

Continuous Level Measurement System Validation for the Pharmaceutical and Bio-tech Industries

The US FDA's regulations and initiatives, such as 21 CFR Part 11 electronic records requirements, have become regulatory requirements throughout the Pharmaceutical and Bio-tech industries.

Looking at the validation process of continuous level measurement instrumentation, we find that instrumentation device checks (calibration verifications) can be implemented relatively simply. In some cases, not only are they a requirement of 21 CFR Part 11, but they also make plain common sense for reliable and repeatable process control.

Instrumentation validations, calibration checks, or calibration certifications have always meant a time consuming and sometimes expensive mandate that can occur several times during a year. There has never been a quick and easy way to certify that the process instruments are producing a "quality" measurement...until now.

In many cases, level measurement systems such as differential pressure level transmitters require the D/P transmitter to be removed from the process vessel to have its calibration checked by means of a dead weight tester. Not only is this time consuming, but it also means that the vessel has to be either emptied or the contents transferred to another location. This adds unwanted and unneeded cost; in some cases this can add several thousand dollars to the system "validation" process.

AMETEK Drexelbrook's HART Smart RF Level transmitters now permit a complete calibration validation that can be NIST traceable. This system validation can be performed without removing the level measurement system from the process vessel or compromising any hazardous materials into the environment. The validation procedure only requires a few minutes of time, not man-days to complete.

The AMETEK Drexelbrook HART Smart RF level systems have all of the Technical Controls for 21 CFR Part 11 compliance built into these products. However, it is still the responsibility of the user to implement the Procedural and Administrative Controls correctly and consistently for overall Part 11 compliance.

RF Level System Validation Overview

Continuous RF Level transmitters derive their input information from a sensing element that produces a variable capacitance value to the RF transmitter based on level. The transmitter output signal is derived from this capacitance value based on the zero and span values determined during the initial system calibration.

System Validation Theory

If the RF Level transmitters minimum (zero) and maximum (span) capacitance values are known, and remain unchanged, the effects of a specific capacitance value within this range can be accurately predicted. If a known capacitance, which can be NIST traceable, within this range produces repeatable results, and the minimum and maximum values remain unchanged, then the RF Level system can be assumed to be operating correctly. With a known capacitance input, the output signal would not be repeatable if the calibration information was altered, or if the RF Level transmitter was not operating within its design specifications.

Validation Procedure Overview

By using PC software specific to the RF level transmitter it is possible to record the actual transmitter calibration, configuration and "Real Time" transmitter signal output. By substituting an NIST traceable "validation" capacitor for the sensing element input to the transmitter, a predictable and repeatable output signal value can be generated. The "validation" capacitor should be of a value that represents a mid-range reading for the best resolution.

The PC software specific to the RF level transmitter allows the user to view the full calibration and configuration values along with the transmitters signal output, as a result of the validation capacitor. In subsequent validation checks, using the exact same "validation" capacitor for this specific transmitter, it can be established that the RF level system is operating correctly and that the calibration information is the same as the initial set-up.

If the information that is shown (or printed) matches the initial readings within system specifications, then it can be said that the calibration and configuration are as originally set. It can also be said that the transmitter's response falls within acceptable tolerances. The system has passed validation tests.

Example of Drexelbrook's HART PC software generated validation report:

Tag-ID: LIT	HART Win	Oct 29 2003 12:39:14 PM
AMETEK Drexelbrook 205 Keith Valley Road Horsham, PA 19044 Telephone: 215-674-1234 FAX: 215-674-2731 Service: 800-527-6297		
Tag-ID: LT 101	Serial Number: 13307	
Scratch PAD: VALIDATION TEST - 50pF cap.	Software Version: 3.1	
Analog Loop Assign: LEVEL	Range Position: 3	
Damping Time: 0 sec.	Type: 30	
Level Configuration	Vessel Configuration	Level Calibration
Level Units: inches	Vessel Units: liters	Lower Level: 5.00 in
Maximum Level: 24.00 in	Maximum Capacity: 1000.00 liter	Upper Level: 24.00 in
Level Type: Standard	Vessel Type: Vertical	Lower Capacitance: 29.91 pf
	LRV (4mA): 0.00 in	Upper Capacitance: 85.65 pf
	URV (20 mA): 24.00 in	
Real Time View		
Level: 12.026 in		
Vessel: 501.08 liter		
Capacitance: 50.63 pF		
Loop Current: 12.02 mA		
Percentage: 50.26 %		
Status: OK		

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