



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 21, 2023

Mr. Harish Vishwanathan
Quality Assurance Manager
Fluke Biomedical Company
28775 Aurora Road
Solon, OH 44139

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF FLUKE
BIOMEDICAL COMPANY NO. 99902107/2023-201

Dear Mr. Vishwanathan:

On February 6 through February 10, 2023, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an inspection at the Fluke Biomedical Company's (hereafter referred to as FBC) facility in Solon, OH. The purpose of the limited scope routine inspection was to assess FBC's compliance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," and selected portions of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

This technically-focused inspection specifically evaluated FBC's implementation of quality activities associated with the design, manufacturing, and testing of radiation monitoring equipment, replacement parts, and calibration services for U.S. nuclear power plants. The enclosed report presents the results of this inspection. This NRC inspection report does not constitute NRC's endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs.

Within the scope of this inspection, no violations or nonconformances were identified.

In accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, which is accessible at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in black ink, appearing to read "Yamir Diaz-Castillo".

Diaz-Castillo, Yamir signing on behalf
of Kavanagh, Kerri
on 03/21/23

Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

SUBJECT: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF FLUKE BIOMEDICAL COMPANY NO. 99902107/2023-201 Dated: March 21, 2023

Docket No.: 99902107

EPID No.: I-2023-201-0004

Enclosures:
Inspection Report No. 99902107/2023-201
and Attachments

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ADAMS Accession No.: ML

NRR-106

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**U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
DIVISION OF REACTOR OVERSIGHT
VENDOR INSPECTION REPORT**

Docket No.: 99902107

Report No.: 99902107/2023-201

Vendor: Fluke Biomedical Company
28775 Aurora Road
Solon, OH 44139

Vendor Contact: Mr. Harish Vishwanathan
Quality Assurance Manager
Email: harish.vishwanathan@fluke.com
Office: (312) 722-8534

Nuclear Industry Activity: Fluke Biomedical Company's scope of supply includes manufacturing of radiation monitoring equipment, replacement parts, and calibration services for U.S nuclear power plants.

Inspection Dates: February 6 - 10, 2023

Inspectors: Dong Park NRR/DRO/IQVB Team Leader
Michael Fitzgerald NRR/DRO/IQVB (Trainee)
Andrea Keim NRR/DRO/IQVB
Aaron Armstrong NRR/DRO/IQVB (Remote)

Approved by: Kerri A. Kavanagh, Chief
Quality Assurance and Vendor Inspection Branch
Division of Reactor Oversight
Office of Nuclear Reactor Regulation

Enclosure

EXECUTIVE SUMMARY

Fluke Biomedical Company
99902107/2023-201

The U.S. Nuclear Regulatory Commission (NRC) staff conducted a limited scope routine inspection at the Fluke Biomedical Company's (hereafter referred to as FBC) facility in Solon, OH, to verify it had implemented an adequate quality assurance (QA) program that complies with the requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The NRC inspection team conducted this inspection on-site from February 6, 2023 through February 10, 2023. This was the first NRC inspection of FBC's facility in Solon, OH.

This technically-focused inspection specifically evaluated FBC's implementation of quality activities associated with the manufacturing of radiation monitoring equipment, replacement parts, and calibration services for NRC's regulated facilities.

These following regulations served as the bases for the NRC inspection:

- Appendix B to 10 CFR Part 50
- 10 CFR Part 21

During this inspection, the NRC inspection team implemented inspection procedures (IP) 43002, "Routine Inspections of Nuclear Vendors," dated April 5, 2022; IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated April 5, 2022; and IP 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019.

Specific activities observed by the NRC inspection team included:

- Inspection of the calibration laboratory and nonconforming material segregation area.

The results of this inspection are summarized below.

Procurement Document Control and Supplier Oversight

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its procurement document control and supplier oversight programs to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. The NRC inspection team reviewed FBC's procedures and methodology for conducting and documenting audits. The NRC inspection team identified one minor issue associated with FBC's implementation of its supplier oversight program. FBC initiated nonconformance report No. 1449 and corrective action report No. 1081 to address this issue. Please refer to the Section 4 in the "Report Details" for more information on this minor issue. No findings of significance were identified.

