Topics in Metrology

> *I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science, whatever the matter may be.*
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> *Lord Kelvin (William Thomson) London 1883.*

Measurement is where theory and practice meet. Science, engineering, industry and economics would have little use for mathematics or arithmetic were it not for measurement. Measurement provides a major component of the interface between theoretical and practical worlds.

This site discusses potentially controversial issues in fundamental aspects of metrology and associated fields. Most of the topics stem from our experience with calibration and testing labs and their customers.

We welcome discussion and comment related to these articles. If you disagree with anything or would like to suggest corrections, additions or a new topic, or write a short article for this site, please contact us.

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1 Why calibrate? Why do we need ISO 17025?

Question: *How do we know when we can believe a measurement?*

Short answer: *We can never have 100% confidence in a measurement.*

Longer answer:

- No measurement is ever correct. The true value is never known. There is always an unknown, non-zero difference between a measured value and the corresponding true value.
- Most instruments have specified or implied tolerance limits within which the true value of the measurand should lie if the instrument is functioning correctly
- One can never be 100% sure that an instrument is operating within its specified tolerance limits.

BUT …

- There are steps we can take to minimise and quantify the probability of a measurement falling outside specified tolerance or uncertainty bands.

Regular *traceable calibration* is a method for gaining quantifiable confidence in a measurement system. In this topic we discuss some fundamental aspects of calibration, why it is necessary at all, and why it is so important that a special standard is required to govern the calibration process.

1.1 Example

Consider the measurement of the gauge pressure of air in a ventilation duct. In this hypothetical example we happen to know in advance that the pressure is typically a constant 4 kPa and should be in the range 2–4.5 kPa. To prevent irreversible damage to the duct the manufacturer specifies pressure may not exceed 5 kPa. In this example we use two different instruments for the measurement—a water-filled U-tube and an electronic manometer with digital display.

1. **Water-filled U-tube manometer.** We half-fill a clean glass U-tube with distilled water, mount it vertically, check that the columns are equal height, and connect one end to the duct, leaving the other end open to atmosphere. All our connecting tubes are transparent and the U-tube is marked in millimetres. The pressure in the duct moves the water in the U-tube and we measure h, the difference in the heights of the columns, with a resolution of approximately 0.5 mm. We can check for factors which we know might affect the measurement, such as leaks, blockages, air bubbles and air flow across the open end of the tube. We can also check the millimetre markings against a metre rule or vernier and measure the water temperature for density calculation. The result of the measurement is a pressure in mm of water

(503 mm in this case) which we convert to kPa, using the equation $p = \rho g h$ where ρ is the density of water ($\rho = 997.77$ kg·m^{-2} at 22°C[1]) and $g = 9.81$ m·s^{-2} is the acceleration due to gravity. Our calculated gauge pressure is $p = 4.92$ kPa. Because we understand the physics of the water manometer well and took care to set it up correctly, without doing any formal uncertainty analysis we intuitively believe that the true pressure is likely to be within about 1 mm of water or approximately 0.01 kPa of our measurement. Therefore we feel confident that the pressure does not exceed the safe upper limit for the duct.

2. **Electronic manometer.** This manometer has a pneumatic connection to an internal temperature-compensated piezoresistive strain gauge pressure transducer, and a digital display in kPa with a resolution of 0.01 kPa. We connect the electronic manometer to the duct, wait for the display to settle and read a pressure of 4.95 kPa from the digital display. The 'accuracy' of the manometer is specified by the manufacturer as ±0.5% of reading ±1 digit, therefore, if we believe the instrument, we have no option but to assume that the true pressure is within approximately 0.04 kPa of our reading, i.e., between 4.91 and 4.99 kPa. How confident can we be that the true pressure is below 5 kPa?

1.2 Comment

The U-tube manometer uses fundamental physical principles in its operation. Unless there is an unseen fault (such as a transparent blockage) the only mechanism that can hold the two menisci at different levels is a pressure difference. There are a limited number of modes of failure, and an experienced technician who understands a little of the physics of fluids can easily verify the absence of faults with a high level of confidence and gain an intuitive, qualitative feel for the uncertainty in the measurement. Instruments such as the fluid manometer based on fundamental principles can be used by experienced technicians with confidence in many applications without reference to a second instrument or standard. The trend, however, is away from this type of instrument which is cumbersome and usually requires a skilled operator, towards instruments that are more compact, portable and simple to operate.

