

ISO/QS CALIBRATION, TERMINOLOGY AND COMPARISONS

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[home](#)

ABSTRACT: The objective of this paper is to answer questions on ISO/QS calibration, costs and options from the viewpoint of a service provider. Also to provide comparisons on inside versus outside calibration and interpretations from experience of providing electronic calibration services. How to better interface with the service to optimize and increase the value added.

The hopeful result of this paper is to increase the awareness for the need of calibration, how to use the results and what to request. In so doing the customer should realize what should be calibrated as a result of the requirements, and be able to clarify this during an audit. A copy of ISO/IEC 17025 is referenced often, since it is an industry standard for calibration service providers.

I. INTRODUCTION

The principal goal of this paper is to improve the ability of calibration labs and their customers to communicate in like terms and priority. Experience has proven that the simplest misunderstanding can cause dissatisfaction on both sides. Included are topics and terms with explanations. The various example forms provided will improve the understanding and give a tangible to reference in the future.

A limited cost table will allow a customer to decide when inside calibration may be a benefit.

II. WHAT IS CALIBRATION AND WHY CALIBRATE

Calibration is the testing and adjustment (if needed) of the measuring equipment used in a test or measurement process. Measuring instruments are the “heartbeat” of your process since they check and measure your production process. They control the quality of your products and are responsible for the success and profitability of your business.

A regular cycle of checks with traceable calibration equipment is essential. Calibration ensures that your quality and the customer’s expectations always match. Calibration is required by any reputable Quality Management System (QMS).

Calibration maintains the next four points

- Consistent quality of your product or process
- Enhanced reliability lowers operating cost
- Access to international markets through international QMS.
- Address quality audit and reviews

After passing the calibration process the unit should have a sticker stating the date calibrated and the next calibration due date, the calibration technicians name or initials and a unique identifier (serial number). Also included, would be a certificate with your company address, a description and unique identifier for the unit calibrated, calibration dates of all equipment and standards listed.

Calibration shows that you have a proactive interest to control your process.

III. WHAT TO CALIBRATE

Most companies choose to calibrate their production final test equipment. This assures that within-tolerance product is supplied to their customers. The customer may realize, after the fact that the line may produce out of tolerance product (scrap). The next step to control the process is to add and calibrate equipment *during* production (“online” or “on the line” testers), therefore identifying scrap earlier and immediately eliminating it’s cause. This choice involves the greatest number of pieces and usually the highest cost.

An internal sample test lab that tests your process randomly will likely be the least expensive area to calibrate. It has less equipment and the calibration team won’t disrupt production as much.

At the customer’s request, the independent lab may calibrate the maintenance department’s equipment that is used to set up and calibrate the process, instead of the online or final testers

IV. WHAT TO LOOK FOR IN A CALIBRATION SERVICE PROVIDER

The scope of the Calibration Laboratory should indicate its integrity. The scope and corresponding uncertainties will define the Labs capabilities. This reflection, when considered by the customers Quality and Engineering staff will determine if the individual Laboratory can do the job expected by the customer and is traceable to the required national standards.

Your engineering staff may have supplied a “process accuracy requirements” sheet, if so, then you may be able to do the comparison yourself. This sheet is a resource during an audit, calibration failures or other crises that may arise. See “Table 2” for an example of this

sheet on one simple product/ line.

Some customers want single supplier calibration labs. This may mean an electronics calibration lab that also does mechanical calibration or vice versa. A singularly focused calibration lab, will generally do one field very well ie. electronics, mechanical or chemical.

Electronics encompasses

- Volts, amps, watts, temperature, resistance, capacitance, inductance etc

Mechanical encompasses

- Indicators, gauge blocks, comparators, micrometers, pin & thread gauges, thickness etc.

Of course an important criterion is; do they pass audits your customers and auditors give you? Are you satisfied with the service provided and is it useful?

