2.4 Meet Stringent Quality Standards with Calibration Services

Incorporating Best Practices for Ensuring Product Quality

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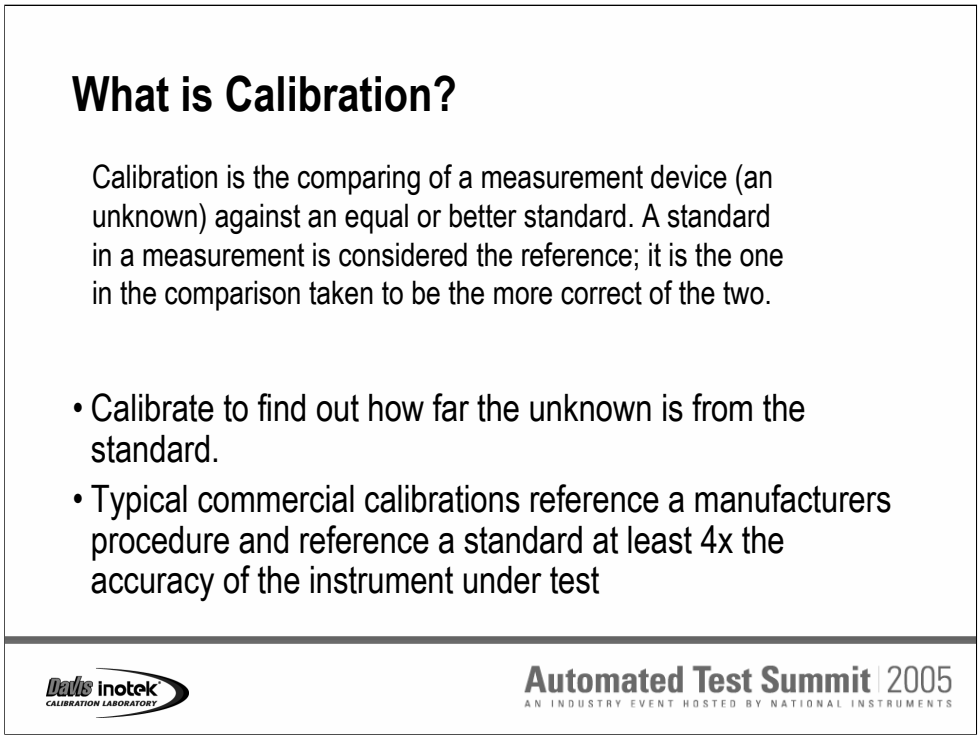

Definition: Calibration is the comparing of a measurement device (an unknown) against and equal or better standard. A standard in a measurement is considered the reference; it is the one in the comparison taken to be the more correct of the two. One calibrates to find out how far the unknown is from the standard.

Typical Calibration: A “typical” commercial calibration references a manufactures calibration procedure and is performed with a reference standard at least four times more accurate than the instrument under test.

Why Calibrate?

- People often consider calibration:
  a) A sticker
  b) A piece of paper
  c) A necessary evil
- Out of Tolerance (OOT) instruments may give false info
  - Unreliable products
  - Customer dissatisfaction
  - Increased warranty costs
  - Good products may fail tests, resulting in unnecessary rework