If we require greater confidence in the U-tube measurement and the associated uncertainty, or an uncertainty substantially lower than (0.01 kPa), then it is possible to analyse and in some cases correct quantitatively the potential systematic errors that might be caused by surface tension effects at the menisci, the angle of the U-tube, the millimetre markings on the glass of the tube, parallax errors, variations in the local value of g, etc.

The electronic manometer indicates a pressure that might be very close to the safe upper limit. This example forces us to think about the confidence we have in our manometer and in its specified tolerance bands. At what level of confidence can we say that the pressure does not exceed the safe upper limit? The number of

modes in which the pressure transducer, the electronic circuitry and the digital display can fail or malfunction is large. Most of the faults and malfunctions would not be visible to an operator therefore it is impossible to verify the absence of faults and electronic drift by simple inspection. We cannot tell by inspection if the instrument has recently been dropped, subjected to an over-range pressure or otherwise mistreated. When we make a measurement in the field we are forced to trust the instrument. The only way we can gain confidence in the electronic manometer is by regularly comparing its response with another similar or preferably superior instrument in which we have high confidence. A quantitative evaluation of the performance of an instrument is called *calibration* or *verification*.

1.3 Calibration

To calibrate our electronic manometer, we could borrow, purchase or hire a similar or superior manometer and a pressure source, and perform a comparison of the two manometers over the pressure range of interest. Our recent experience in measuring a pressure that appears to be very close to a safety limit motivates us to attempt to estimate at each calibration point the range within which the true pressure is likely to lie (the *uncertainty* of the reference), and the uncertainty of the calibration, which includes the repeatability and other imperfections in our manometer. In this case, quantitative analysis of the uncertainty associated with the reference pressure, however, is immediately frustrated by our lack of confidence in the manometer we are using as a reference, and the unknown uncertainty associated with that instrument. If we attempt a more complete uncertainty analysis we may come across other factors that are not controlled or monitored during the comparison, e.g. fluctuations in the source pressure, environmental temperature, humidity and barometric pressure. If we are honest with ourselves we soon appreciate that to truly gain confidence in our electronic manometer we require at least the following conditions:

1. a high level of confidence in the manometer we use as reference:
2. the conditions under which the comparisons are performed should be well controlled and monitored,
3. the technician doing the comparison should have the technical competence and experience to enable him/her to identify and control external factors that might affect the comparisons.

1.4 Obtaining a calibration in which we have confidence

To calibrate our manometer in a manner that fulfils our requirements as enumerated above we have two options.

1. Perform the calibration ourselves. In this way we have full control over all the technical and quality aspects of the calibration process.
2. Request an independent laboratory to perform the calibration but audit that laboratory thoroughly to ensure that they have reference instruments in which we have confidence, a controlled environment in which to perform the

calibration, competent technicians who understand our requirements well, and procedures for producing error-free calibration reports.

Both options are feasible under limited circumstances. Maintaining our own dedicated calibration lab, however, is time-consuming and costly. We also soon discover that if we calibrate our instruments ourselves that our customers start auditing us to verify that we are competent, doing the job properly and keeping proper records etc. We are likely to find that managing audits of our labs and regularly auditing other laboratories we use is time consuming and costly.

After a little honest thought we come to the conclusion that we (and probably many other organisations that regularly make measurements in which a high level of confidence is required) would benefit from a national or international system that would give us confidence in calibration laboratory services. A system that provides confidence intervals around our critical measurements would be extremely valuable.

1.5 ISO 17025 *General requirements for the competence of testing and calibration laboratories*

ISO 17025[2] is an international standard governing most of the important aspects of calibration processes. Laboratories meeting this standard should operate a quality control system, be technically competent and be capable of producing technically valid results. The intention of ISO 17025 is to provide a functional system or hierarchy of calibration laboratories in which we can have confidence. Any calibration performed by a lab accredited to ISO 17025 should:

- be performed by competent technicians in a controlled environment
- use reference instruments or materials in which we can have confidence
- operate a quality system similar to ISO 9001.

