

Ensuring traceability in Australian laboratories





Traceability is now a common part of accreditation systems and business expectations. This paper provides an overview of the various accreditations, certifications and standards that are applicable to Australian laboratories.

With major audits conducted in Australian laboratories every two to four years, assessors are tasked with checking all necessary documentation to ensure accreditation is maintained. This process checks that the laboratory has the correct practices and quality systems in place to undertake the work they are contracted to do.

Failure to provide the right documentation and certificates, can lead to corrective actions and in some cases, loss of accreditation. This can have vast implications on the overall business. Put simply, if your accreditation is at risk, your business is at risk.

In recent years, traceability has become an increasing focus for assessors. Advancements in technology have seen an increasing number of businesses use analytical processes as part of their systems. This has led to a greater understanding of traceability, which is now a common part of accreditation systems and general business expectations.

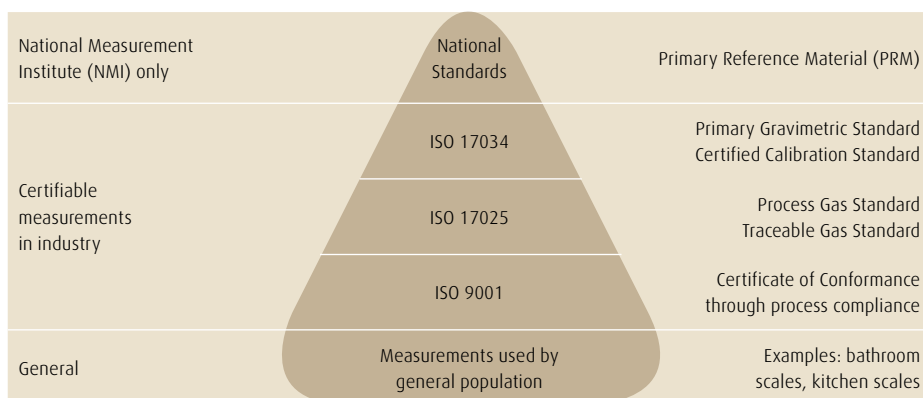
For example, accreditation is important for laboratory managers in the food sector, with requirements around residue testing which can have significant impacts for food exporters. In the instance that a residue test fails and food has already been exported, this may result in food being dumped which would have massive cost implications for the business.

In the defence sector, certification is of critical importance. For example, in a submarine where there is welding gas used to perform critical welds, businesses must prove that the welding gas meets a certain specification. Otherwise, if something happens to the submarine because of the weld, the liability sits with the business. For multi-billion dollar projects, the cost of using appropriately certified products becomes negligible. On these types of projects, customers need to use products that come with traceability so they can demonstrate they've used the right product if an accident were to happen.

This paper provides an overview of the various accreditations, certifications and standards that are applicable to Australian laboratories. It will discuss these in the context of traceability and provide insights on how you can prepare for your next audit.

Standards are integral to maintaining a laboratory quality system and help ensure product traceability.

Hierarchy of gas standards



Key standards for testing and calibration laboratories

ISO 17025 testing and calibration

An international standard which defines the minimum requirement for laboratories to operate competently and to generate valid results. It provides a framework for laboratories to supply calibration standards in a way that is recognised by other laboratories or accreditation agencies.

ISO 17034 general requirements for the competence of reference material producers

An international standard (previously known as ISO Guide 34) that specifies the minimum requirement for the competence of reference material producers. It ensures a reference material has been produced in a competent way, allowing other laboratories to perform calibrations using the reference material.

It is a stricter requirement than ISO 17025 and is not common internationally, despite being frequently used in Australia and New Zealand. BOC provides this standard.

What is the difference between ISO 17025 and ISO 17034?

An important distinction is that ISO 17034 covers the creation of certified reference materials, thus providing certainty around homogeneity and shelf life. ISO 17034 certification also guarantees the product specification will be stable for the length of the shelf life.

ISO 17025 does not provide this and does not allow for the creation of certified reference materials.

Additional relevant standards

ISO 9001 quality management

An international standard that applies to a variety of sectors and industries, large and small.

This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. According to ISO, there are more than one million companies and organisations in over 170 countries certified to ISO 9001.

ISO 14001 environmental management system training

An international standard that specifies requirements for an effective environmental management system. It provides a framework that an organisation can follow, rather than establishing environmental performance requirements. ISO 14001 can be integrated with other management systems standards, most commonly ISO 9001. Together, they can help a business achieve their organisational goals.

Accreditation identifies qualified operator businesses and allows you to trust in the process.

What is accreditation and why do we need it?

Accreditation is a way to identify someone as being qualified to perform an activity. It is a recognition, typically performed by a third-party, which allows other businesses or individuals to trust something will be carried out correctly.

Robust accreditation is critical for high quality laboratory testing and can build confidence in the work done in Australia. Accreditations are also used by suppliers of specialty gases to ensure their products are credible and competent. It is also critical for researchers who rely on calibration and replicable results.

How is accreditation done in Australia?