A. A certified calibration lab or an uncertified calibration lab?

A lab certified to a national or international standard, with a valid registration through an approved registrar will greatly simplify an on-site audit. The valid registration indicates approved methods and observed standards are in place. A certified lab may be compared to the ISO/IEC 17025 requirements. The criteria for 17025 may be considered as the first step. Other items such as uncertainties, inter-lab comparisons are being included in the subject of competency.

An uncertified lab may be used, but your work is increased. You must certify them yourself via audits (usually at their facility) with documentation. ISO/IEC 17025 will give you guidance on the requirements the lab must meet.

B. Other indicators and considerations

Lab size may be a factor if limitations exist in trained personnel, turn around time (expedites) or large quantity on-sites.

Medium to large labs (3 to 12 technicians) have multiple trained personnel and more equipment to rely on. Any doubts that may arise due questionable performance may be rechecked with spares.

Often, an automatic computer program is used to insure required fields are complete, such as standards and their due dates are current, tracing of data and personnel. This type of program decreases human error and increases overall quality. A reverse trace program recalls any equipment the calibration lab suspects has doubtful performance, due to a questionable standard. A program like this insures every piece effected by the standard in question, is returned to the lab for re-evaluation.

Independent Calibration Labs versus Internal “Do it yourself” calibration.

The cost of an independent lab may drive the customer to consider internal calibration. Internal lab certification is more stringent than independent lab due to the possibility of conflict of interest.

The cost figures provided may let you realize the value that an independent calibration lab provides.

As table 1 shows, if your yearly calibration costs less than \$25,000, service by an independent calibration lab is a bargain. One technician, one limited multicalibrator costs \$60,000 the first year and at least \$35,000 per year after.

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V. REQUESTS AND INTERFACING WITH A CALIBRATION LAB

A request for quotation should include the same language as the resultant purchase order [PO] to follow. A PO may have two conditions; see table 3; on-site or in-house (at the lab address). A request for service for an on-site calibration; secondly, sending the unit under test [UUT] to our facility.

An on-site request should contain a list or reference a list of equipment with the following; manufacturer, model, quantity of like items and serial number is very helpful.

VI. COMMON TERMS**A. CYCLE, INTERVAL**

Cycle pertains to time elapsed between calibrations. Calibration cycle often is defined in the original equipment manufacturer [OEM] manual at one year, maybe less if specified. If a cycle isn't defined, a one-year cycle is the average on equipment you frequently use and has proven reliability. Unproved equipment should have a calibration cycle less than the amount of time it may drift out of its tolerance or effect your process.

Some conditions such as humidity or industrial contaminants may adversely effect your equipment and cause a shorter cycle.

B. ON-SITE [O/S]

This describes calibration performed at your facility “ON-SITE”. This benefits your production scheme with fewer interruptions to your process. Furthermore there is no need for spares to replace equipment being calibrated; or call your provider for status and return dates for

your equipment, shipping costs etc. All of your equipment calibrations are done at once, and technicians are there to answer your questions that may arise.

C. ISO/IEC 17025 or [17025]

This standard is the latest and best guide that you can use to grade your existing lab or find a new one. It is the standard to compare any lab certified to it and many of those seeking good lab practices use it. Any departure from it may be a result in interpretation or an inapplicable section.

A copy of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" standard is a helpful reference.

D. DATA, Before and after data,

This is the actual numerical test result documented during calibration. This data is required if the Unit is found out of tolerance and useful to judge if the error effects your process.

E. DATA IF OUT

This is a term worth remembering. Some customers have their Quality Manual written to require data on all calibration activities. Each data sheet costs you. Experience has shown us that approximately 5% of the items we calibrate for a customer may be out of tolerance. Out of tolerance tested units are the items you MUST get data on and calculate the ramifications or effect on your process. Your "process accuracy specification sheet" would prove useful for this comparison. A 17025 lab is required to take and keep data EVEN if you don't request it.

F. TOLERANCES or SPECIFICATIONS

These are the values that the unit is tested and compared to. Normally OEM specifications are used unless otherwise requested. Other options include customer specified tolerances (preferred if no OEM specs are available).

