ISO Guide 34 and beyond

The bright future for accredited specialty gases

By Stephen B. Harrison

© NPL

The hierarchy of accredited calibration gas mixtures has, in recent years, been relatively stable. At the base of the pyramid there is a simple ISO 9000 accreditation to demonstrate compliance with internal quality systems. The middle tier has been filled by the ISO 17025 range of accredited calibration gas mixtures. At the peak of the pyramid has been the exclusive ISO Guide 34 accreditation.

Together, this range of mixtures are used for high precision measurement applications such as environmental emissions monitoring from smoke stacks and natural gas custody transfer.

Within this accreditation framework, two fundamental changes have recently shaken up the established order for producers and users of specialty gases. Firstly, the publication of the ISO 17034:2016 standard three years ago replaced the ISO Guide 34 standard. The implications here are global and calibration gas producers as far apart as Australia, Brazil and the UK have been working hard to update their quality systems and achieve the new accreditation and maintain their competitive advantage in these product groups.

Secondly, there have been moves by national accreditation bodies to re-focus the ISO17025 accreditation towards laboratory processes and ensure that the ISO 17034:2016 standard is the exclusive accreditation that is relevant to produce reference material calibration gas mixtures. This is driving the market towards the top of the specialty gases quality pyramid, where the levels of expertise, production →

> “This is driving the market towards the top of the specialty gases quality pyramid...”

costs and sales prices are highest. In business terms, it translates to growth because of higher barriers to entry and improved profit margins for those that are committed to staying in the game.

There is life after Guide 34...

To understand the implications of moving beyond ISO Guide 34, **gas**world spoke to Arul Murugan, Senior Research Scientist in Energy Gases at NPL in the UK. He informs us that, "one big change is that ISO Guide 34 was just that: a guide, whereas ISO17034:2016 is a normative reference."

"As an analogy, the guide said what should be done, the new standard now says what *must* be done. The main benefits for users of these accredited gas mixtures are that the ISO17034:2016 reference materials have certified homogeneity and stability during the stated shelf life of the product. In my opinion, this is a key additional benefit which they provide over ISO17025 accredited gas mixtures."

The challenge of change management can be quite intimidating. But Murugan has some reassuring words on this topic. "I took on the additional role of managing our group's quality system about a year ago and I was confronted on day one with the task of the ISO Guide 34 to ISO 17034 transition. I am very fortunate that our team had done a great job of documenting more than 50 operating procedures, some of which reference ISO 6142-1 for sequential gravimetric gas mixture preparation techniques, ISO 6145 for dynamic blending filling methods and ISO 19229 which is relevant for the analysis of pure gases, such as methane or nitrogen, which are used as balance gases in mixtures."

"This meant that for the gases reference materials team at NPL there were no technical changes required in our processes to make the transition to ISO 17034:2016."

"We needed to change the way in which we documented the evidence behind our stability analysis, but that was the only major hurdle we needed to jump. We had our UKAS accreditation audit last year and were awarded our new ISO 17034:2016 certificate in December 2018. It has the same broad scope as before covering hydrogen, synthetic natural gas, VOC's, breath alcohol, environmental gases and more. The components are the same and the amount fraction ranges are the same, so our customers will be able to source the same range of products from us in the future as they have done in the past."

The NPL are not alone in making this transition in the UK and BOC have also recently followed the same path. Other reference material producers will need to follow suit soon because UKAS has phased out ISO Guide 34 accreditations. Audits in 2019 and beyond will take place according to ISO 17034:2016.