Other Inspection Areas

The NRC inspection team determined that FBC established its programs for Design Control, Commercial-Grade Dedication, Procurement Document Control, Supplier Oversight, Test Control, Control of Measuring and Test Equipment, Nonconforming Material, Parts, or Components, and Corrective Action in accordance with the applicable regulatory requirements of Appendix B to 10 CFR Part 50. In addition, the NRC inspection team determined that FBC is implementing its 10 CFR Part 21 program for evaluating deviations and reporting defects that could create a substantial safety hazard in accordance with regulatory requirements. Based on the limited sample of documents reviewed and activities observed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with these programs. No findings of significance were identified in these areas.

REPORT DETAILS

1. 10 CFR Part 21 Program

a. Inspection Scope

The U.S. Nuclear Regulatory Commission (NRC) inspection team reviewed Fluke Biomedical Company's (hereafter referred to as FBC) policies and implementing procedures that govern the implementation of its Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance," program to verify compliance with the regulatory requirements. In addition, the NRC inspection team evaluated the 10 CFR Part 21 postings and a sample of FBC's purchase orders (PO) for compliance with the requirements of 10 CFR 21.21, "Notification of Failure to Comply or Existence of a Defect and its Evaluation," and 10 CFR 21.31, "Procurement Documents." The NRC inspection team also verified that FBC's nonconformance and corrective action procedures provide a link to the 10 CFR Part 21 program.

Furthermore, for a sample of 10 CFR Part 21 evaluations performed by FBC, the NRC inspection team verified that FBC had effectively implemented the requirements for evaluating deviations and failures to comply. The NRC inspection team verified that the notifications were performed in accordance with the requirements of 10 CFR 21.21, as applicable.

The NRC inspection team also discussed the 10 CFR Part 21 program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its 10 CFR Part 21 program in accordance with the regulatory requirements of 10 CFR Part 21. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the 10 CFR Part 21 program. No findings of significance were identified.

2. Design Control

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its design control program to verify compliance with the regulatory requirements of Criterion III, "Design Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

The NRC inspection team selected a sample of safety-related products and reviewed relevant POs, design reports, customer specifications, drawings, test procedures, and

engineering change notices for the sampled radiation monitors and parts. The NRC inspection team verified that these documents contained the required technical information in accordance with FBC's procedures and the applicable design specifications. The NRC inspection team reviewed design and design change packages for TP876-1-89, Radiation Monitoring Systems (RMS) Test Procedure, and TP876-1-89, Power Supply, P/N 21-2178-680, Electrolytic Capacitor, and the S/N844-213A-5, RMS Auto Flow Control Assembly.

Seismic Qualification

The NRC inspection team reviewed the Seismic Qualification Test Report for the 876A-1 containment monitor read out. The NRC inspection team reviewed nine Fluke seismic testing anomalies that were documented and evaluated, which confirmed the modifications incorporated into the design of the 876A-1 containment monitor read out have not degraded from the original qualification performed in Fluke reports 950.301 and 950.310A. The NRC inspection team also reviewed the Seismic Qualification Test Report for the N960PS-210-M1 Power Supply. The NRC inspection team reviewed four Fluke seismic testing anomalies that were documented and evaluated, which confirmed that the modification incorporated into the design of the N960PS-210-M1 met the requirements of the original qualification test plan.

The NRC inspection team also discussed the design control program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its design control program in accordance with the regulatory requirements of Criterion III of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the design control program. No findings of significance were identified.

3. Commercial-Grade Dedication

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its commercial-grade dedication (CGD) program to verify their compliance with the regulatory requirements of Criterion III and Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed the CGD packages for an O-ring, filter cap, and potting resin. Each CGD package documented the development of critical characteristics (CCs), technical evaluations, failure mode and effects analysis, acceptance criteria methods, sampling methodology, checklists, commercial-grade survey reports, and

associated POs. The NRC inspection team evaluated a sample of technical evaluations and concluded that the technical evaluations appropriately identified the CCs necessary to provide reasonable assurance that the item would perform its intended safety function. In addition, the NRC inspection team verified that commercial-grade survey reports contained the objective evidence necessary to demonstrate that commercial vendors adequately control the CCs during the fabrication process or service activities.

The NRC inspection team also reviewed FBC's measures established for the use of the International Laboratory Accreditation Cooperation (ILAC) accreditation process in lieu of performing commercial-grade surveys for procurement of calibration and testing services as part of the CGD process. FBC currently implements this process as described in the Nuclear Energy Institute document No. 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1, dated September 2020, which was recognized for use by the NRC in a safety evaluation dated November 23, 2020 (Agencywide Documents Access Management System Accession (ADAMS) No. ML20322A019).

