysis for issues is commensurate with the significance of the problem. Formal causal analysis is normally performed on issues that involve Significant Deficiencies.” Paragraph 3.7

states that “[e]ffectiveness evaluations are conducted for Significant Deficiencies and when directed by management.”

- Paragraph 3.5.1 of FBP’s QAPD states that “[c]orrective actions [for identified problems] are developed and implemented in a graded approach depending on the significance of the issue.... Consideration is also given to...[a]ctions that verify the effective resolution of the problem.”
- Paragraph 3.8.1 of FBP’s QAPD states that “[l]ine management has the primary responsibility for the implementation of quality improvement activities, including event investigation, root cause analysis and corrective action determination. QA and [Contractor Assurance] personnel provide oversight of these processes.”
- Paragraph 9.2.9 of FBP’s QAPD states, “QA... validates CAPs [corrective action plans] for QA Program Audits.”

FBP-QP-PRO-00020, *Problem Reporting and Issues Management*, Revision 18, dated March 19, 2019, paragraph 8.1.G, defines “significant deficiency” as “[a] deficiency which could have a serious effect on safety, health, the environment, plant operations, regulatory, or contract compliance.” The examples of significant deficiencies provided in FBP-QP-PRO-00020 include programmatic breakdowns.² Paragraph 6.8.4 of this procedure requires that when resolving significant deficiencies, the responsible manager “[a]ssign[s] a Qualified Investigator to investigate and perform a root cause analysis.”

FBP-QP-PRO-00020 also implements contractor requirements for identifying and managing issues. It includes requirements that an “actionee”—the individual assigned to complete a corrective action—must follow in resolving deficiencies in the issues management process. Beginning with Revision 5, issued in October 2013, this procedure had included direction that the actionee assigned an issue identified through a QA audit (an independent assessment) must “contact the auditor for closure verification and document concurrence prior to action closure.” Revision 16, issued in April 2018, removed that procedural requirement, although it remained a requirement of the QAPD, as described above. Additionally, the requirement was contained in the procedure revisions that were in effect during the QA activities in 2015 and 2017 that identified SQA program deficiencies.

Contrary to the above requirements, FBP failed to perform formal causal analysis of the significant deficiencies in SQA program implementation that were identified in 2015, 2017, and 2018; line management did not develop actions to verify effective resolution of the problems; and QA personnel did not provide oversight of CAP development:

1. On three occasions, FBP failed to perform causal analyses for noncompliances identified and documented during assessments, or to develop effective corrective actions to resolve these noncompliances:

² Revision 18 of FBP-QP-PRO-0020 was current at the time of the investigation. Based on the Office of Enforcement’s review of prior revisions, this definition has been in place without substantive change since at least December 2015.

- a. In March 2015, FBP’s QA personnel performed independent assessment CM-IA-FY15-1646, which identified “a consistent lack of compliance” with the QAPD and implementing procedures for SQA processes, “particularly in developing and documenting information required to be maintained in the Software Documentation Folders.” The assessment report noted that SQA implementing procedures were marginally effective and that the process did not consistently produce the expected result. It further noted that software owners’ implementation of procedural requirements was ineffective—that personnel were unaware of required procedures or were unaware of their responsibility to perform in accordance with procedures. Even though assessment CM-IA-FY15-1646 documented programmatic breakdowns—marginally effective procedures being ineffectively implemented—in its SQA program, which met the definition of a significant deficiency, FBP did not perform a root cause analysis.
 - b. A 2017 surveillance performed by DOE (PORT-17-IS-101146, *U.S. Department of Energy Portsmouth/Paducah Project Office Surveillance of Fluor-BWXT Portsmouth LLC QA Software Quality Assurance*, March 15, 2017) documented findings similar to those documented in the 2015 QA independent assessment.
 - c. The subsequent independent assessment performed by FBP QA in May 2018 (CM-IA-FY18-6311) again documented deficiencies in the FBP SQA program. FBP again did not develop and implement effective corrective actions to verify effective resolution of the SQA program deficiencies.
2. Following the 2015 and 2018 independent assessments, QA personnel failed to provide required oversight of CAP development. Individuals interviewed during the investigation indicated that interactions with QA personnel required by FBP-QP-PRO-00020 and the QAPD during resolution of QA-identified issues had never been standard practice. These required interactions included QA validation of CAPs, and verification and concurrence by QA personnel prior to action closure. Despite these program requirements, QA personnel did not typically review actions taken in response to audit issues until the next scheduled audit three years later, and then only to verify documentation of completion, not the effectiveness of the actions taken.