ISO 17025 maximises confidence in reference instruments and materials by requiring that they are traceable to the International System of Units (SI units).[3] SI units are defined by an international agreement overseen by the General Conference on Weights and Measures (CGPM) which is headquartered at the International Bureau of Weights and Measures (BIPM) in Paris.[4]

The International Laboratory Accreditation Cooperation (ILAC) considers accredited technical competence to be an essential component of metrological traceability to the SI.[5]

Mutual recognition agreements (MRAs) between accrediting authorities in different countries extend the framework of trusted laboratories world-wide. In the case of the kilogram, the framework is pyramid-shaped with the BIPM at the apex. The international prototype of the kilogram, an artefact made of a platinum-iridium alloy, is kept at the BIPM under carefully controlled conditions. All important mass measurements should be metrologically traceable[5] to this artefact. The six other Si units are defined in terms of physical constants such as the speed

of light, and physical properties of selected materials, and can be realised in any good metrology lab. The CGPM plans a revision of the definitions of the SI units towards the end of 2018, in which the kilogram, the ampere, the kelvin and the mole will be defined in terms of physical constants.[6]

Traceability to SI units ensures that measurements made in Sydney, Australia can be compared with similar, traceable measurements made in many other countries. For example, if the ventilation duct in the example described above is made in Holland, we can have confidence that the Dutch kPa is the same as the Australian kPa.

1.5.1 Calibration definition

Calibration is defined as:[7]

> *[an] operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.*

Calibration may or may not involve adjustment of the instrument or device under test (DUT) to minimise differences between reference and indicated values.

The calibration process should provide a certificate that includes:

- clear identification of reference instruments and the DUT,
- a table of reference values and corresponding values indicated by the DUT, both before and after adjustment if the DUT was adjusted,
- the corrections that should be applied to values indicated by the DUT at each calibration point
- uncertainty estimates associated with each correction, and the corresponding level of confidence.

In addition, we may request the calibrating laboratory to report whether or not our manometer is performing within the manufacturer's specifications at each calibration point. The calibrating laboratory should consider the uncertainty of calibration when making these decisions.[8]

1.6 Calibration intervals

Once our manometer bas been calibrated, how long can we trust its performance? The manometer is exposed to vibration, varying temperatures, humidity etc during storage and transport. After the initial calibration (which in some cases is performed by the manufacturer) we have no information concerning its drift and response to normal handling. Only after the second and (preferably) subsequent calibrations do we have information from which we can deduce whether or not the performance of the instrument *between calibrations* is adequate.

Calibration interval is an aspect of calibration that can be critically important to the validity of measurements and confidence intervals, but is highly instrument-specific and hence is not covered by a general standard like ISO 17025. Most manufacturers recommend calibration intervals (often one year) for their instruments. The Australian National Association of Testing Authorities (NATA) recommends calibration and check intervals for a wide range of reference and general instruments.[9, 10] In practice, however, the user should determine the calibration interval based on analyses of successive calibration reports, the costs of calibration, the manner in which the instrument is stored and treated during normal use, and the consequences of out-of specification measurements.

1.7 Discussion

Making a measurement is simple. Anyone can do it. We have all done it. Making measurements in which we have a *quantifiable level of confidence*, however, is *not* a trivial task. Achievement of a measurement that can be compared with confidence with other measurements, possibly made in a different country, is even more difficult. Confidence and trust are critical in serious measurements. While it is feasible for small groups of individuals or organisations to audit each other, the development of mutual trust and confidence among larger groups of organisations and between nations is not feasible without some type of standard to which everyone agrees. To facilitate measurement comparisons between organisations in different countries this standard has to be international.

If a standard is to govern a world-wide activity successfully, it should be unique, a genuine industry standard. Therefore there can be no alternative standards for calibration laboratories or users of calibrated measurement systems. A calibration is either performed by an ISO 17025 accredited laboratory and hence has documented confidence intervals and is traceable, or it is not. If the system is to work there can be no grey areas. Unfortunately, if you don't like ISO 17025 your only recourse is to participate in the system and change it from within.