The NRC inspection team also discussed the CGD program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its CGD program in accordance with the regulatory requirements of Criterion III and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the CGD program. No findings of significance were identified.

4. Procurement Document Control and Supplier Oversight

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its procurement document control and supplier oversight programs to verify compliance with the requirements of Criterion IV, "Procurement Document Control," and Criterion VII of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed FBC's approved vendors list (AVL) and a sample of POs, a supplier audit, and receipt inspection records. On the AVL, FBC has one safety-related supplier and 17 ILAC accredited laboratories. For a sample of POs reviewed, the NRC inspection team verify the POs included, as appropriate, the scope of work, right of access to the suppliers' facilities, requirements for sub-suppliers, and the applicable technical, regulatory and quality requirements.

The NRC inspection team also discussed the supplier oversight program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

The NRC inspection team reviewed the objective evidence for the contracted audit performed on the one safety-related supplier. The NRC inspection team noted that FBC had not performed an annual evaluation for this supplier. The NRC inspection team determined this issue to be minor since FBC and the supplier were in discussions to resolve issues identified during the last audit and FBC plans to perform a full audit prior to the required tri-annual interval. FBC initiated corrective action report (CAR) No. 1081 to address this issue.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its procurement document control and supplier oversight programs in accordance with the regulatory requirements of Criterion IV and Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the procurement document control and supplier oversight programs. No findings of significance were identified.

5. Test Control

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its test control program to verify compliance with the requirements of Criterion XI, "Test Control," of Appendix B to 10 CFR Part 50. There were no safety-related testing activities performed during the week of the inspection. As such, the NRC inspection team reviewed the test documentation associated with the testing of an electromagnetic interference line filter. The NRC inspection team confirmed the test documentation included the applicable FBC's testing controls, equipment calibration, test performance data and results, and any nonconformances in accordance with FBC's policies and procedures.

The NRC inspection team also reviewed the training and qualification records of the test technician who performed the test and confirmed that testing personnel had completed all the required training and had maintained the applicable qualification and certification in accordance with FBC's policies and procedures.

The NRC inspection team discussed the test control program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its test control program in accordance with the regulatory requirements of Criterion XI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the test control program. No findings of significance were identified.

6. Control of Measuring and Test Equipment

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its measuring and test equipment (M&TE) program to verify compliance with the requirements of Criterion XII, "Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of M&TE on the shop floor as well as the records for selected M&TE to ensure the M&TE had the appropriate calibration stickers and current calibration dates, including the calibration due date. The NRC inspection team verified that the calibration records reviewed contained the following information: as-found or as-left conditions, accuracy required, calibration results, calibration dates, and the due date for recalibration. Furthermore, the NRC inspection team also verified that the selected M&TE were calibrated using procedures traceable to known industry standards.

The NRC inspection team confirmed that when M&TE equipment is found to be out of calibration, FBC generates an M&TE out-of-tolerance condition to identify items that were accepted using this equipment since the last valid calibration date and to perform an extent of condition review. The NRC inspection team also performed a walk-down of FBC's laboratory to observe that M&TE were labeled, handled, and stored in a manner that indicated the calibration status and ensured its traceability to calibration test data.

The NRC inspection team also discussed the M&TE program with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its M&TE program in accordance with the regulatory requirements of Criterion XII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the M&TE program. No findings of significance were identified.

7. Nonconforming Materials, Parts, or Components and Corrective Action

a. Inspection Scope

The NRC inspection team reviewed FBC's policies and implementing procedures that govern the implementation of its nonconforming materials, parts, or components and corrective action programs to verify compliance with the requirements of Criterion XV, "Nonconforming Materials, Parts, or Components," and Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50.

The NRC inspection team reviewed a sample of nonconformance reports (NCRs) to verify that FBC: (1) dispositioned the NCRs in accordance with the applicable procedures; (2) documented an appropriate technical justification for various dispositions; and (3) took adequate corrective action with regard to the nonconforming items. In addition, the NRC inspection team confirmed that the nonconformance process provides a link to the 10 CFR Part 21 program.

The NRC inspection team also reviewed a sample of CARs to verify: (1) adequate documentation and description of conditions adverse to quality; (2) an appropriate analysis of the cause of these conditions and the corrective actions taken to prevent recurrence; (3) direction for review and approval by the responsible authority; (4) a description of the current status of the correction actions; and (5) the actions taken to verify timely and effective implementation of the corrective actions. In addition, the NRC inspection team confirmed that the corrective action process provides a link to the 10 CFR Part 21 program.