Calibration is an insurance policy

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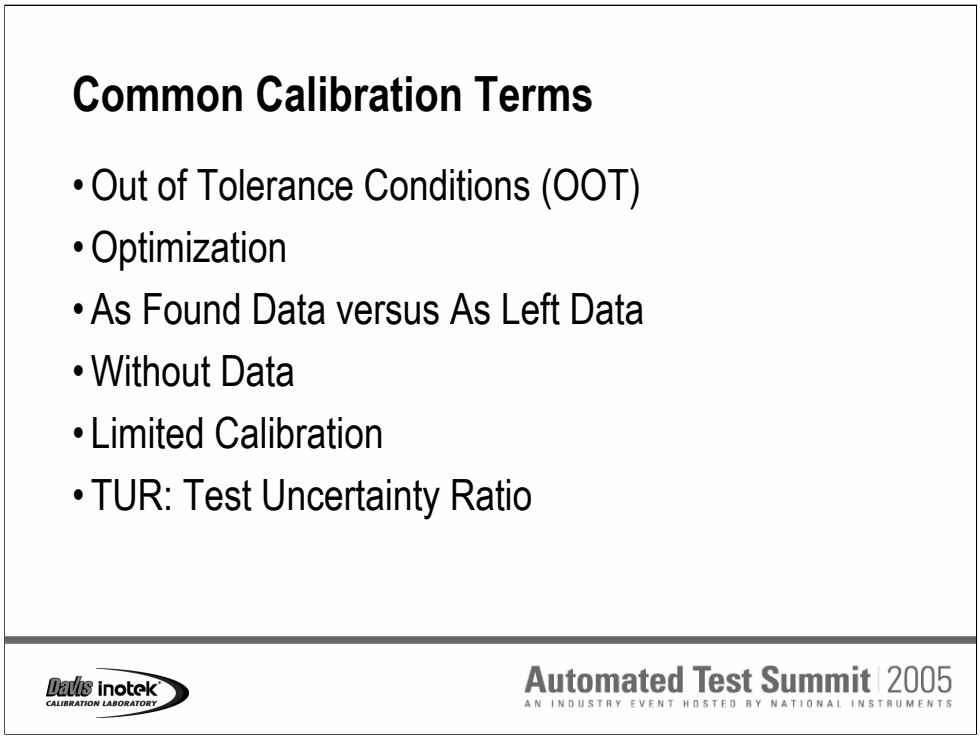
Some people consider calibration a necessary evil, or in some case just a sticker and piece of paper to satisfy an auditor. In fact, Out of tolerance (OOT) instruments may give false information leading to unreliable product, customer dissatisfaction and increased warranty costs. In addition, OOT conditions may cause good products to fail tests, which ultimately results in unnecessary rework costs and production delays.



Out of Tolerance Conditions—If the results are outside of the instrument's performance specifications it is considered an OOT (Out of Tolerance) condition and will result in the need to adjust the instrument back into specification.

Optimization—Adjusting a measuring instrument to make it more accurate is NOT part of a typical calibration and is frequently referred to as *optimizing* or *nominalizing* an instrument (this is a common misconception). Only reputable and experienced calibration providers should be trusted to make adjustments on critical test equipment.

As Found Data—The reading of the instrument before it is adjusted.

As Left Data—The reading of the instrument after adjustment or *Same As Found* if no adjustment was made.

Without Data—Most calibration labs charge more to provide the certificate with data and will offer a *no-data* option. In any case *as-found* data must be provided for any OOT condition.

Limited Calibration—Sometimes certain functions of an instrument may not be needed by the user. It may be more cost effective to have a limited calibration performed (This can even include a reduced accuracy calibration).

TUR: Test Uncertainty Ratio—The ratio of the accuracy of the instrument under test compared to the accuracy of the reference standard.

What is Required for ISO 9000?

Any ISO Calibration Must Have:

- An Accredited Calibration Lab Performing the Work
- Documented Calibration Procedures
- Trained Technicians
- Traceable Assets
- Proper Documentation


EAGLE Registrations Inc

Certificate No. 3048 (Revised 03/22/2004 - 5 Copies)
10/8/2003 through 10/8/2006

Certificate of Registration

This is to certify that the Quality Management System of

Davis Inotek Instruments

4701 Mount Hope Drive, Baltimore, Maryland 21215 USA
4400-O Stuart Andrew Blvd., Charlotte, North Carolina 28217 USA
11212 Indian Trail, Dallas, Texas 75229 USA
5730 Ayala Avenue, Irwindale CA 91706 USA

Has been assessed by EAGLE Registrations Inc. and conforms with the following standard:

