

Using Bar Codes to Ensure Data Integrity in Process Calibration

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ABSTRACT

Integrity of data for field calibrations in the process industries has been a challenge for instrumentation professionals. Quality and regulatory forces such as ISO 9000, NRC CFR50, OSHA-1910 and the FDA GMPs are driving these professionals to improve the data integrity of field calibrations to provide a good audit trail. Manual record keeping, prone to transcription errors, has led to the development of the Documenting Process Calibrator. With these calibrators, however, the user was still required to make some data entries or task selections that could introduce errors into the calibration data.

Bar code devices have long been used in inventory control for quickly and accurately identifying materials. The accuracy and utility of these bar code devices has resulted in a variety of new identification applications, one of which is Process Calibration.

Requirements for improved Calibration Documentation

Calibration documentation for process instrumentation has evolved over time. Initially, documenting calibration was not a requirement in most industries. There was nominal documentation on critical components where calibration had known effects on specific processes. Over time, the demand to have a track record on these critical devices increased, as these critical devices directly affected the quality of the outgoing product. Calibrations were also determined to be essential for many safety and environmental requirements. Calibration documentation requirements for these critical components are now written into most of the modern standards that instrumentation professionals are required to follow. Governmental standards, such as the Nuclear Regulatory Commission's NRC-CFR50, OSHA-1910, and the Food and Drug Administration Good Manufacturing Practices and quality initiatives such as ISO 9000 and ANSI/NCSL Z540-1 are examples of the many regulations that require appropriate documentation of field calibrations.

Record keeping for calibration

Prior to the advent of the documenting class of calibrators, the instrumentation professional would manually document these critical measurements during the calibration process. This process often called for a structured paper form to record the data. In other cases, simple field notes would be taken. While this activity solved the requirement for documenting the calibration, there were several drawbacks to this approach.

Using structured forms, the document either needs to be general in nature due the many different types of devices that need calibration, or there needs to be a different form for each type and class of device. To be certain the test parameters are correct, the test setup needs to be copied onto the form prior to going out to perform the calibration. Besides being a cumbersome and inefficient process, it leaves a lot of room for transcription errors both in the field when the results are recorded and in the shop when the test detail is documented.

This manual process is still prevalent in many industries today. One regulatory force currently driving manual transcription is the FDA. Manual annotation of data is still a requirement for calibrations performed in FDA regulated industries. This regulation may be changing in the future as electronic signatures on data are slowly becoming accepted.

The Field Process Calibrator

Several field calibrators are marketed with the intent of providing a multifunctional documenting calibration tool that assists with the management of calibration data. Figure 1 shows four examples of calibrators and a partial list of their feature sets.

	Ametek Modcal II	Hathaway DHT922	Unomat TRX-II	Fluke 743B DPC
V, I, Ohms, Hz	X	X	X	X
TCs, RTDs	X	X	X	X
Pressure	X	X	X	X
PC Interface	Std	Opt	Std	Std
Weight, lbs	16	7	2.6	3
Bar code				X

Figure 1: Examples of Field Process Calibrators

This class of documenting calibration tool helps improve the integrity of the documentation in several ways. First, the procedures used are documented in the calibrator and/or in the database used to manage the process. The calibrator is a computerized device that provides computational assistance in comparing measured versus nominal value comparisons in a calibration and generates dependable, documented results by automatically capturing the data while in the field.

Many of the documenting calibrators currently on the market today have the ability to “dock” with a computer. The addition of an instrumentation management database application compatible with these docking calibrators provides the technician responsible for overseeing the maintenance and calibration of instrumentation a powerful set of tools for managing this process.

Bar Codes and Bar Coding of Instrumentation

Bar code devices are used in inventory control to accurately identify materials and eliminate the need for an operator to key in lengthy identification codes. Industry statistics show that the rate of mistakes for human data entry occur at a rate of 1 in every 300 entries, compared to 1 error in 3,000,000 with bar code entry systems. With thousands of tags in a given process plant the probability of mistakes with manual entry is still very high. More and more, bar coding is being used to identify the instrumentation in process plants, utilities and other manufacturing industries. The accuracy and utility of these bar code devices has led to a variety of new identification and tracking applications for process calibration.

Integrated Calibration Solution for use in Regulatory Environments

The tools described create a comprehensive solution for managing calibration procedures and data when combined. The three key elements of this integrated solution are:

1. Asset management database software
2. Documenting Process Calibrator (DPC)
3. Instrumentation bar code identification (labeling) and a bar code reader

Asset Management Software is a tool for managing the calibration activity in a facility. It can record and track many different variables about a particular instrument asset. including:

- > General information about a tag
- > Instrument specific specification information
- > Calibration test procedures
- > Test equipment used to perform the calibrations
- > Historical calibration records
- > Scheduling and task management tools
- > The technician performing the calibration

The Documenting Process Calibrator (DPC) provides multifunctional measurement parameters similar to a multimeter with additional functions unique to process instrumentation. This tool needs to be able to source these parameters as well and do so

simultaneously while measuring. A partial list of these parameters would include Volts DC and AC, milliamps DC, frequency, thermocouples, resistance temperature detectors (RTDs) and pressure. It needs to be rugged enough to endure abuse as the environment where the calibrator is used is often harsh and inhospitable. For the purposes of the application example that follows, the DPC needs to be able to accept input from a bar code reading device and be capable of bi-directional communication with the asset management software.