The NRC inspection team also discussed the nonconforming materials, parts, or components and corrective action programs with FBC's management and technical staff. The attachment to this inspection report lists the documents reviewed and personnel interviewed by the NRC inspection team.

b. Observations and Findings

No findings of significance were identified.

c. Conclusion

The NRC inspection team concluded that FBC is implementing its nonconforming materials, parts, or components and corrective action programs in accordance with the regulatory requirements of Criterion XV and Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspection team also determined that FBC is implementing its policies and procedures associated with the control of nonconforming materials, parts, or components and corrective action. No findings of significance were identified.

8. Entrance and Exit Meetings

On February 6, 2023, the NRC inspection team discussed the scope of the inspection with Mr. Harish Vishwanathan, and other members of FBC's management and technical staff. On February 10, 2023, the NRC inspection team presented the inspection results and observations during an exit meeting with Ms. Mirela Kirr and other members of FBC's

management and technical staff. The attachment to this report lists the attendees of the entrance and exit meetings, as well as those individuals whom the NRC inspection team interviewed.

ATTACHMENT

1. ENTRANCE/EXIT MEETING ATTENDEES

Name	Title	Affiliation	Entrance	Exit	Interviewed
Harish Vishwanathan	Quality Assurance & Regulatory Affairs Manager	Fluke Biomedical Company (FBC)	X	X	X
Jeremy Preston	Nuclear Power Engineering Manager	FBC	X	X	X
Steve Fisher-Jones	Principal Engineer	FBC	X	X	X
Deanna Wodecki	Operations Manager	FBC	X	X*	
Daryl Wells	Lead Quality Engineer	FBC	X	X	X
Jon Hale	Senior Quality Technician	FBC	X	X	X
Jim Ingersoll	Vice President of Global Operations	FBC		X*	
Neal Zech	Vice President of Engineering	FBC	X*		
Mirela Kirr	Vice President of Regulatory Affairs & Quality Assurance	FBC	X*	X*	
Brian Malone	Quality Assurance Regulatory Affairs & Director	FBC	X*	X*	
Abdallah Mizra	Radiation Safety Officer	FBC	X*	X*	
Timothy Hradek	Manufacturing Engineer	FBC		X*	X
George Buck	Reliability Engineer	FBC		X*	
Mohammed Herbawi	Project Engineer	FBC		X*	
Kerri Kavanagh	Branch Chief	Nuclear Regulatory Commission (NRC)		X*	
Dong Park	Inspection Team Leader	NRC	X	X	

Name	Title	Affiliation	Entrance	Exit	Interviewed
Michael Fitzgerald	Inspector	NRC	X	X	
Andrea Keim	Inspector	NRC	X	X	
Aaron Armstrong	Inspector	NRC	X*	X*	

*Remote

2. INSPECTION PROCEDURES USED

Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and Programs for Reporting Defects and Noncompliance," dated May 16, 2019

IP 43002, "Routine Inspections of Nuclear Vendors," dated April 5, 2022

IP 43004, "Inspection of Commercial-Grade Dedication Programs," dated April 5, 2022

3. DOCUMENTS REVIEWED

Policies and Procedures

- Fluke Biomedical Company (FBC) Quality Manual, Revision 28, Document Number: Quality Standard Procedure (QSP) -100, dated July 13, 2021 (Intalex)
- FBC Nuclear Procedure (NUP)-221, "Commercial Grade Dedication," Revision 4, dated October 20, 2022
- FBC Nuclear Procedure (NUP)-05-08, "Engineering/Document Change Procedure," Revision 1, dated February 4, 2023
- FBC CSOP-03-03, "Sale, Design, Production, Servicing and Calibration of Class 1E Qualified New Systems and Spare Parts," Revision 4, dated January 25, 2023
- FBC Nuclear Procedure (NUP)-06-06, "Commercial Grade Item Supplier Procurement Requirements," Revision 4, dated January 20, 2023
- FBC NUP-14-02, "Nuclear Reporting Procedure," Revision 2, dated January 21, 2023
- FBC NUP-14-04-F4, "10CFR21 Discovery and Evaluation Checklist," Revision 2, dated October 5, 2021
- FBC NUP-206, "Nuclear Purchasing Procedure," Revision 5, dated January 20, 2023
- FBC NUP-210, "Inspection and Test Procedure," Revision 5, dated January 20, 2023
- FBC NUP-211, "Control of Inspection, Measuring and Test Equipment," Revision 2, dated February 3, 2023
- FBC NUP-213, "Nonconforming Material Receipts," Revision 1, dated January 20, 2023

