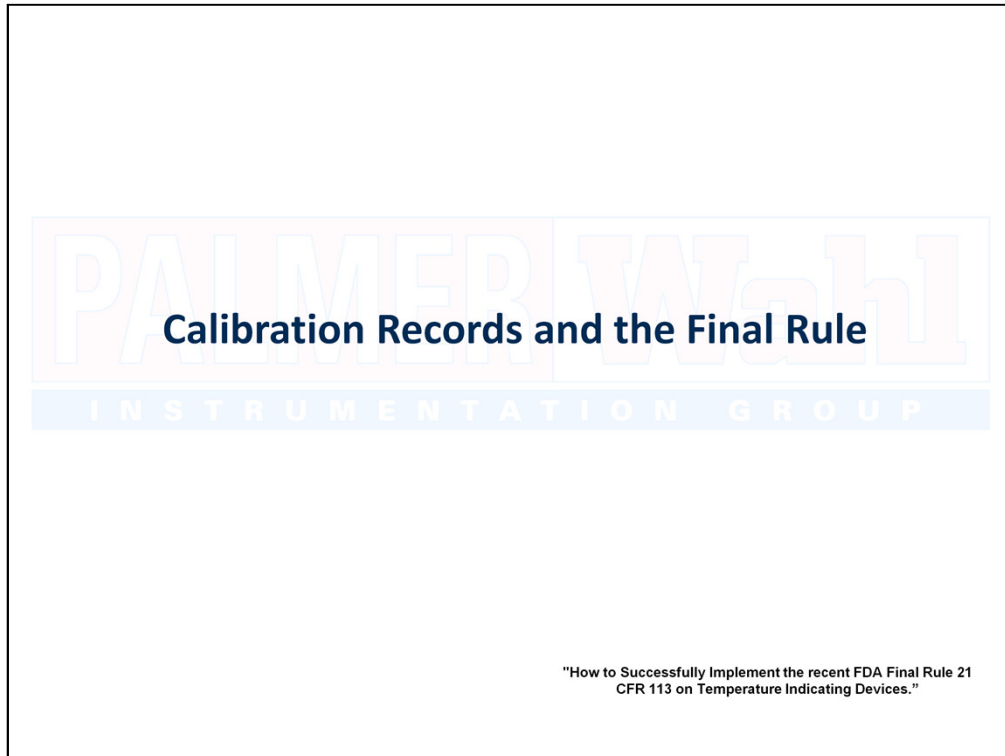


PALMER **Wahl**
I N S T R U M E N T A T I O N G R O U P



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As you probably know, 21CFR also includes requirements for the calibration of thermometers.

21CFR Part 113.40 (a) (1) states:

“Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference device for which the accuracy is traceable to a National Institute of Standards and Technology (NIST), or other national metrology institute, standard reference device by appropriate standard procedures,

- upon installation
- and at least once a year thereafter,
- or more frequently if necessary, to ensure accuracy during processing”

So, thermometers are to be verified for accuracy before use, and at a minimum, re-checked annually. But how do we know if they should be verified “more frequently?”

21CFR Part 113.40 (a) further states:

“Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with § 113.100(c) and (d).”

INSTRUMENTATION GROUP

We have to create and maintain records. By reviewing the results of the calibration record and by comparing to the results of previous tests, a performance profile of the instrument is determined. If the instrument is found to be out of calibration, the calibration interval should be shortened. We should also review the effect the out of tolerance condition might have had on the process being measured. The information required will shape the design of the calibration report which we will review a bit later.

RISKS OF INCORRECT CALIBRATION INTERVALS

- If the calibration interval is too short, the cost associated with calibration increases, creating the potential of lost \$\$\$
- If the calibration interval is too long, there is a risk of bad measurements and out of control processes. Product recall and potential liability risks arise, creating the potential of lost \$\$\$

Properly established and maintained calibration schedules improve cost effectiveness and reduce risk exposure.

**OTHER STANDARD REQUIREMENTS CONTROLLING
CALIBRATION ARE:**

ISO9001:2008-Quality management system requirements states: *“Where necessary to ensure valid results, measuring equipment shall...be calibrated or verified at specified intervals, or prior to use...”*

ANSI/NCSL Z540-Calibration and Measuring and Test Equipment General Requirements

states: *“M&TE requiring calibration shall be calibrated or verified at periodic intervals, established and maintained to assure acceptable reliability, where reliability is defined as the probability that MT&E will remain in tolerance throughout the interval.”*

It is established then, that we have to verify the accuracy of our instruments, periodically re-verify to assure that they remain accurate while they are in use, and maintain records to support our actions.