The bar code reading device in this example needs to be able to recognize a specific instrument's bar code and use this identification to select the unique calibration routine for this asset or tag in the DPC. It also needs to be compact and rugged as it will also go out into the process environment where the calibration is performed. The instrument to be calibrated needs a compatible bar code label affixed with its unique tag identification number. To capture the identification of the user performing the calibration it is preferable to have a bar code label on the technician's identification badge.

How the process works...

Procedures are first created in the shop where reference data on the devices to be calibrated is available for consultation and are cataloged in a database application dedicated to this function. With procedures configured and controlled in this fashion, the execution of these procedures is consistent and the output of the process is dependable and ensures procedure integrity. Figure 2 shows the test parameters for a tag.

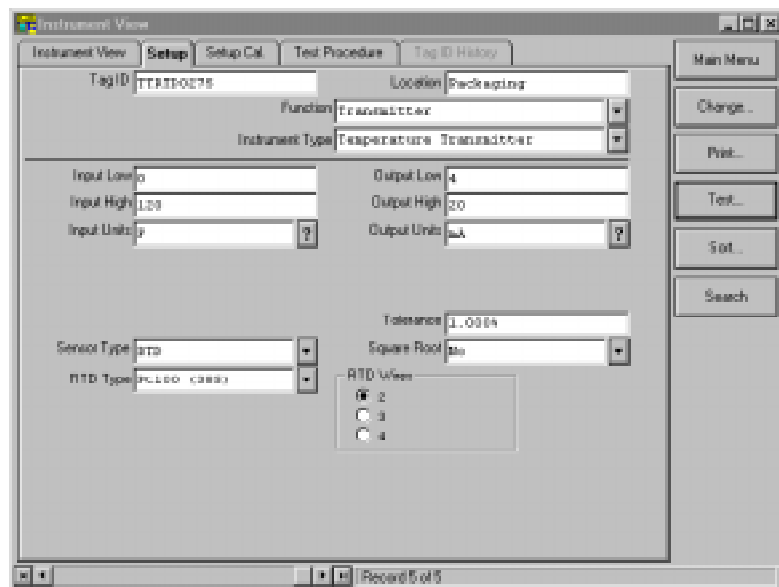


Figure 2; Instrument test parameters

Figure 3 shows the test procedure used for a tag that is to be loaded into the calibrator for calibration.

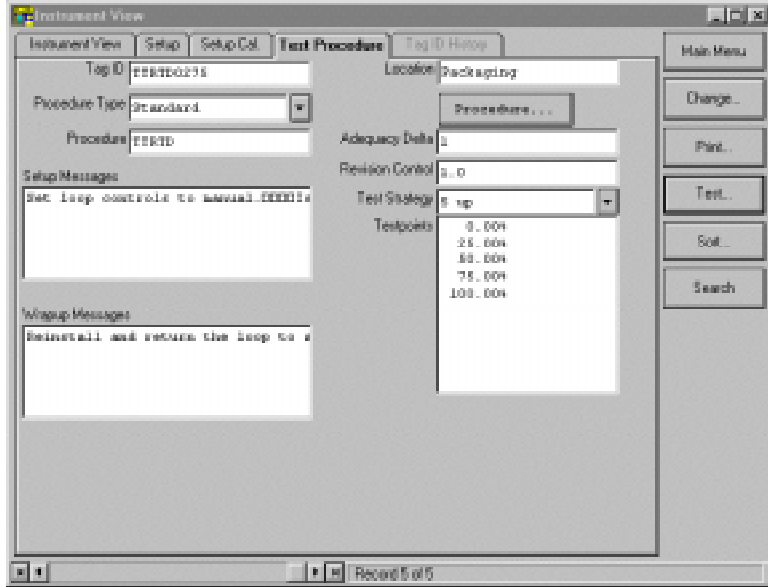


Figure 3: Test Procedure Parameters

Once the procedures are initialized in the database, the field calibration activity begins with the Instrumentation Supervisor loading a grouping of calibration tasks into the calibrator. Selection criteria for this step might be based on date, geographic location, building, process variable, loop, or device depending on how a particular instrumentation group addresses the workload.

Once in the field, the Instrumentation Technician will be able to review the tags loaded into his route either from the calibrator itself or from a hard copy printout of the downloaded calibration tasks.

Task list selection

When the Instrumentation Technician begins the calibration of an instrument, the bar code wand is used to identify the asset to be calibrated by reading its' bar code asset or tag label. Once the bar code label has been read, the DPC will automatically select the corresponding task from the list of calibration tasks loaded into the calibrator (Figure 4). Once selected, this task forces the user to perform the calibration per the stored procedure and preserves the procedure to tag identification integrity.