- FBC NUP-214, "Corrective and Preventative Action Procedure," Revision 2, dated January 20, 2023
- FBC NUP-217, "Internal Audit Process," Revision 5, dated January 31, 2023
- FBC QSP-204, "Product Development/ Design Control," Revision 17, dated September 1, 2021
- FBC QSP-205, "Document and Data Control," Revision 20, dated August 17, 2021
- FBC QSP-05-08-F2, "Nuclear Power System Reliability Checklist," Revision 5, dated April 19, 2021
- FBC NUP-05-03, "Commercial Grade Item Dedication – Technical Evaluation," Revision 2, dated October 20, 2022
- FBC NUP-05-08, "Engineering/Document Change Procedure," Revision 1, dated February 4, 2023
- FBC NUP-06-04, "ILAC Supplier Procurement Requirements," Revision 3, dated October 25, 2022
- FBC NUP-06-06, "Commercial Grade Item Supplier Procurement Requirements," Revision 4, dated January 20, 2023
- FBC NUP-11-03, "ILAC Accreditation in Lieu of Commercial Grade Survey," Revision 6, dated February 3, 2023
- FBC NUP-SW-010, "ILAC Accredited Testing Service Purchasing Requirements," Revision 5, dated June 10, 2022
- FBC NUP-211, "Control of Inspection, Measuring and Test Equipment," Revision 1, dated January 20, 2023
- FBC NUP-217-1, "External Audit Process," Revision 7, dated January 31, 2023
- FBC NUP-217, "Internal Audit Process," Revision 6, dated January 31, 2023
- FBC QSP-11-01, "Metrology Program," Revision 18, dated February 6, 2023
- FBC QSP-18-01-F1, "Nuclear Inspector, Examiner, and Tester Qualification Form," Revision 1, dated May 18, 2021

Engineering Change Requests (ECR)

- ECR W2230131, Update wire lists for harnesses instructions, dated January 27, 2022
- QSP-05-08-F2, Nuclear Power Systems Reliability Checklist - wire harnesses, Revision 4, dated January 21, 2022

- MI1042WM-200-35, Manufacturing Instructions for 1042WM-200 Series UDR Cable Assemblies, Revision 6
- ECR W2230990, 960PS-210-5M1 seismic requalification for power fail connector change, dated February 9, 2022
- Drawing No. 960PS-210-5M1, 960PS Power Supply Assembly, Revision D
- Document No. 950.401, "Seismic Qualification Test Report for the N960PS-210-M1 Power Supply," Revision 2
- ECR W2230406, 844-213A-5 (3646068) corrections to main assembly and two machined components, dated February 4, 2022
- Drawing No. 844-213a-5 Motor & Valve NEMA 4 Assembly, Revision 6
- First Article Inspection Record, Part # 21-2187-680 Electrolytic Capacitor, Revision 2
- ECR W2237069, Part#21-2178-680 (3632843) Electrolytic Capacitor, August 4, 2022
- Drawing No. 21-2178-60 capacitor, Axial, 68, 16V electrolytic, Revision 2
- ECR W2233583, 943-25T RMS Detector Beta Scintillation, dated April 15, 2022
- CAL-BETA1, Beta Scintillation Point Source Calibration, Revision 19
- ECR W2232394, P/N TP876-1-89 (4051913) Corrections and Additions, March 21, 2022
- TP876-1-89, Test Procedure for 876-1-89 Power Supply P.C. Board, Revision 2
- NUP-QIP-Systems-Final, Nuclear Systems Final Inspection (All Products), Revision 1, dated May 20, 2022

Design and Commercial-Grade Dedication Records

- Purchase Order (PO) No. 684897 FTIR Analysis Of O-Ring, Part# 3636789, Fluke Model 46-29 June 15, 2022, Revision 1
- NUP-06-02-F2 ILAC-MRA In Lieu of CG Survey Checklist-FTIR Analysis, Revision 5, dated August 15, 2022
- PO No. 684897 for FTIR Analysis Testing Services, Revision 1, dated June 10, 2022
- NUP-06-02-F2 ILAC-MRA In Lieu of CG Survey Checklist-Solder Positive Material Identification, Revision 4, dated September 21, 2021
- PMI Test Report-Solder Revision 0, dated September 20, 2021
- PO No. 678583 for Solder PMI Testing Services, Revision 0, dated September 21, 2021