G. HISTORY, HOW DOES IT HELP?

Occasionally an audit might discover a piece of equipment used in production that isn't certified or was overlooked in the equipment calibration schedule. If you or production can show that no deviation occurred from recent or past data, then "history" can be used to downgrade the impact. The equipment can then be calibrated with data, thereby diminishing the negative impact.

A point to note, if all of your production test equipment passed the annual calibration visit, then it indicates that your past years product is good. In the same logic, if 5% of that equipment failed, it may have adversely effected your product. When did the test equipment fail? Maybe it failed one month or ten months ago? Equipment can fail 5 minutes after a calibration, the risk of this must be accounted for and in some cases dealt with by "Gold standards" or less time between calibrations.

I. CERTIFICATION or CERT

This should come with every calibrated piece of equipment, usually at no extra charge if the data is not included. If data is required, then a charge for the extra time or data sheet usually is added. Note if you need data, request it with "Data before and after" in the language of your request. See the example provided. ISO/IEC 17025 has the criteria the certification must meet.

J. LIMITED CALIBRATION

Limited calibration is a passed calibration condition with specified limited performance. The customer equipment may have a function that is inoperable or out of specification (and not repaired). This condition may be tolerable for the customer, because the function isn't used. For example the AC volt section of a multimeter might be inoperable but the customer only uses the meter to test DC volts. This condition should be specified on the sticker and certification as "Limited cal, NO AC volts" etc.

K. GOLD STANDARD

A Gold Standard may be any controlled specimen that has been tested and has a known value. This value is often from your calibration provider or other traceable equipment. The gold standard may be used at the start of every day or shift to insure your test equipment is functioning within tolerance.

VII. RELATIONSHIPS OF RECENT GUIDES/STANDARDS REFERENCED ENTITIES

A. Guide 25 was the guideline for calibration and test (medical) labs (expires December 2002). Some calibration & test labs used ISO 9000 and Guide 25. The 17025 standard will replace this guide and standard combination.

B. ISO 17025 is the applicable standard for test and calibration laboratories. The ISO/IEC committees took the applicable sections of ISO 9002 and guide 25 and improved them. This does imply that any 17025 certified lab meets an ISO 9001/2000 (and 1994 edition) customers needs.

C. ISO-9001 & 2 (1994) standards tentatively expire December 2002, **ISO 9002** was written for companies that manufactured but didn't conduct design activities. As of this writing, 90 to 95% of manufacturers have chosen to maintain the 1994 edition. They believe ISO 9001/2000 is the same as the 1994 edition but with number and organization changes.

D. ISO 9000 was a guideline for when to apply 9001,9002 or 9003.

E. ISO 9001/2000 is the latest release of the standard and is intended to be a generic standard for manufacturing and service business. The new standard is a complete rewrite and contains substantial philosophical and upgraded requirements. It is considered to be more than a basic QMS standard and allows the organization to establish a quality management system appropriate for the business conducted. This standard applies to all organizations and becomes, as scheduled, the only QMS standard in December 2003.

F. ISO 9004/2000 this is a guideline for use and implementation of ISO 9001/2000

G. QS-9001 system was the standard developed by the auto industry (AIAG) which was intended for their tier 1 suppliers. They developed QS 9000 as a supplier quality standard for their supplier base. QS impacted calibration labs supplying to the auto industry in that it required (as interpreted) them to be certified by a single registrar, A2LA. Due to resistance from the calibration industry and "restraint of trade" issues the IAIG released an interpretation which allowed other suppliers and methods of approval. One method added was a tier one supplier could audit (under special conditions) and approve a lab for its own use.

H. A2LA "American Association for Laboratory Accreditation" is a company that provides the service of registration to ISO and QMS.