Together, these noncompliances constitute a Severity Level I violation.

Base Civil Penalty – \$642,000 (\$214,000 per day for three days—one day for each instance

FBP had documented notice of the problem but failed to correct it)

Mitigated Civil Penalty (prior to adjustment for fee reduction) – \$642,000

Proposed Civil Penalty (as adjusted) – \$0

D. Documents and Records

Title 10 C.F.R. § 830.122(d), *Criterion 4—Management/Documents and Records*, requires contractors to “(2) [s]pecify, prepare, review, approve, and maintain records”.

FBP implements this requirement in Section 4 of its QAPD. Paragraph 4.4 of FBP’s QAPD states that “FBP has established a federal records management system that provides for the

identification, generation, authentication, maintenance, and final disposition of programmatic and administrative records, which offer documentary evidence that items or activities meet specified requirements.”

Paragraph 11.1.E of FBP’s QAPD requires that “[s]oftware owners maintain software supporting SQA documentation in a Software Documentation File” (SDF). Appendix D of FBP-BS-PRO-00091 lists the documentation to be maintained in the SDF, as required by Sections 6.1 and 6.2 of that procedure.

Contrary to the above requirements, FBP failed to maintain programmatic and administrative records documenting that items or activities (specifically software) meet the specified requirements. FBP had identified the lack of record keeping as early as 2015, during an independent assessment (CM-IA-FY15-1646) that identified “numerous problems...including lack of documents required to be developed and maintained in the SDF” and “Software Documentation Folders not available/never developed, folder information incomplete..., owners unaware of software assigned to them, [and] inconsistent categorization between the forms in the SDF and the [Software Inventory List].” During a subsequent independent assessment in 2018 (CM-IA-FY18-6311), FBP identified that “software document folders and software quality assurance implementation plans are listed as records, however these documents cannot be found listed on any current FBP software owners file plans.” The Office of Enforcement requested several SDFs for safety software, including the bioassay database and the software used for environmental monitoring; the SDFs provided were incomplete as compared to the list of required records in Appendix D of FBP-BS-PRO-00091.

This noncompliance constitutes a Severity Level III violation.

Base Civil Penalty – \$0

Mitigated Civil Penalty (prior to adjustment for fee reduction) – \$0

Proposed Civil Penalty (as adjusted) – \$0

II. REPLY

Pursuant to 10 C.F.R. § 820.24(b), FBP is hereby obligated to submit a written reply within 30 calendar days after the date of filing of this PNOV. The reply should be clearly marked as a “Reply to the Preliminary Notice of Violation” and must be signed by the person filing it.

If FBP’s reply states that FBP waives any right to contest this PNOV, then pursuant to 10 C.F.R. § 820.24(d), this PNOV will constitute a Final Order upon the filing of the reply.

If FBP disagrees with any aspect of this PNOV, then as applicable and in accordance with 10 C.F.R. § 820.24(c), the reply must: (1) state any facts, explanations, and arguments that support a denial of an alleged violation; and (2) discuss the relevant authorities that support the position asserted, including rulings, regulations, interpretations, and previous decisions issued by DOE. In addition, 10 C.F.R. § 820.24(c) requires that the reply include copies of all relevant documents.

Please send the appropriate reply by overnight carrier to the following address:

Director, Office of Enforcement
Attention: Office of the Docketing Clerk, EA-10
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290

A copy of the reply should also be sent to the Manager of the Portsmouth/Paducah Project Office.

Pursuant to 10 C.F.R. § 820.33, *Default order*, subsection (a), if FBP fails to submit a written reply within 30 calendar days after the date of filing of this PNOV, the Director of the Office of Enforcement may pursue a Default Order.

III. CORRECTIVE ACTIONS

Corrective actions that have been or will be taken to avoid further violations should be delineated with target and completion dates in DOE's Noncompliance Tracking System.



Kevin L. Dressman
Director
Office of Enforcement
Office of Enterprise Assessments

Washington D.C.
This 13th day of January 2021