The way in which accreditations are carried out varies across the world. In Australia, NATA is the national accreditation body tasked with serving the public interest by ensuring organisations are compliant with relevant international and Australian standards and therefore competent to provide consistently reliable testing, calibration, measurement and inspection data.

For laboratories to be recognised internationally they must be accredited by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory.

The below table outlines some common accreditation authorities, and their ILAC-MRA status. The ILAC-MRA relates to ISO 17025 accreditation and does not relate to ISO 17034 accreditation. International suppliers with ISO 17034 accreditation may not have their credentials recognised in an audit scenario.

Assessor	Country	ILAC-MRA ISO 17025 Status
NATA National Association of Testing Authorities	Australia	✓
IANZ International Accreditation New Zealand	New Zealand	✓
UKAS United Kingdom Accreditation Service	United Kingdom	✓

Certification. Different certificate types require different manufacturing methods, and provide differing levels of traceability.



In addition to receiving valid accreditations, laboratories are required to retain certain certificates that represent a written assurance by a third party of the conformity of a product. Certificates are used to show results to the customer and provide required statements to add on the certificate. These statements say how the product was made, what standards were met and who accredited it.

In Australia, there are three common types of certificate – Certificates of Analysis (CoA), Batch Certificates and Certificates of Conformance (CoC). These certificate types require different ways of manufacturing the product, and provide differing levels of traceability to the customer.

Certificates of Analysis

To produce a Certificate of Analysis, each individual sample must be tested. The analysis results or gravimetric values are reported on a certificate as the actual values of the product (or minimum detection limit for impurities), providing a direct link between the sample (cylinder) and a set of results. This means the certificate can specify the actual concentrations, therefore making these certificates valid for calibration. Accreditation is also an important aspect of calibration.

When is it used?

Calibration, Life science applications or critical processes.

What is the cost?

The cost varies with each sample but is significant, typically hundreds of dollars.

Certificates of Conformance

Typically used to show what specification a product was manufactured to. They do not contain actual analysis results, but are linked to individual samples. These provide limited traceability, but are useful to document what was used for a process. These are not valid for calibration as they do not report actual concentrations and may not involve actual testing or analysis.

When is it used?

Typically for industrial applications (e.g. welding) or standard processes.

What is the cost?

Certificates of Conformance may be offered with the product documentation.

Batch Certificates

Amalgamation of a Certificate of Analysis and Certificate of Conformance. They provide a higher degree of traceability than a Certificate of Conformance but without the cost of individual testing. A limited number of samples are taken from a batch and then tested to specification. The results from that cylinder are applied to the entire batch in the form of a batch certificate. These are not valid for calibration as they may not record the actual results for the individual cylinder being used.

When is it used?

Typically for high value or critical industrial applications (e.g. welds on an LNG pipeline).

What is the cost?

A specific number of samples need to be analytically tested, so the cost of the individual test(ing) is distributed amongst the entire batch. A batch certificate has a typical attributable cost of \$50–\$150 per sample.

Traceability.

What is traceability?

Traceability is how we know that a measurement is accurate. It involves linking the value that we say we have achieved, to an international measure. It involves comparisons in measurements and considers how many steps are involved. A high level of traceability is something that has fewer 'steps' in the traceability chain. The fewer steps involved, the better, as there is less risk for error and lower uncertainty about the measurement.