ISO 9001:2000
Exclusion: 7.3 Design and Development

Scope of Registration

Calibration and Repair of Inspection, Measuring and Test Equipment

Registration Manager

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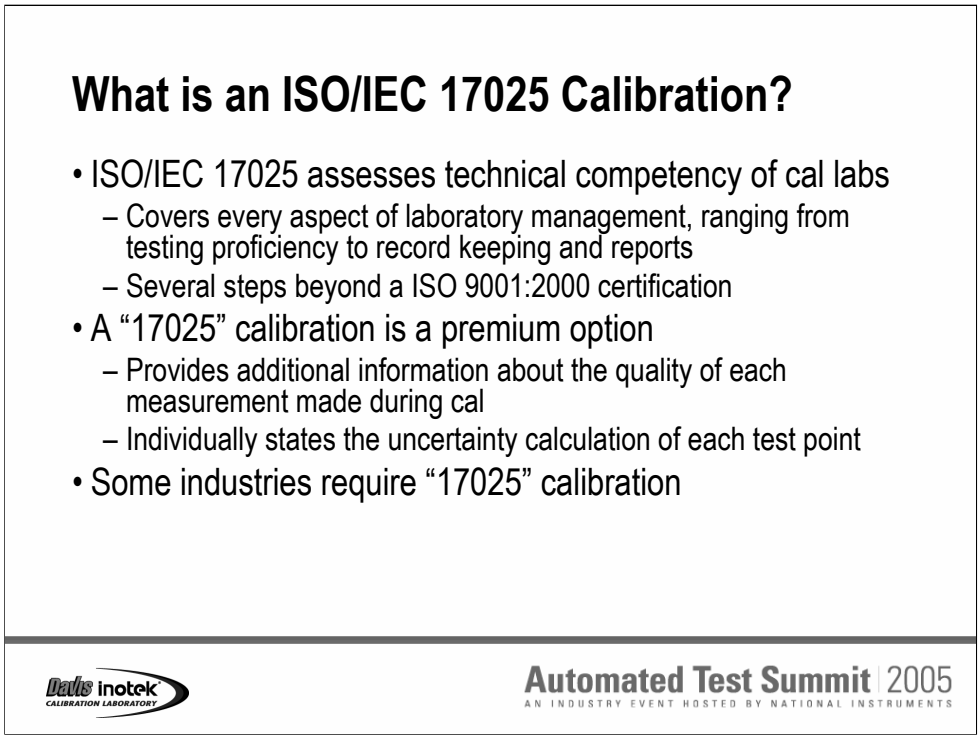
An Accredited Calibration Lab Performing the Work—The calibration laboratory employed to perform the calibration must be an ISO 9001:2000 accredited lab or be the original equipment manufacture.

Documented Calibration Procedures—It is critical that a valid calibration procedure be used based on the manufacturer's recommendations and covering all aspects of the instrument under test.

Trained Technicians—Proper training must be documented for each discipline involved in performing the calibration.

Traceable Assets—The calibration provider must be able to demonstrate an unbroken chain of traceability back to NIST.

Proper Documentation—All critical aspects of the calibration must be properly documented for the certificate to be recognized by an ISO auditor.



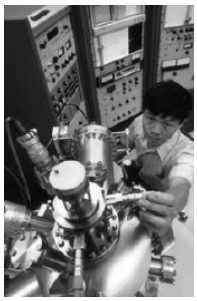
ISO/IEC 17025 is an international standard that assesses the technical competency of calibration laboratories. ISO/IEC 17025 covers every aspect of laboratory management, ranging from testing proficiency to record keeping and reports. It goes several steps beyond a ISO 9001:2000 certification.

A 17025 calibration is a premium option that provides additional information about the quality of each measurement made during the calibration process by individually stating the uncertainty calculation of each test point.

As a general rule 17025 calibrations are required by anyone supplying the automotive industry and it has also been voluntarily adapted by numerous companies in FDA regulated industries.

How are Calibration Intervals Determined?