The fluid-filled manometer can be thought of as an instrument that realises a pressure unit based on a fundamental physical law $p = \rho g h$, and constants ρ and g. Instruments based on fundamental physical principles, such as the fluid-filled manometer, can, in skilled hands and under controlled conditions, deliver performance acceptable for many applications. With a few exceptions these instruments tend to be bulky, costly and/or difficult to operate and the modern trend is towards instruments that are more compact and easier to use. To improve or verify confidence in instruments such as the fluid-filled manometer, or to fulfil contemporary ISO 17025 traceability requirements, these instruments are often formally calibrated.

It is of interest to note that at present all the base SI units with the exception of mass are defined in terms of fundamental physical constants and properties of selected materials, and hence can be reproduced in any laboratory by skilled engineers, physicists and technicians with the right equipment. Many national

measurement laboratories reproduce a number of the base units using these instruments and compare their realisations with the BIPM or other national labs.

1.7.1 Guarantees and probabilities

No standard can *guarantee* that a calibrated instrument performs within specified limits or according to the calibration certificate. Immediately after a calibration in an ISO 17025 accredited lab an instrument should perform within the parameters reported on the calibration certificate. To maintain that performance until the next calibration it is the user's responsibility to ensure that the instrument is not mishandled, subjected to environmental extremes, and to select an appropriate calibration interval.

1.8 Conclusions

The original question: *How do we know when we can truly believe a measurement result?*

Answer:

If we wish to make a measurement and estimate a range of values within which the true value is likely to lie with a quantifiable level of confidence, then our manometer should be calibrated regularly by an ISO 17025 accredited laboratory. In our example above, a traceable calibration would include uncertainty estimates at each calibration point, and may, if we request it or if regulations require it, state whether or not our electronic manometer operates within specifications at the pressures investigated. Uncertainty estimates would enable us to estimate a range of values within which the true pressure lay, and hence facilitate the determination at a specified confidence level, of whether or not the pressure in the duct exceeded the upper safety limit.

2 ISO 9001, ISO 17025, calibration and traceability

If you cannot measure it, you cannot improve it.

Lord Kelvin (William Thomson)

2.1 Summary

ISO 9001[11] certified organisations have to make decisions regarding calibration of measuring instruments. Many calibration laboratories are accredited to ISO 17025 but some are not. Many accredited laboratories are not accredited for all the services they offer. The use of non-accredited calibration labs, or non-accredited services of partially accredited labs, may reduce operating costs in the short term, but could turn out to be costly in the long term. Careful examination of ISO 9001 (2015) and ISO 17025 suggests that ISO 9001 certified organisations should select their calibration labs carefully and make sure that the labs they use are properly accredited for the services they provide.

2.2 Introduction

ISO 9001 certified organisations that rely on measurements to maintain and improve the quality of their goods and services are required to ensure that their measurement systems are suitable, and the measurements are always fit for purpose, valid and reliable. A number of measurement issues need to be addressed to ensure that these conditions are met:

- Appropriate selection and design of measurement systems.
- Correct installation and setup.
- Appropriate environmental conditions (e.g. temperature, humidity, barometric pressure, power supply) for the measurement system.
- Calibration at appropriate intervals by competent technicians against reference devices in which the organisation has high confidence.

ISO 9001 (2015)[11] advises certified organisations to consider whether traceable calibration is an essential part of providing confidence in the validity of measurements. Legal issues or regulations may require some measurements to be traceable to national measurement standards. If traceable measurements are necessary, measuring equipment should be calibrated or verified or both, at specified or carefully designed intervals against measurement standards traceable to national or international standards. Records of calibrations and verifications should be kept and corrective action taken when measurement equipment is found to be out of specification.

In this topic we discuss some of the implications of calibration and traceability requirements for ISO 9001 certified organisations and for calibration and test laboratories. We investigate the meaning and components of the term ‘traceable’ and show that ISO 9001 certified organisations should use laboratories accredited

to ISO 17025 for the calibration of all test and measurement equipment used to verify or control quality.

