Calibration Point Selection

Who makes the call?

Presented by:

Joe Petersen
Metrology Engineer
Abbott Laboratories
Common Questions

• Do calibration points have to cover the range of the instrument?
• How many calibration points are needed?
• Are 10, 50, 90 % of full scale appropriate?
• Should zero be used?  Is it valid?
Introduction

- Calibration points effect measurement reliability
  - ISO 17025 addresses many quality issues;
    - calibration point selection is not directly addressed
    - perhaps indirectly addressed by:
      - 5.4 Methods, or
      - 5.7 Sampling
Agenda

- General principles
- Who makes the call?
- A form of sampling?
Learning Objectives

After this session, the participant should be able to:

• List key considerations for selecting calibration points

• Promote best practices for using a team approach to define calibration points
Where are calibration point selection requirements defined?

QM
Policy
General Operating Procedure
Specific Calibration Procedure (Work Instruction)
Example of Policy / General Procedure

• “The selection of calibration points will vary with the normal use of the meter ....”
  – Usage

• “For example, a meter which monitors a fixed value can be spot calibrated at the critical value.”
  – Single Point Calibration

• “Meters which may indicate any value within their ranges will require a linearity test at full scale and at least three equally spaced divisions on one range, and a full-scale test on each remaining range.”
  – Full Calibration

• “Other meters, such as those used over a narrow range, may require calibration over a restricted portion of the scale.”
  – Limited Calibration

– CALIBRATION OR QUALIFICATION OF PANEL METERS, Metrology Bulletin, Oct '64--USN Metrology Engineering Center, Pomona, Calif. ; as published in National Conference of Standards Laboratories, NCSL NEWSLETTER 67-4, 1967
Example of Policy / General Procedure

- “In general, for each TI characteristic being calibrated, the smallest number of test points consistent with obtaining verification of the TI performance over its specified range should be used.”
  - Risk based approach

- “The number and choice of required test points will vary, depending on the characteristics of the TI.”
  - Consider design and technology

- “Guidance concerning choice of test points for selected generic classes of equipment is contained in Calibration Requirements Documents (CRDs).”
  - Specific requirements are in individual calibration procedures

- “In some cases, TI application/use requirements will dictate test point selection.”
  - Consider use

- REQUIREMENTS FOR PREPARATION OF INSTRUMENT CALIBRATION PROCEDURES
  - NAVAIR 17-35TR-4
  - NAVY METROLOGY ENGINEERING CENTER
  - 15 AUGUST 1990
  - 3.7.2.10 Calibration Test Points.
Key Considerations for Point Selection

• Measurement Technology
• External Guidance Documents
• Calibrated Range
  – full or limited
• Assigned Accuracy
  – (maximum permissible error)
• # of adjustment points
• User requirements
  – critical usage points may be preferred calibration points
### Are 3 points sufficient?

**Balance calibration guidelines**

<table>
<thead>
<tr>
<th>Publication</th>
<th>Minimum # of Accuracy/Linearity Test Points (excluding zero)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OIML R76-1</td>
<td>5</td>
</tr>
<tr>
<td>UKAS LAB14</td>
<td>10</td>
</tr>
<tr>
<td>Code of Practice for Industrial Weighing Machines, United Kingdom Weighing Federation</td>
<td>5</td>
</tr>
<tr>
<td>SANAS R15-03 (South African National Accreditation System)</td>
<td>5</td>
</tr>
<tr>
<td>Mettler Balance Tolerances</td>
<td>typically 4</td>
</tr>
<tr>
<td>Sartorius Tolerances for Testing Metrological Specifications</td>
<td>typically 4</td>
</tr>
<tr>
<td>ASTM E898</td>
<td>10</td>
</tr>
<tr>
<td>EA-10/18 Guidelines on the calibration of non-automatic weighing instruments</td>
<td>5 or more</td>
</tr>
</tbody>
</table>
EURAMET Guidelines on the Calibration of Digital Multimeters

• cg-15
  – Previously EA-10/15
3.4.1 “… consider the working principles of the instrument …”

“[obtain guidance] from the manufacturer's instructions, although the points listed therein should not necessarily be considered exhaustive.”

‘trust but verify’
**EURAMET Guidelines on the Calibration of Digital Multimeters**

<table>
<thead>
<tr>
<th>Table</th>
<th>Accuracy Class (Resolution)</th>
<th>Recommended # of calibration Points*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4 1/2 digits or less (e.g. 20,000 counts)</td>
<td>58 to 70</td>
</tr>
<tr>
<td>2</td>
<td>5 1/2 digits or more (e.g. 200,000 counts)</td>
<td>100 to 114</td>
</tr>
</tbody>
</table>

* Based on five parameters and five ranges per parameter.

- Conclusion: The extent of testing should be based on instrument accuracy.
# of calibration Points

- Factors to Consider
  - Calibrated Span
  - Assigned Accuracy
  - Measurement Technology
    - First principles
    - Empirical
  - Cost
  - Risk

Assume ± 2 %RH
Hind Sight is 20/20

• Given an excessive # of calibration points, it is easy to see which points are unnecessary

• You generally can’t tell you have enough points until you’ve tested more than enough
  – Type testing
  – Retrospective review of historical results
Hind Sight is 20/20
Stir Plate Calibrations

Average Error, % of reading -- 1 standard deviation Error Bars

![Graph showing average error and speed (rpm)]
“Test results showed that measurements made at 50 test points were sufficient to allow accurate predictions of the instrument's performance at all 255 test points specified by the manufacturer.”