DETERMINING CALIBRATION INTERVALS

-INTERNATIONAL LABORATORY ACCREDITATION
COOPERATION

ILAC-G24:2007 “Guidelines for the determination of
calibration intervals of measuring instruments”

<http://ilac.org/>

-NATIONAL CONFERENCE OF STANDARDS
LABORATORIES

NCSL RP-1 “Establishment and Adjustment of Calibration
Intervals”

<http://www.ncsli.org/>

Two sources of information for determination of calibration intervals are
ILAC-G24 and NCSL RP-1

if you enter the NCSL address, be sure to note “NCSLI” or you’ll end up at the
National Conference of State Legislatures, which we likely would not care to be

ILAC-G24:2007

Provides guidance on:

- Initial choice of calibration intervals
- Methods of reviewing calibration intervals

Factors to consider when determining the Initial choice: instrument manufacturer's recommendation, use conditions (extent & severity), environmental conditions, the needed uncertainty of the measurement, maximum permissible error, adjustment or change in individual instruments, influence of the measured quantity (high temp effect on T/C, available data on similar devices, etc.)

ILAC-G24:2007 (cont.)

5 methods for reviewing calibration intervals are provided in this document:

- Automatic adjustment (calendar time)
- Control charts
- In-use time
- In service checking
- Other statistical methods

We may find that instruments are less reliable than expected; the usage may not be as anticipated; may be sufficient to be used to perform only limited calibrations of some instruments; the change in calibration results may show that longer calibration intervals may be possible without increasing risk.

1. Instrument adjusted on routine basis, extend interval if within 80% permissible error, extend if not. May result in frequent adjustment of cal intervals, may be difficult to balance the calibration workload, and maintenance of large number of certificates may be cumbersome.
2. SQC charting in which significant calibration points chosen and plotted over time. Drift is calculated and plotted allowing the calculation of the optimum calibration interval. This method is considered difficult to apply and is typically used with automatic data processing.
3. Calibration interval is expressed in hours of use. Examples, thermocouples used at extreme temps., length gauges or gauges subject to mechanical wear
4. Suitable for complex instruments or test consoles; instruments subjected to frequent checks, once daily or more. If check shows out of permissible error, instrument is returned for complete calibration. How often is the "checking instrument" calibrated?
5. Statistical analysis of an individual instrument or instrument type.

Software packages

Many software packages are available to help maintain calibration schedules:

- GAGEtrak from CyberMetric
<http://www.cybermetrics.com>
- GAGE pack from PQ Systems
<http://www.pqsystems.com>
- Interval Max by ISGMax
<http://www.isgmax.com>

Costs of software can run from 990.00 for Gage Pack. Prices are dependant upon the number of licenses purchased and in the case of Interval Max will vary by the number of items inventoried.

Calibration Documentation

- The Calibration Test Report is a document detailing all pertinent information for a specific calibration performed
- Required for Temperature Indicating Devices and Reference Devices that are maintained by the processor...in accordance with 113.100(c)(d).

Ref. 21CFR: 113.40(a)(1)(ii)

Calibrations must be documented, whether they are performed by an outside source or performed internally. Without the document, there is no proof calibrations were actually performed.

Calibration Documentation: 21CFR 113.100 (c):

“(c) Records of the accuracy of a temperature-indicating device shall include:

- (1) A reference to the tag, seal, or other means of identity used by the processor to identify the temperature indicating device;
- (2) The name of the manufacturer of the temperature-indicating device;
- (3) The identity of the reference device, equipment, and procedures used for the accuracy test and to adjust the temperature-indicating device or, if an outside facility is used to conduct the accuracy test for the temperature indicating device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a National Institute of Standards and Technology (NIST) or other national metrology institute standard;
- (4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the temperature-indicating device;
- (5) The date and results of each accuracy test, including the amount of calibration adjustment; and
- (6) The date on or before which the next accuracy test must be performed.”

21CFR 113.100(c) details the information that is required in the documentation

Calibration Documentation: 21CFR 113.100 (d):

“(d) Records of the accuracy of a reference device maintained by the processor shall include:

- (1) A reference to the tag, seal, or other means of identity used by the processor to identify the reference device;
- (2) The name of the manufacturer of the reference device;
- (3) The identity of the equipment and reference to procedures used for the accuracy test and to adjust or calibrate the reference device or, if an outside facility is used to conduct the accuracy test for the reference device, a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes a statement or other documentation regarding the traceability of the accuracy to a NIST or other national metrology institute standard;
- (4) The identity of the person or facility that performed the accuracy test and adjusted or calibrated the reference device;
- (5) The date and results of each accuracy test, including the amount of calibration adjustment; and
- (6) The date on or before which the next accuracy test must be performed.”

If you are performing calibration of your TIDs in-house, records of your standard or “reference” devices must be maintained as well. If the calibration of your TID’s are performed by an outside source, they will be responsible for maintenance of the reference device records. 113.100 (d) defines the information required in the documentation. Notice that this information is basically the same as that required for the TID.