2.3 ISO 17025 (2005)

Many calibration laboratories claim accreditation to ISO 17025.[2] ISO 17025 replaced ISO Guide 25 in 1999 and was revised in 2005. In Australia NATA,[12] a not-for-profit organisation operating under memoranda of understanding with Australian federal and state Government governments, is the accrediting body. Accredited Australian labs are entitled to use the NATA logo on their documents and web pages. Accrediting bodies in some other countries are listed in Table 1 below. ISO 17025 is an international standard that specifies quality and technical competence requirements for testing and calibration laboratories. A more comprehensive list of accreditation bodies can be found at the BIPM: http://www.bipm.org/links/.

Table 1. Some ISO 17025 accrediting bodies

UK:	UK Accreditation Service	http://www.ukas.com
Canada	Canada: Standards Council of Canada	http://www.scc.ca
New Zealand	International Accreditation New Zealand	http://www.ianz.govt.nz
USA	American Association for Laboratory Accreditation	https://www.a2la.org
South Africa	African National Accreditation System	http://www.sanas.co.za

2.4 ISO 17025 accreditation

The process of accreditation by NATA is well described on the NATA website,[13] therefore only a brief overview is given here. The ISO 17025 accreditation process includes an initial on-site visit by a NATA assessor who advises the laboratory on preparation for accreditation. The assessment, carried out by a NATA lead assessor and a volunteer technical assessor, usually includes inspection of the facilities, observation of a calibration, and discussions with technical laboratory staff to allow them to demonstrate their knowledge and expertise. These activities are designed to bring to light any deficiencies in the technicians' understanding of the calibration processes. Subsequent to the initial assessment, the laboratory's performance is regularly assessed through surveillance visits by the NATA lead assessor, and reassessment visits by both the NATA lead assessor and a technical assessor. Laboratories are usually required to participate in proficiency testing[14] which involves regular round-robin calibration or testing of pre-prepared artefacts, instruments or samples, and comparison of individual lab results with either a consensus result or a reference lab result.

ISO 17025 accredited labs are required to perform internal audits (section 4.14) to verify that their operations continue to comply with the requirements of their quality systems. Labs are also encouraged to maintain in-house quality checks on

their calibration standards so that departure from specified performance is detected early (ISO 17025 section 5.9). For example, a voltage calibration lab might calibrate a stable in-house voltmeter regularly and statistically evaluate deviations from mean values to warn of possible problems with their voltage calibrator.

2.4.1 Costs

Services from ISO 17025 accredited labs are usually a little more costly than apparently identical services from non-accredited labs. Calibration labs that are not accredited to ISO 17025 have reduced costs and hence can deliver lower cost calibration services. In an era when share prices and quarterly returns rule, it is very tempting to shop around and simply use the cheapest service. This article attempts to show that this approach may not be optimal in the long term.

2.4.2 Errors and non-conformance

Hiring and keeping competent technical staff, internal audits, maintenance of in-house quality checks and participation in proficiency testing programs improves the likelihood of an error-free service but can never guarantee complete absence of non-conforming work and calibration or other errors. However, customers of ISO 17025 accredited labs can expect to be informed promptly and fully of errors and non-conforming work when they are discovered, and of the particular consequences related to the calibration of their equipment (sections 4.9, 4.10, 4.11).

2.5 Calibration, uncertainty and metrological traceability

Requirements for traceable calibration of test and measurement equipment raise questions concerning the term 'traceable'. We examine definitions and components of traceability extracted from ISO 9001, ISO 17025 and other documents, and discuss the implications.

2.5.1 Metrological traceability

VIM[7] defines metrological traceability as the '*... property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty*'.

The unbroken chain of comparisons is called a '*traceability chain*'.[7]

An unbroken chain of comparisons is a logical and easily understood component of traceability. In its simplest form a traceability chain can be thought of as a pedigree or list of makes, models and serial numbers of instruments or artefacts in the chain. The manager of a non-accredited lab might claim that his/her calibrations are traceable because he/she is able to trace the calibration pedigree of the reference instruments and materials he/she uses. However, there is more to traceability than a simple list of hardware.