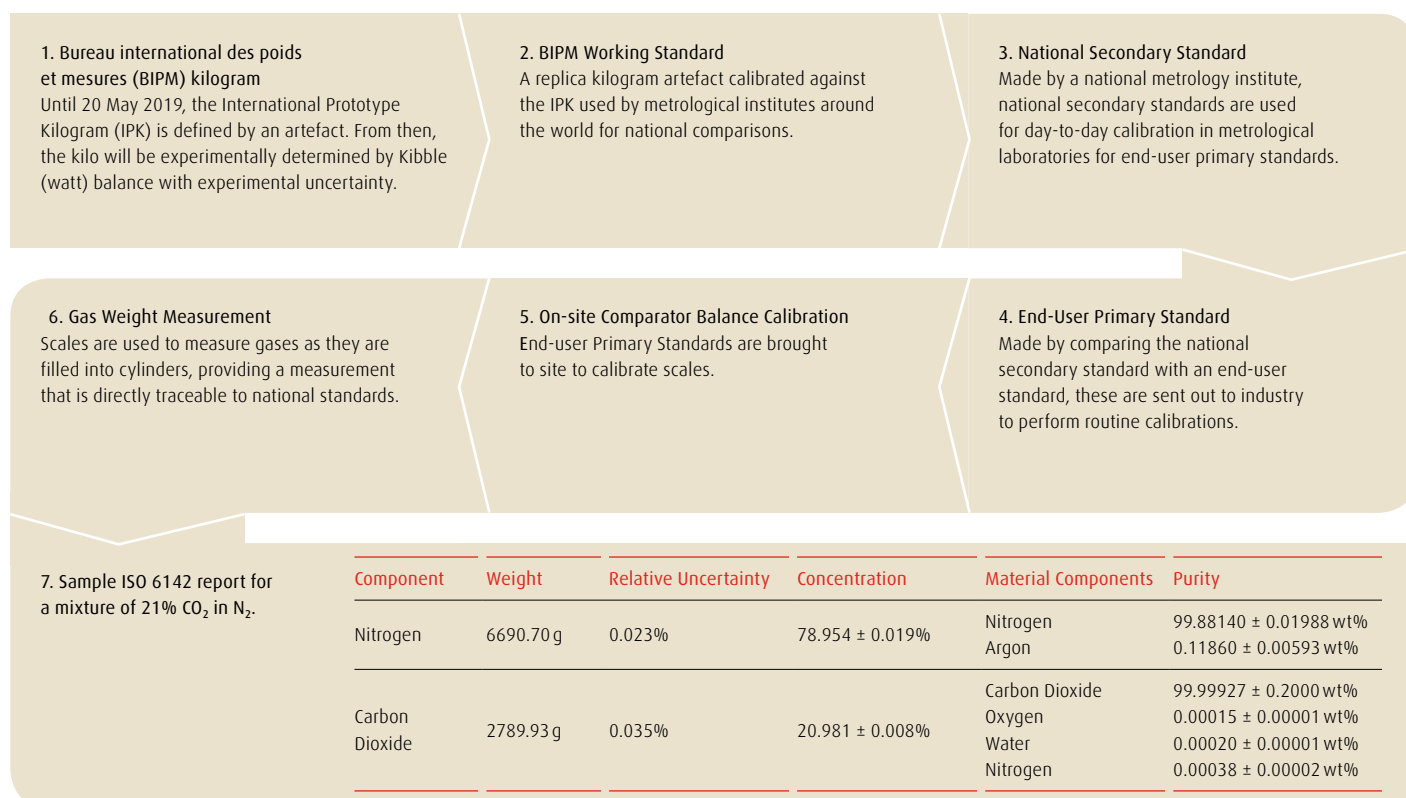
Why is traceability so important?

Traceability is vital in ensuring measurements are accurate and that they meet required standards. Failing to use an accredited standard could break the traceability chain, costing time and money.

For example, if a laboratory were to use pure gas without a certificate to calibrate an instrument, they could be subject to corrective action in an audit. Pure gases are sold with a minimum purity, but they are not certified as such. Helium 99.99%, as an example, could be 99.99% pure or 99.995% pure or 99.9999% pure, but because the actual value is unknown, it can't be used to calibrate an instrument. Therefore, it breaks the traceability chain because it is not certified. Using a certified pure gas provides the confidence that the instrument has a certified percentage of purity and the accredited certificate to back it up. If an accredited standard is not used, it could invalidate analytical results used for the period in which the unaccredited pure gas is used, wasting time and money.

By using reputable suppliers (i.e. accredited ones) who meet high standards, decision makers in laboratories can rest assured that they are operating to internationally accredited standards.

Traceability chain



What do I need to do as laboratory manager to be ready for my next audit?

In order to be prepared for the next audit, laboratory managers should ensure they have all of their documentation together to show how they've used the correct reference materials made under a standard, by an accredited company with a valid certificate. In some cases, your accreditation may also require certified products as part of your processes e.g. carrier gases for your gas chromatography.

If you can show you've retained this documentation, you're likely to be in a good position for your audit. If you have reference material you've used in a process where you need certified products, you ultimately can't prove that what you did was correct and therefore can expect corrective action.

What questions should I be asking my gas supplier about traceability?

Traceability should be top of mind to ensure accuracy of measurements and minimised errors. Asking your gas supplier about the traceability of its products, looking for the accreditation on the product, and checking what standard it is made to is highly advisable.

For example, ISO 17034 is required to calibrate an instrument doing ISO 17025 accredited work, if you're using something that only has ISO 9001 accreditation to cover the manufacture and certification of the product, you're using the wrong product. When selecting a gas supplier, choose one that can provide high quality products that you can be assured align with global standards. The supplier should be able to tell you what standard the gases are made in accordance with, and who is the accreditor – i.e. how it's made and how they can prove it. By choosing a reliable, high quality gas supplier, you can help future-proof your laboratory.

Conclusion. Traceability is an increasing focus and it is vital for Australian laboratories to have the right level of certification and accreditation.

Traceability is an increasing focus for assessors and is of vital importance for Australian laboratories to demonstrate the quality of testing. Standards, accreditations and certificates are all important aspects for laboratory managers to consider to ensure traceability.

When preparing for an upcoming audit, laboratory managers should ensure they have all evidence together to show how they've used the correct reference materials made under a standard, by an accredited company with a valid certificate. If they are unsure about the traceability of their products, they should reach out to their gas supplier.

It is highly advisable to speak to a specialist and make sure you have the right level of certification and accreditation for your business.

BOC has a large team of scientific specialists who can advise on the correct gases to use, and are supported by a technical team. A simple conversation today can save a painful corrective action later. BOC also has the capability to supply documentation online for ease of doing business.

For more information, please visit www.boc.com.au



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