- Intervals should be determined by the owner based on manufacturer recommendations
- Commercial calibration laboratories can suggest intervals but are not familiar with the application
- OEM intervals are typically based on parameters like mean drift rates for components within the instrument
- Other factors should be taken into consideration:
  - Required accuracy versus the instrument's accuracy
  - Impact an OOT will have on the process
  - Performance history of the instrument in your application



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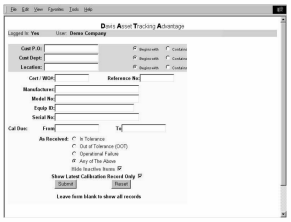
Calibration intervals are to be determined by the instrument owner based on manufacturer recommendations. Commercial calibration laboratories can suggest intervals but in most cases they are not familiar with the details of the instrument's application.

The OEM intervals are typically based on parameters like mean drift rates for the various components within the instrument. However, when determining calibration intervals as an instrument owner several other factors should be taken into consideration such as: the required accuracy versus the instrument's accuracy, the impact an OOT will have on the process, and the performance history of the particular instrument in your application.

Six Tips to Improve a Calibration Process

1. Make an accurate recall list of your equipment
   - Use unique identifiers
   - Asset management software
   - Bar-coding systems
   - Physical inventories
2. Include often forgotten items
   - Modules/Plug-ins
   - Small handheld tools
   - "Homemade" measuring devices (for example, Test Fixtures)
3. Identify which instruments may *not* require calibration



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Any successful calibration program must begin with an accurate recall list of your test, measurement and diagnostic equipment. The list should contain a unique identifier which can be used to track the instrument, the location, and the instrument's custodian (Often asset management software, bar-coding systems, and physical inventories are used to help establish accurate recall lists).

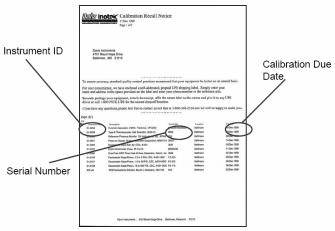
It is important when assembling a recall list that modules, plug-ins, and small handheld tools are not overlooked. Also, you may have several "home-made" measuring devices (for example, Test Fixtures) which will also need to be captured on your equipment list for a reliable calibration program.

The next step is to identify all of the instruments on your recall list which may not require calibration due to redundancies in your testing process. A commercial calibration laboratory should be able to aid you in identifying these instruments.

Six Tips to Improve a Calibration Process

4. Create procedures for changes
   - Adding new instruments
   - Removing old (or disposed) instrumer
   - Changes in instrument custodianship
5. Run recall reports ahead of deadlines
   - Ensures unit calibrated with minimal impact on production
6. Send a late report for 100% conformity

   Full service cal labs will supply recall reports and special escalation reporting when equipment is not returned