2.5.2 Competence as an essential component of traceability

We discuss this aspect by example. Assume we keep a set of masses which we use to check balances in a chemical laboratory. If we can show that our masses are calibrated against masses that have a traceability chain that leads to the standard

kilogram in Paris can we claim that our masses are traceably calibrated? Consider briefly the process of using a balance to compare our masses with a set of calibrated masses. The balance should have resolution and repeatability necessary for the uncertainty required in the final result. It must be properly serviced and maintained, mounted on a level, rigid and vibration-free bench in a temperature controlled environment, and not abused in any way. Air movement around the balance may need to be restricted, as may the effects of heat radiated and convected from the operator's body. If the masses to be compared are of different densities, compensation for buoyancy might be necessary. Buoyancy compensation might require measurements of air temperature, humidity and barometric pressure. If the lab provides other calibration services then the presence of other equipment nearby may alter the environment in the vicinity of the balance, e.g. a temperature calibration oven might alter the mean radiant temperature in the vicinity of the balance.

If we appreciate the potential complexity of the calibration process then we should require that the lab calibrating our masses employ a technician with sufficient competence and training to appreciate all the potential sources of error in the calibration. He/she should be capable of setting up the equipment properly and deciding which errors are significant and which can be ignored for a particular calibration.

Competence as a component of traceability is addressed in ISO 17025 section 5.6.2.1.1: "*… traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability*". The use of the word 'shall' in a standard usually means that there is no other way to achieve compliance. ISO 17025 further notes that:

- 'Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent.'
- "A calibration certificate … from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability".

The International Laboratory Accreditation Cooperation (ILAC) considers accredited technical competence to be an essential component of metrological traceability to the SI.[5]

Hence traceability as defined by VIM[7] and ISO 17025,[2] and supported by ILAC contains a recursive element that requires ISO 17025 accreditation at each step.

2.5.3 Uncertainty as an essential component of traceability

No measurement is ever true. There is always a difference between the true value of a measurand and the output of an instrument. Measurement uncertainty is a quantitative, statistical estimate of the limits of that difference.

VIM[7] defines measurement uncertainty as a '*non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand*'. Uncertainties associated with measurements and calibrations are usually

estimated using standardised methods described in a document known in the metrology community as the ISO GUM or simply the GUM.[15]

There are a number of reasons for the inclusion of uncertainty estimates as essential components of traceability. We discuss two below.

- An uncertainty estimate and the procedure used to derive it document essential aspects of the calibration process. It is not logical to compare arbitrarily two measurement systems of widely disparate capabilities. Uncertainty estimates document the rationality and consistency of the comparisons. A traceability chain is a documented set of comparisons between consecutive pairs of instruments or measurement systems: A–B, B–C, C–D, etc. Usually instrument A is compared with instrument or reference B for the purposes of calibrating A, and the uncertainty estimated is that associated with that calibration process. The contribution of instrument or reference B to the overall calibration uncertainty is typically 4–10 times smaller than the contribution of A. Properly calculated and documented uncertainty estimates in a calibration chain indicate the 'direction' of traceability. As a corollary, uncertainty estimates should prevent inadvertent recursive or re-entrant calibration, in which, for example, instrument A is calibrated against B, B against C, and C against A.

  More than one calibration lab has commented to us that some of their customers do not appear to be interested in uncertainties associated with the calibration of their instruments. The customer should view uncertainty estimates as confirmation that his/her instrument was calibrated against a reference of adequate performance and that all potential sources of error were under control during the calibration process.

- Calibration often involves the use of more than one standard or reference measurement. For example, calibration of a volume gas flow meter by comparison with a mass flow meter requires simultaneous measurement of gas density to facilitate inter-conversions between mass and volume. If the gas is clean ambient air the density may be calculated from measurements of barometric pressure, temperature and humidity. When a calibration involves multiple measurements or comparisons, the traceability chain develops multiple branches at that point. The uncertainty analysis documents the branches of the traceability chain and indicates the relative contribution of each of the associated measurements to the uncertainty in the final result.

2.5.4 Summary: Essential components of traceability

1. Traceable calibration involves comparisons with traceable standards or reference materials.
2. Traceable calibrations can be performed only by laboratories that demonstrate their competence by accreditation to ISO 17025.
3. A traceable calibration certificate must contain an estimate of the uncertainty associated with the calibration.