Points associated with secondary parameters

<table>
<thead>
<tr>
<th>Primary Parameter</th>
<th>Secondary Parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC voltage</td>
<td>frequency</td>
</tr>
<tr>
<td>optical transmittance</td>
<td>wavelength</td>
</tr>
<tr>
<td>relative humidity</td>
<td>temperature</td>
</tr>
</tbody>
</table>
Full matrix

Spectrophotometer Calibration Points
- Commercially Available Filters
- Visible Light Region

![Graph showing calibration points for optical density or absorbance against wavelength in nm.](image-url)
Risk based approach

AC Voltage Calibration Points
EURAMET cg-15/v.01

measurement point, % of full scale

frequency, Hz

One Intermediate Range
 Others
Uncertainty increases as calibration points decrease

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Target uncertainty, $U(pH)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration (1-point), $\Delta pH =</td>
<td>pH(X) - pH(S)</td>
</tr>
<tr>
<td>Calibration (2-point) by bracketing</td>
<td>0.02 - 0.03</td>
</tr>
<tr>
<td>Multipoint (5-point) calibration</td>
<td>0.01 - 0.03</td>
</tr>
</tbody>
</table>

International Union of Pure and Applied Chemistry
# of calibration Points

• Summary of General Requirements
  – Typically **three** or more to verify linearity
  – **One** is suitable for devices which are inherently linear (e.g. flow totalizers, stopwatches, frequency counters)
  – **Two** are suitable for very narrow portions of a range
  – **Five or more** may be appropriate for some technologies
    • Often recommended in guidance documents
Specific Principles

• Primarily related to technology
  – Analog v. Digital
  – First Principles v. Empirical
  – Mechanical v. Electronic
Who makes the call?

- Instrument Manufacturer
- Calibration Supplier
- Metrological Confirmation Group
- Instrument Owner / User
Who makes the call?

Going back to key considerations

– Instrument Manufacturer
  • Measurement technology
    – (perhaps biased view)
    – Perhaps the most expertise
  • Likely failure modes

– Calibration Supplier
  • Available calibration standards
  • Perhaps an unbiased view of measurement technology based on experience with multiple manufacturers

– Instrument Owner / User
  • Critical Points
Best practice for using a team approach

1. Obtain input from stakeholders
2. Calibration laboratory proposes calibration points
3. Owner reviews and approves

- Aligns with ISO 17025, 4.4 Review of requests, tenders and contracts
Is calibration point selection a form of sampling?
Is calibration point selection a form of sampling?

• ISO 17025 - 5.7 Sampling
  – 5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. …
  – NOTE 1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole.

• How many organizations have a defined procedure for selection of calibration points?
Is calibration point selection a form of sampling?

5.7 Sampling – Not Applicable for calibrations

(How many have seen this or a similar statement in a quality manual?)

• “Sampling does not apply. This laboratory only performs calibration, not testing.”

• “The laboratory does not sample items submitted for calibration.”

• “Sampling is not a part of our calibration process.”
Is calibration point selection a form of sampling?

• Three interpretations of ISO 17025 for point selection
  1. a form of sampling covered by 5.7, “Sampling”
  2. not sampling but is covered by 5.4, “Test and calibration methods and method validation”
  3. not covered by 17025
Inadequate Calibration Points

Device Range:
-10 to 70 °C
0 to 100 %RH

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Standard °C</th>
<th>Unit Under Test °C</th>
<th>Error °C</th>
<th>Uncertainty °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>23.04</td>
<td>23.1</td>
<td>+0.06</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relative Humidity</th>
<th>Standard % RH</th>
<th>Unit Under Test % RH</th>
<th>Error % RH</th>
<th>Uncertainty % RH</th>
</tr>
</thead>
<tbody>
<tr>
<td>50.3</td>
<td>52.8</td>
<td>+2.5</td>
<td>1.4</td>
<td></td>
</tr>
</tbody>
</table>

Approved by: J. Jones  03/30/2013

ISO 17025 Accredited Calibration
Accreditations Universal
Between Point Uncertainty

• If user specifies range
  – Reliability and uncertainty between points is lab’s responsibility

• If user specifies points
  – Reliability and uncertainty between points is user’s responsibility

Between Point Uncertainty

Sample certification statement:

• If user specifies range
  – “Instrument meets manufacturer’s specifications throughout all functions and ranges.”

• If user specifies points
  – “Instrument meets manufacturer’s specifications at all points tested.”
Appeal to Accreditation Bodies

• Whether point selection is an element of calibration methods or sampling:
  – Establish directives to assure adequate calibration points
    • Eliminate the quality system gap
    • Level the playing field
  – Prohibit single point certificates that imply a fully calibrated instrument
    • (except as appropriate)
    • Some instruments, purchased new, come with an accredited calibration
Conclusion

• Risk of too few calibration points
  – Untested regions
  – Undetected linearity errors

• Calibration point selection is technology dependent

• Each laboratory should establish a general policy / procedure

• Guidelines should also be defined in specific calibration procedures

• Team approach is desirable

• Accreditation should address point selection