- NUP-06-02-F2 ILAC-MRA In Lieu of CG Survey Checklist-Buehler Rockwell Hardness Testing, 11/1/2022, Rev 5
- Part No. 672284, Buehler Rockwell Hardness Test Report, dated October 25, 2022
- FBC Po 687536 For Buehler Rockwell Hardness Testing, Revision 2, dated October 11, 2022
- CAL-GM6, 897A GM Detector Factory Calibration Procedure, Revision 7
- NUP-06-02-F1, Part # 897 A-221 ILAC-MRA in Lieu of CG Survey Checklist, Revision 4, dated March 21, 2022
- CAL-ION2, 977 Series Ion Chamber Detector Calibration, Revision 16
- NUP-06-02-F1, 977-210-M4A, ILAC-MRA in Lieu of CG Survey Checklist, Dated 12/9/2022, Revision 4
- Calibration Certificate, F-977-210-5986001, Revision 16, dated December 9, 2022
- PO No. 688765, 977 Series Ion Chamber Detector Calibration Services, Revision 0, dated November 30, 2022
- NUP-210-F2, 977-210-M4A NUPOW Device History Record Form, Revision 3, dated November 18, 2022
- CAL877-1, Calibration Procedure for Model 877-1, Revision 15
- NUP-06-02-F1, 877-1, ILAC-MRA in Lieu of CG Survey Checklist, Revision 4
- Calibration Certificate F-877-1-5459001, Revision 15, dated October 5, 2021
- Dedication Package for SO#32445751, Fluke Model 46-29, O-ring
- Dedication Package for SO#32411053, Fluke Model 92-9015A, Line Filter
- Dedication Package for SO#31897029, Fluke Model NMSJ-4375, Resin

Measuring and Test Equipment Records

- IRM – 0445, 0570, 2368

Purchase Orders, Audit Report, and Commercial-Grade Surveys

- PO Nos. 687138, 687536, 678583, 684897, 688864, 687486, 688862
- Sales Order Nos. 31897029, 31937328, 31937853, 32445751

Nonconformance Reports

- Nonconformance Reports (NCR) Nos. 265, 323, 409, 410, 411, 591, 784, 895, 906, 912, 1016, 1019, 1035, 1036, 1073, 1074, 1233, 1234, 1243, 1244, 1252, 1378, 1449
- Non-conforming Material Receipt (NCRM) Tag - 11253894, 11263857, 11246159, 11212123, 11251764

Corrective Action Reports

- Corrective Action Reports (CAR) Nos. – 275, 325, 350, 351, 352, 477, 618, 753, 769, 780, 781, 852, 907, 910, 914, 915, 916, 1015, 1081, 1349

Corrective Action Reports Opened During the NRC Inspection

- NCR – 1449 (CAR – 1081)

Test Records

- FBC Document Number 950.393, "Qualification Test Report, N877-60 Seals and N878-1-9 Cable, dated June 28, 2021
- FBC Document Number 948.410, "Qualification Test Plan Addition for the 876A-1 Containment Monitor," Revision 2, dated May 20, 2022
- FBC Document Number 948.411, "Seismic Test Plan Addition for the 876A-1 Containment Monitor," Revision 3, dated April 8, 2020
- FBC Document Number 950.392, "Qualification Test Report Addition for the 876A-1 Containment Monitor Readout," Revision 6, dated January 20, 2022
- FBC TP876-1-89, "Test Procedure for 876-1-89 Power Supply P.C. Board," Revision 2, dated March 21, 2022
- FBC Document Number 950.401, "Seismic Qualification Test Report for the N960PS-210-M1 Power Supply," Revision 2, dated June 17, 2022
- FBC Document Number TP897A Test Data Sheet, "Electronic Test Procedure 897A-2X0 and 897A-2X1 Detectors" for S/N 5856001, Revision 4, dated August 1, 2022
- FBC Document Number TP1042WM-200-M1 Test Data Sheet, "Test Procedure 1042WM-200-M1, Shine UDR" for S/N 5454001, Revision 3, dated September 24, 2021

Training Records

- Personnel Training Record of Stacey Torres
- Personnel Training Record of Jon Hale
- Personnel Training Record of Rick Horvath

- Personnel Training Record of Dennis Kopp

Miscellaneous

- FBC Document Number MI1042WM-200-35, "Manufacturing Instructions for 1042WM-200 Series UDR Cable Assemblies," Revision 6