2.6 Comment

The authors have seen evidence that measuring instruments from ISO 9001 certified top-100 Australian companies have been calibrated in laboratories that are not NATA accredited. These organisations might be making small savings in the short term by using non-accredited labs. If, however, inadequately calibrated instruments are used to verify or control quality, then those organisations may find themselves in an embarrassing situation if their products are subsequently found to be out of specification. In extreme cases it may be necessary to recall all products manufactured since the last time the instrument was traceably calibrated. Organisations using non-accredited labs to calibrate measuring instruments used to control quality may not conform to ISO 9001 and should not claim conformance.

Some calibration laboratories offer a wide range of calibration services but are accredited for only a subset of those services. In some cases labs claim 'ISO 17025 accreditation' or "NATA accredited" but are vague about exactly which services are accredited and which are not. ISO 9001 organisations should be careful to select calibration labs that are explicitly accredited for the services they are using. In Australia NATA[12] keeps an up-to-date publicly available list of accredited labs with details of the calibration services for which they are accredited and their least uncertainties of measurement.

Often, in a manufacturing environment, more than one measurement system is used to monitor or control the quality of the product, and inevitably some measurements contribute more than others to uncertainty in product quality. ISO 9001 (2015) places the decision regarding traceability of measurements in the hands of the certified organisation. The organisation is required to identify the measurements that contribute significantly to the control or verification of the quality of the product. One approach to this problem might be to perform uncertainty analyses on quality-related measurements using techniques similar to those outlined in the ISO GUM to determine which measurement systems require calibration and the maximum associated uncertainties.

2.7 Conclusions

ISO 9001 certified organisations should analyse the measurement systems they use to verify and/or control quality, make informed decisions on which instruments require calibration, and have these instruments calibrated by carefully selected ISO 17025 accredited labs.

3 Calibration and adjustment

3.1 Introduction

Our experience suggests that there is disagreement, even among some metrologists, about what constitutes calibration. Much of the disagreement concerns *adjustment*. Some instruments and reference materials, e.g. mercury-in-glass thermometers, gauge blocks, hydrometers, cannot be adjusted if they are found to be out of spec at calibration. Many instruments, however, can be adjusted to make the indicated value equal to the reference value, within uncertainty limits. In this topic we discuss pros and cons of adjustment as part of a calibration process.

3.2 Adjustable instruments

Various circumstances may be associated with a given calibration.

- The customer might be monitoring the long-term stability of the instrument (e.g. as part of a process for determining calibration intervals) and adjustment might confound the stability analysis. In this case an acceptable outcome might simply comprise a calibration certificate with a table of indicated *vs* reference values or corrections.
- The customer might simply want the instrument returned 'within specification' and leave any adjustment decision up to the calibration lab. ISO 17025 (section 5.10.4.3) advises that if an instrument is adjusted the certificate should include 'as found' or 'before adjustment' values, and 'as left' or 'after adjustment' values on the calibration certificate. This information should allow some analysis of stability to be performed post-calibration, but might increase the costs of calibration.
- An adjustable instrument might deviate from the reference by a large proportion (e.g. 80–90%) of the instrument's specified uncertainty. This instrument is technically within specification, but if left unadjusted, might drift out of specification soon after the calibration, resulting in problems for the user that may be detected only one year later. Customers who are aware of this possibility sometimes request adjustment only if the indicated value deviates from the standard value by more than a pre-determined proportion of the tolerance. Some calibration labs have standard procedures which specify the conditions under which in-tolerance adjustments should be made.

3.3 Non-adjustable instruments

For completeness we briefly discuss non-adjustable instruments. The calibration certificate of non-adjustable items may contain various items of information depending on the calibration lab operating procedures and the customer's requests.

- A simple ‘in specification’ or ‘out of specification’ report may be given. In this case the user is not able to analyse the stability of the instrument or reference material. ISO 17025 accredited labs, however, are obliged to keep detailed records of all such calibrations (section 5.10.4.2), so clients should be able to obtain those details after the event.
- The calibration certificate may contain a table of indicated values *vs* reference values, or corrections *vs* indicated values, or both.

3.4 Conclusion

It is important that the customer discuss with the calibration laboratory, before work commences, the details of any adjustment procedure to be followed during the calibration.

4 ISO 9001 certified calibration

4.1 Introduction

It might seem reasonable that an ISO 9001 certified calibration laboratory should be capable of calibrating instruments for an ISO 9001 certified organisation. In this short article we examine ISO 9001 and ISO 17025 for evidence for and against this possibility.