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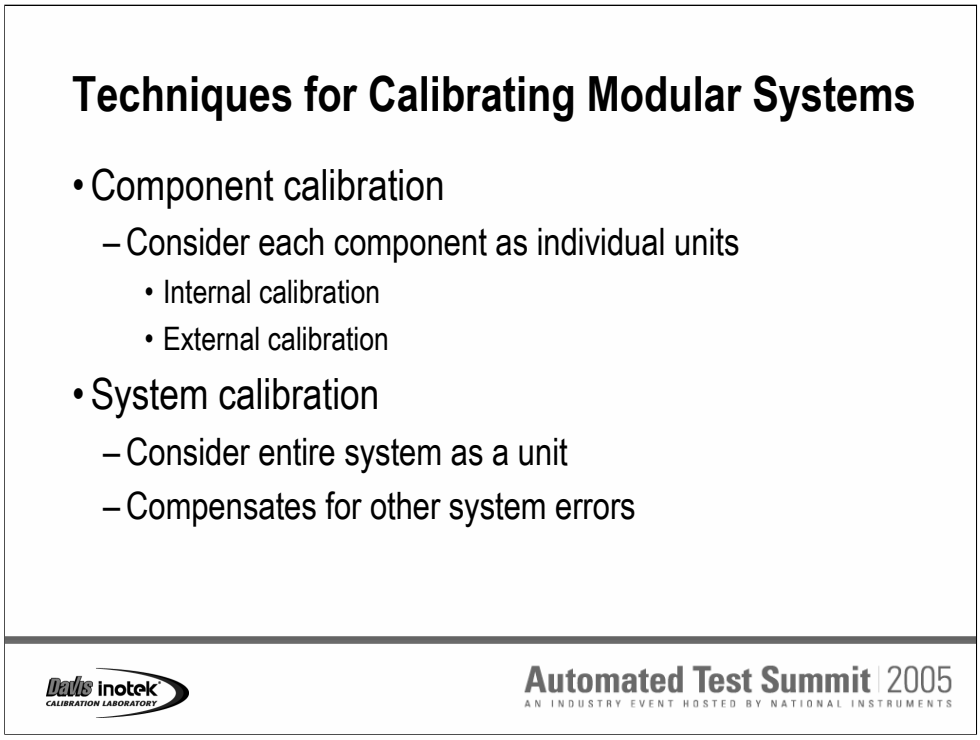
After creating an accurate recall list procedures must be established for adding new instruments, removing old or disposed instruments, or making changes in instrument custodianship. Recall reports should be run with sufficient time for both the end user and the service provider to have the unit calibrated with a minimal impact on production.

A late report identifying any units about to expire or already expired will ensure 100% conformity. A full service calibration laboratory will supply these recall reports and will provide special escalation reporting when equipment is not returned for service.

Some calibration houses offer the choice of web-based equipment management systems that allow their customer to perform recall reports, late reports and keep electronic versions of their calibration certificates.



There are different levels of calibration

Component Calibration—consider each device as a separate unit

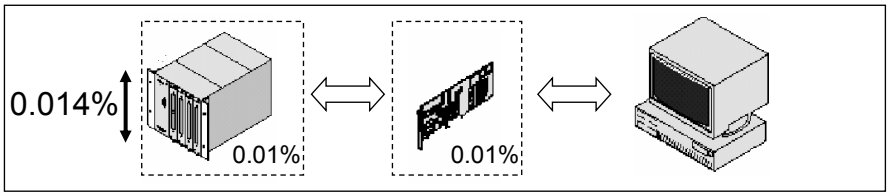
Common examples of component calibration are internal calibration and external calibration (we will discuss soon)

System Calibration—consider the entire system as a unit

With this, you can compensate for other system errors (cables, sensor, differences in each unit of a multi-device system)

We will discuss this soon also.

External Component Calibration



- Calibration of individual system components
- Determines each component's uncertainty
- With calibrated components, you can:
  - Calculate system's absolute accuracy = $\sqrt{a^2 + b^2}$
  - Replace devices
  - Change computers/chassis without affecting calibration

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Component Calibration

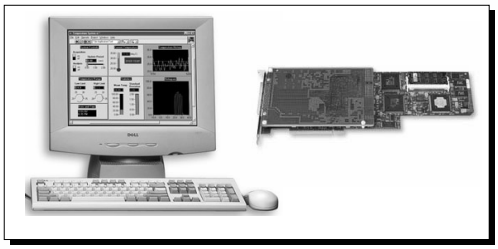
- Calibrate each component separately
- Determine the uncertainty of each component
- Use the "Calculating System Accuracy" equation to determine overall accuracy

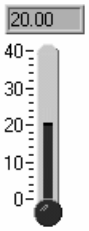
Note: Your system may only have one component

When each component is calibrated, you are now free to:

- Swap in and out any calibrated components without changing your system accuracy
- Move your system to other environments without changing your system accuracy

Internal (Self) Calibration





- Adjusts the instrument to your environment
  - Change in temperature
- Maintains uncertainty defined by external calibration
- Requires an onboard reference source and temperature sensor