Calibration Documentation

NIST TRACEABLE CERTIFICATE OF CONFORMANCE

Customer Info → CUSTOMER: _____
PURCHASE ORDER NO: _____ ORDER NO: _____
MODEL/PART NO: _____ QTY: _____
SERIAL NO.(S): _____

→ This is to certify that the instrument(s) listed above were calibrated to meet the published catalog specifications. ← **Standards**

Uncertainty Statement → Our Quality Management System is certified to conform to ISO9001:2008. We maintain a calibration system in conformance with ANSI/NCSL Z-540 and MIL-STD-45662A. Calibrations are performed against standard instruments, traceable to the National Institute of Standards and Technology (NIST). Unless otherwise indicated, the standards used have a test ratio of four times greater than the unit being calibrated. Measurement uncertainties are estimated at a confidence level of 95%. This report shall not be reproduced, except in full, without written approval of the laboratory.

ATTACHMENT: NIST Traceable Calibration Data Sheet(s) are included and are a part of this certification.

→ APPLICABLE PROCEDURE(S): _____ ← **Procedure (Method used)**

Report # → TEST REPORT NO.s : _____

NAME: _____ ← **Signatures**
TITLE: _____
DATE: _____

This slide and the next two, provides information on what we should have in our calibration documentation. If the test was conducted by an outside source, a test report cover sheet should be provided. This sheet will contain the information shown, although format will vary by cal lab. This sample follows the format used by Palmer-Wahl. Note that a unique report number is issued for ease of tracking archived data. Customer data is provided to create traceability to the customer order and clearly ties the report to the calibrated instrument by part number and serial number. The instrument also is identified by a calibration tag that also provides the information required by 21CFR and ties the instrument to the test report. The method used is shown and person reviewing and approving the test report is identified by signature and title.

Calibration Documentation

CALIBRATION DATA SHEET FOR NIST TRACEABILITY
DST/DSX 500/600 SERIES METER DISPLAY SECTION

Customer Name: _____ Test Report Number: _____
 Meter Model Number: _____ S/N: _____
 Probe Model Number: _____ S/N: _____

Data Type → DATA: As Rec'd _____ As Lab _____ Temp _____ NRH: _____

Accuracy specification is: $\pm 0.001(148.89C) \pm 3F/2C$; $\pm 0.001(148.89C) \pm 25\%$
 As left spec is As received * TZ

°F Data						
Test Point	Temperature Source	Bath Temperature		Display Reading	Error °F	P/F Status
		Norm °F	Adj °F			
Test Point 1						
Test Point 2						
Test Point 3						
Test Point 4						
Test Point 5						

°C Data						
Test Point	Temperature Source	Bath Temperature		Display Reading	Error °C	P/F Status
		Norm °C	Adj °C			
Test Point 1						
Test Point 2						
Test Point 3						
Test Point 4						
Test Point 5						

Notes: Measurements are made at 70° and 100° unless otherwise specified.
 For newer meter versions, attach QCP-104 for transmitter data.

INST NO.	DESCRIPTION	MODEL NO.	SERIAL NO.	CALIB		TEST	
				DATE	DUE	WFO	NO
IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A
IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A
IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A
IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A
IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A	IN/A

Conducted by: _____ Date: _____
 Q.C. Acceptance: _____ Date: _____

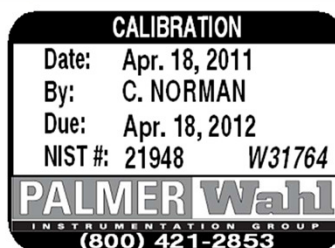
General Info → (Customer Name, Test Report Number, Meter Model Number, S/N, Probe Model Number, S/N)
Data Type → (DATA: As Rec'd, As Lab, Temp, NRH)
Data → (°F Data, °C Data tables)
Standard Instruments → (INST table)
Person performing test → (Conducted by, Q.C. Acceptance)
Date performed → (Date)

The information provided in the test data sheet is applicable, whether from internal calibration or from an external calibration source. The general info with the test number, clearly ties this page to the test report cover from the previous slide. Data type provides information on the instrument prior to any adjustments in calibration. This data is important for review as it provides the basis for determining the calibration recall. If data indicates the item out of calibration, the calibration cycle will need to be shortened and the effects of the out of tolerance condition will need to be reviewed. This data should also be compared to previous test results to assist in determination of calibration intervals. The standard instruments used are shown; this provides a link in the chain of traceability to NIST. Also shown is the person who performed the testing and the date it was performed.

21 CFR 113 requirements

“Each temperature indicating device should have a tag, seal, or other means of identity.”

MODEL	
DST600XXXX	
SERIAL	DATE
31764.001	04/18/2011



A calibration sticker attached to the instrument can easily meet this requirement. NIST traceable calibrations performed by Palmer-Wahl will result in a sticker attached to the instrument that shows the person performing the test, the date performed and a date due for re-calibration. This calibration due date interval is routinely assigned at one year by Palmer-Wahl, unless other arrangements are made by the customer; this allows the customer the opportunity to establish and maintain his own calibration cycle, based upon their review of the test data. It should be noted that ISO17025 states that calibration laboratories should not assign a due date unless in agreement with the customer. Palmer Wahl typically recommends that calibration occur at one year at a minimum. This creates agreement with the 21CFR requirement and still allows the customer to change the due date if needed. A unique test number, which in this example is 21948, ties the sticker and instrument to the calibration report.



Questions?