I. LAB "Laboratory Accreditation Bureau" is a company that provides the service of registration to ISO and QMS.

VIII. ISO/QS PROCEDURES FOR CALIBRATION

These are defined by the customer's QA manual, which should be written to a national standard, previously listed. Experience has shown that industry normally specifies the OEM calibration procedure. OEM calibration procedures are usually in the manual provided for the UUT. (OEM manuals stored in a single or controlled location benefit all parties.)

The second best method would be, a customer written calibration procedure. This may be the case if the unit is custom built, and could still be considered an OEM procedure.

Procedures may be written by the customer to test only the functions of a UUT they use, or "Limited Calibration".

Some equipment calibration procedures do not exist due to age or other reasons. This problem may be solved if the calibration provider writes a procedure or applies a "generic procedure". A generic procedure is used if the UUT can be classed with similar equipment.

X. CONCLUSIONS

This information should save you money through the knowledge of what and how to ask for your calibration. A greater understanding of what to expect from calibration and how to use it, in some situations results or information that could save an audit and customers.

Many points and observations discussed may have been already realized however useful new information hopefully will improve your calibration service in the future. The resources and answers are available. I would encourage you to ask your service provider any and all questions you may have. We as service providers always strive for satisfied customers that will return year after year. This paper with updates may be downloaded at our home page "<http://www.CLC2@aol.com>".

REFERENCES

[1] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*.

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Table 1.

<u>Table of minimum expected costs for internal calibration</u>					
<u>Year</u>	<u>one</u>	<u>two</u>	<u>three</u>	<u>four</u>	<u>five</u>
- Calibration tech \$	\$35,000	\$35,000	\$35,000	\$35,000	\$35,000
- Multi-calibrator \$	\$25,000				***
- Yearly calibration \$	\$0	\$1400	\$1400	\$1400	\$1400
- Repairs	\$3700		\$3700		
- Totals	\$63,700	\$36,400	\$40,100	\$36,400	\$40,100

- This table is very conservative and does not include raises or the expected double salary figure for the technician.

- *** This equipment is at the end of its expected life and may need replaced for reliability. The multi-calibrator has the most capabilities for the dollars spent, it is limited in its abilities.

End of table 1

Table 2.

Your address "XYZ Company Your full address" X		PO # X		
Your phone number X		Date X	Date required X	
		FOB		
		Ship via X		
		Terms X		
TO (The full address to where item shall be shipped to) X		SHIP TO ON RETURN "XYZ Company and your street address" X		
QUANTITY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL PRICE
X	X	X Example of units sent out for calibration; STATE THE SERVICE YOU REQUIRE: ("Calibration to OEM Specifications with data, if repair required please QUOTE BEFORE REPAIR"). LIST THE ITEM/S SENT; (Manufacturer, Model, Serial Number & Accessories included.)	XX	X
		Example of an On-Site request to calibrate: "Calibrate to OEM specifications at (your address) Quantity/description of pieces or refer to "see attached list" Note that over-night and travel expenses may effect your estimate."		

We have seen PO's 5 pages long due to rhetoric the customer believes is ISO required. The example above tells the lab what to do, what the item is and how to do it, by the words "OEM or Custom" if they provided it. An "X" indicates a field you should fill out.

End of table 2.

Table 3.

Your address "XYZ Company Your full address" X		PO # X		
		Date X	Date required X	FOB
Your phone number X		Ship via X		
		Terms X		
TO (The full address to where item shall be shipped to) X		SHIP TO ON RETURN "XYZ Company and your street address" X		
QUANTITY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL PRICE
X	X	X (Example of units sent out for calibration;) STATE THE SERVICE YOU REQUIRE: "Calibration to OEM Specifications with data, if repair required please QUOTE BEFORE REPAIR". LIST THE ITEM/S SENT; Manufacturer, Model, Serial Number & Accessories included.	XX	X
		(Example of an On-Site request to calibrate:) "Calibrate to OEM specifications at (your address) Quantity/description of pieces or refer to "see attached list" Note that over-night and travel expenses may effect your estimate."		

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