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You must always adjust your instrument to changes in the environment

Examples include:

- Change in temperature
- Changing computers (really just another change in temperature)

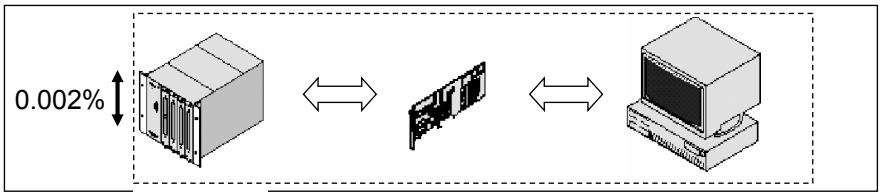
You compensate for these changes with an Internal Calibration

- Adjusts your measurement circuitry
- Maintains the uncertainty specification of your instrument
- Requires an onboard reference source where you know how temperature affects the source's value. Also requires a temperature sensor so you know the temperature in your environment.

Note: This is required for traditional instruments (like scopes) and our instruments. In other words, it is not something special we have to do because we are computer-based. Every instruments has to do it.

- Our instruments do this—we call it self-calibration

System Calibration



- Referred to as “end-to-end” calibration
- Reduces system measurement uncertainty
  - Cables, software, sensor
- Apply adjustments in software
- Cannot change system components

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To recap, we have covered

- Internal calibration – compensates for changes in temperature
- External calibration – compensates for changes in time.
- These are both types of component calibration

Now we will cover System Calibration.

System calibration considers the entire system as a single unit

- Also called an end-to-end calibration
- Quantifies all of the measurement errors in your system, and compensates for them in software
- Therefore, it reduces the overall measurement uncertainty
- Does not replace Component Calibration, but compliments it
- You can no longer replace components without performing another system calibration

Common Questions—How often do I need to perform a system calibration (how long does it last)?

The same factors apply as component calibration—temperature (environment) and time (component drift). It basically comes down to how important it is to you. Typical response is six months to a year.

How Do I Get Equipment Calibrated Without Shutting Down The Line?

- Onsite calibrations (>20 calibrations)
  - Saves time and lowers cost
  - Requires a calibration provider with sufficient capabilities to calibrate nearly all of your equipment in one visit
- Other options for reducing downtime
  - Mobile calibration lab services
  - Calibrations during shutdowns
  - Scheduled pick-up and delivery
  - Weekend or nightshift calibrations

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Look for a calibration service provider that can perform onsite (or in-place) calibrations at your facility. Often when your volume is more than 20 calibrations, scheduling onsite calibration saves time and lowers cost. Make sure you find a “one-source” calibration provider that has sufficient capabilities to calibrate nearly all of your equipment during the onsite, reducing the delays and the expense of using an additional subcontractor.

Other options for reducing downtime include mobile Calibration lab services, scheduled depot calibrations, calibrations during shutdowns, scheduled pick-up and delivery, and weekend or nightshift calibrations.

What About Performing Calibrations Internally?

- With the right expertise and staffing, it is possible
- Keep in mind the following:
  - Cost of standards = expensive assets
  - Requires developing procedures
  - Cost of management
  - Calibration is often not a core competency
- Consider permanent calibration lab staff at your facility

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Cost of standards—Often, the cost of the assets with the required accuracy to perform the calibration is prohibitive. It could take years of calibrations to pay for one standard.

Developing Procedures—Many manufacturer's procedures are not readily available. Sometimes they require research and development. This can cost hundreds of hours of labor.

Productivity of Technicians—Often a non-commercial calibration laboratory's productivity per employee is only a fraction of what can be obtained through an external commercial calibration laboratory who specializes in automation, efficient procedures and experienced management.

Cost of Management—Managing the employees, assets, maintenance and processes of a calibration lab can be burdensome on existing management staff.

Not a core competency—The overall management burden of the operation distracts from the core competency of the company

Commercial calibration companies can offer solutions to maintain permanent staff at your facility.