

January 20, 2020

SENT VIA OVERNIGHT COURIER (UPS)

U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Document Control Room

Re: **10 CFR Part 21 Interim Report re: Nickel Seal Rings**

Pursuant to 10 CFR § 21.21(a)(2) we are notifying you of a compliance gap.

During the course of a periodic audit, Fluke learned of a possible non-conformance in commercial grade dedication of nickel seals, model numbers 877-1-60-1 and 877-1-60-2. The audit identified a requirement for observation of heat treatment of nickel seal rings provided by a commercial supplier. The heat treatment process was not witnessed by Fluke personnel nor was it controlled by a Fluke-approved commercial grade survey.

Fluke/Victoreen Models affected:

- Model N877-1-60-1, nickel seal ring, mating connectors
- Model N877-1-60-2, nickel seal ring, connector-backshell
- Model N878-1-15, termination kit
- Model N878-1-5-6, terminated cable, 6-foot long
- Model N878-1-5-200, terminated cable, 200-foot long
- Model 875, high range containment monitor

Fluke promptly documented the issue in its corrective action program and initiated an evaluation of this Part 21 compliance gap. We plan to have replacement components (N877-1-60-1, N877-1-60-2) available in April 2020. Our evaluation involves obtaining evidence of heat treatment with respect to the above-mentioned parts. Fluke has identified customers potentially affected by this non-conformance and is issuing recommendations.

Fluke expects its evaluation will take longer than 60 days from discovery to full completion. Fluke anticipates completing the evaluation approximately June 2020.

Please contact Kevin O'Guinn at kevin.oguinn@flukebiomedical.com or +1 (440) 542-3627 with any questions.

Sincerely,



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