01/20/98 12:33:17 pm			
Task List 5 of 5			
TempCon33	Usage	Count:	0
TTItoP88534	Usage	Count:	0
TTK1088	Usage	Count:	0
TTPtoI0012	Usage	Count:	0
TTRTD0275	Usage	Count:	0
Go To Task	Prev. Page	Next Page	Done

Figure 4; Selected Task on Calibrator

01/20/98 12:44:25 pm Loop 24V		
SOURCE	MEASURE	ERROR %
0.0°F	3.967mA	-0.21
30.0°F	8.051mA	0.32
60.0°F	12.124mA	0.78
90.0°F	16.173mA	1.08
120.0°F	20.224mA	1.40

Abort	Prev. Page	Next Page	Continue
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Figure 5; As-Found Result

If a failure is recognized by the DPC, instrument adjustment needs to be performed. Once the adjustment is completed, the post adjustment As-Left data needs to be recorded and labeled. When the calibration is completed, the DPC can instruct the user how to bring the instrument back on line, reverse lockout/tagout procedures etc.

When the task is completed, the Instrumentation Technician can review the task list in the DPC and observe the downloaded list of tags and determine from the usage count which tags are completed and the workload that remains to be calibrated that day.

Once the day's calibrations are completed, the DPC task list can be reviewed by the Instrumentation Supervisor to manually confirm that the usage count on the tasks loaded into the DPC have incremented. This confirms that the downloaded tasks have been executed as written in the asset management database where the tasks originated.

Next, the calibration results from the days activities can be uploaded from the DPC to the Asset Management Software and reviewed for pass/fail in tabular format (Figure 7). This step eliminates the need for manually transcribing the data from the DPC.

Once that is complete, the pre-adjustment As-Found calibration data is automatically captured insuring the integrity of the results data (Figure 5). Tag and serial number information is filled in from the procedure and the Instrumentation Technicians identification is gathered from the users Identification badge using the bar code wand (Figure 6) eliminating transcription errors.

01/20/98 12:52:56 pm			
Press ENTER to Change			
Tag TTRTD2075			
S/N 3357443			
ID JIM SHIELDS 19390			
Abort			Done

Figure 6; ID from Badge Bar Code

Input	Output	% Error
0	3.98	-0.1304
30	8.051	0.0184
60	12.124	0.0784
90	16.196	-0.0284
120	20.282	-0.1184

Result	Passed
Max Dev	-0.1304
Linearity	0.1081

Figure 7; Tabular Calibration Results

Figure 8 is a graphical representation of the As-Found As-Left result data plotted against the tolerance band. With data available in this format a devices performance can be predicted.

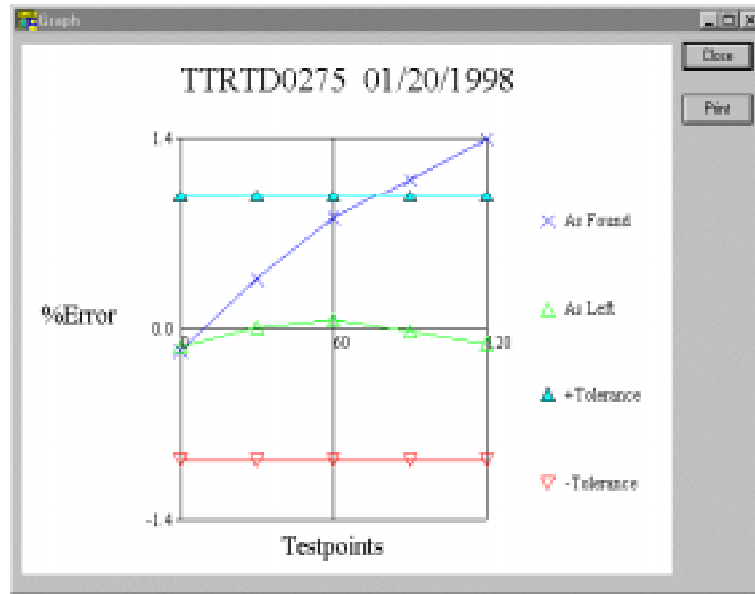


Figure 8; Graphical As-Found, As-Left Plot

Tasks not completed are identified by the software's unloading utility can be marked for return to the DPC for later execution.

With the day's calibrations completed, the results can be printed out as certificates or retained electronically in the database for later evaluation. Calibration dates are updated and traced to the DPC that performed the calibration meeting the need of regulatory forward and reverse traceability issues.

Summary

The enhanced capabilities of the modern Documenting Process Calibrators when coupled with an Asset Management Software application and bar code reading devices form a seamless solution for ensuring the integrity of process calibration data. The table below in Figure 9 summarizes the roles each component has in this solution..

Issue	Asset Management Software	Documenting Process Calibrator	Bar Code Reader
Tag / Instrument specifications	XXX		
Test procedure documentation	XXX	XXX	
Asset Identification			XXX
Test procedure selection			XXX
Field calibration data		XXX	
Technician Identification			XXX
Traceability	XXX	XXX	
Historical Calibration information	XXX		

Figure 9; Summary table

This combination of tools; Asset Management Software, Documenting Process Calibrator and bar code readers, lifts the burden of documenting field calibration and ensures integrity of data.

Bibliography

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