4.2 ISO 9001 and ISO 17025

ISO 17025 (2005) section 1.6 states that laboratories that '*comply with the requirements of this International Standard … will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001*". The same section, however, states that ISO 17025 '*covers technical competence requirements that are not covered by ISO 9001*'. The technical competence requirements of ISO 17025 are found in section 5.

4.3 Discussion

An ISO 9001 certified lab may operate an appropriate quality management system but it does not necessarily have the required technical competence for performing calibration services. In the metrology environment, ISO 17025 can be considered to be a superset of ISO 9001. Appendix A of ISO 17025 (2005) provides a cross-reference between ISO 17025 (2005) and ISO 9001 (2000).

ISO 9001 was updated in 2015.[11] We have not examined the updated version carefully enough to comment on its similarity to ISO 17025 (2005), However, we suspect it doesn't cover technical competence to the same extent as ISO 17025.

4.4 Conclusions

ISO 9001 certification can be considered to be a necessary but not sufficient condition for the provision of calibration services. Potential customers should select labs that are accredited to ISO 17025 for their specific calibration requirements.

5 Uncertainty and proficiency testing

5.1 Introduction

ISO 17025 accredited labs are required (section 5.9) to '*… have quality control procedures for monitoring the validity of tests and calibrations undertaken. … This monitoring … may include … participation in inter-laboratory comparisons or proficiency-testing programs*'. Australian ISO 17025 accredited labs are required to participate in proficiency testing programs ideally at least once every two years for each major area of accreditation, unless no suitable program is available.[14]

Proficiency testing programmes in Australia are run by the National Measurement Institute (NMI)[16] and various other organisations dedicated to that task and accredited to ISO/IEC 17043:2010 *Conformity assessment: General requirements for proficiency testing.*

5.2 Commercial issues for calibration and testing labs

Most calibration and testing labs are commercial concerns and need to attract and keep enough customers to cover costs and make a profit. If a lab can lower its 'least uncertainty of measurement', it is in a position to increase the charge for its service. In addition, a lower uncertainty enables a lab to calibrate a wider range of instruments and hence attract more customers.

5.3 Evaluation of proficiency tests

Calibration and testing labs participating in proficiency tests are requested to calibrate or test an instrument or artefact. Reference values may be obtained by arranging for the instruments or artefacts to be calibrated or tested by a reference laboratory (e.g. the NMI), or consensus values may be used. Results are analysed using robust statistical methods.[17] Robust statistical methods exhibit reduced sensitivity to small departures from assumptions (e.g. normality) and are also minimally affected by outliers.

Results from laboratories participating in calibration proficiency tests are assessed by calculating a normalised error (E_n):

$$E_n = \frac{X_{lab} - X_{ref}}{\sqrt{U_{lab}^2 + U_{ref}^2}} \qquad 1$$

Where:

X_{lab} and U_{lab} are the participating laboratory's result and expanded uncertainty respectively

X_{ref} and U_{ref} are the reference result and associated expanded uncertainty respectively

E_n should lie between −1 and +1 in 95% of cases. E_n values outside this range are considered unsatisfactory and the lab is asked to investigate and explain its result.

The participating lab's uncertainty estimate appears in the denominator of equation 1. Therefore, all other things being equal, a lab with a large uncertainty (U_{lab}) is less likely to be asked to explain a large E_n than a lab with a small uncertainty.

Calibration laboratories are therefore faced with conflicting motives when they develop procedures for estimating uncertainties. On the one hand low uncertainty estimates may increase turnover and revenue. On the other hand high uncertainties decrease the probability of failing a proficiency test. During participation in proficiency tests calibration labs can expect to be asked to calibrate an instrument or artefact with a specification that is close to its best measurement capability, and hence contributes little to the overall uncertainty of the result. In other words, usually $U_{ref} << U_{lab}$.

5.4 Conclusions

Proficiency testing can be viewed as an evaluation of both calibration ability and uncertainty estimates. As far as we are aware, proficiency tests are the only occasions when uncertainty estimates are evaluated quantitatively.

Calibration labs should take care to develop procedures for estimating unbiased, realistic uncertainties for their calibrations.

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