



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

December 29, 2022

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

SUBJECT: VENDOR INSPECTION OF FLUKE BIOMEDICAL COMPANY'S QUALITY ASSURANCE PROGRAM AND TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 21 PROGRAM IMPLEMENTATION

Dear Mr. Vishwanathan:

This letter documents the U.S. Nuclear Regulatory Commission (NRC) staff's plan to perform an inspection of Fluke Biomedical Company's Appendix B, "Quality Assurance Program 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," programs as they pertain to activities conducted at your facility related to the manufacturing of radiation monitoring equipment, replacement parts and calibration and repair services for NRC's regulated facilities.

As discussed through e-mail on December 20, 2022, the NRC inspection team plans to arrive at your facility on Monday, February 6, 2023, and will conduct an inspection through Friday, February 10, 2023. Subsequent to the inspection, a report will be issued and transmitted to you via letter. The lead inspector for this effort is Mr. Dong Park, and you may contact him at (301) 415-0001 or via electronic mail at Dong.Park@nrc.gov.

This inspection activity has been assigned the following docket number: 99902107. Please reference this number on any correspondence relating to this inspection activity sent to the NRC.

Sincerely,

A handwritten signature in black ink, appearing to read "Kerri Kavanagh".

Signed by Kavanagh, Kerri
on 12/29/22

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

Docket No.: 99902107

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DISTRIBUTION:

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NRR-106

OFFICE	NRR/DRO/IQVB	NRR/DRO/IQVB
NAME	DPark	KKavanagh
DATE	12/29/2022	12/29/2022

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