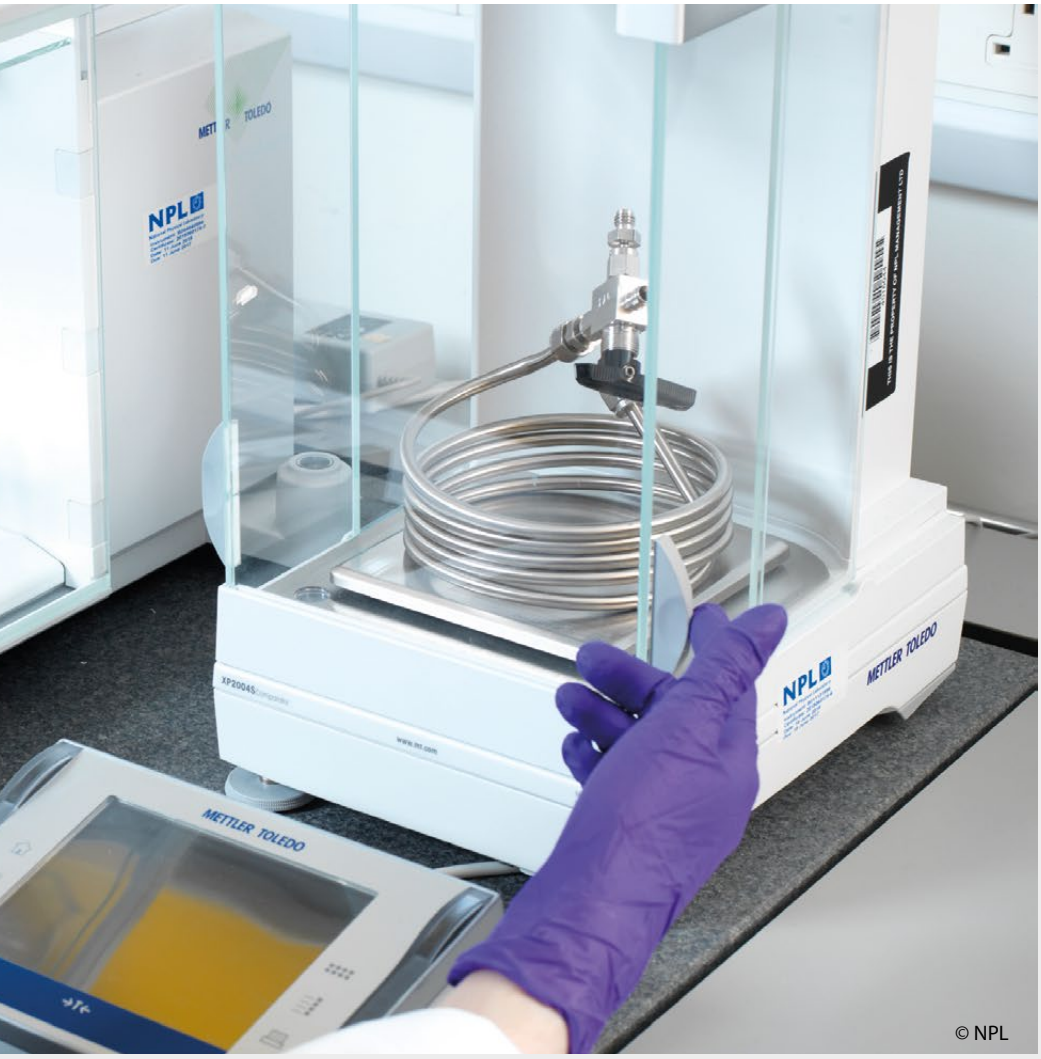
Pure gases step up to the plate

One of the most fundamental changes from the ISO Guide 34 to the new ISO 17034:2016 level is that it is now possible to produce and certify accredited pure gases such as nitrogen.

Jorge Duarte Guimarães, an industrial and specialty gases consultant at JDuarteG Consultoria in Sao Paulo, Brazil, comments "For the past years, I have supported many gas detection equipment manufacturers and service laboratories to source accredited calibration gas mixtures and zero gases for calibration of their devices under an ISO 17025 scheme of accreditation. For that purpose, they have traditionally been using ISO Guide 34 calibration gas mixtures for the span reading and normal nigh purity nitrogen for the zero test."

> "A common cause of confusion is the difference between traceable gas mixtures and accredited gas mixtures... "

"To be honest, I always found it inconsistent that premium calibration gas mixtures are required, but the zero gas was really nothing special. However, the introduction of the updated ISO 17034:2016 standard has meant that we can now apply consistent quality levels at both end of the sensor's range and I have been helping my customers to source accredited high purity nitrogen from a



© NPL

trusted international supplier which has achieved accreditation for nitrogen in their ISO 17034:2016 scope. On the one side, it means that the market for the highest value specialty gases is growing. On the other hand, I simply feel safer knowing that these gas detectors are being manufactured and serviced in this way here in Brazil."

Scope of accreditation is a major differentiator

With many companies in each major geography able to wear a badge that states the same hierarchical level of accreditation, be it ISO 17025, ISO Guide 34 or ISO 17034:2016, we might fall into the mistaken belief that their product offers are equal: not so!

It is possible for a producer to achieve accreditation for one single gas mixture at a defined concentration, for example 100 ppm (parts-per-million) NO in nitrogen. Another producer may have the same level of accreditation for an extremely broad range of components at a broad range of concentrations, allowing the production of hundreds of different combinations and permutations of accredited gas mixtures within their broad accreditation scope. So, the breadth of the accreditation scope remains a vibrant differentiator between competitors in a given geographic market.

Navigating the technical terminology

When talking about calibration gas mixtures it is sometimes the case that various phrases which have a very precise metrological meaning are inadvertently mixed up in this complex jungle of jargon.

A common cause of confusion is the difference between traceable gas mixtures and accredited gas mixtures. Traceability refers to the un-broken chain that can link a calibration gas mixture to a reference material, for example the SI unit of mass. Accreditation, on the other hand, refers to the independent assessment of a quality system.

Interestingly, the Euro 6 regulations that govern the calibration gases that should be used to validate exhaust gas emissions analytical instrumentation calls for 'traceable' gas mixtures. However, the documentation makes no statement to require that the calibration gases should be accredited.

Accreditation underpins harmonisation

A fundamental question that is often raised by customers is, "how can we be sure that the calibration gas mixture itself is accurate?"

This chain of dominoes is the essence of traceable measurement and, for the measurement of chemical concentration, the roots end up at the international prototype kilogram (IPK) mass stored at the International Bureau of Weights and Measures (BIPM) in Saint-Cloud, France.

In the Asia-Pacific region, NATA (the National Association of Testing Authorities, Australia) represents the gold standard when it comes to validation that calibration gas mixtures have been produced under a quality management scheme that will ensure traceability to SI units of measurement which forms the link to the IPK. They accredit certain laboratories that have a demonstrated capability to produce certified reference materials under ISO 17034:2016.

Alan Watkins, Executive General Manager for Coregas in Australia, explains how this works in practice. "ISO 17034:2016 is the general guideline for making a reference material. At our laboratory in Yennora, near Sydney, we achieved our ISO 17034:2016 accreditation in Q4 of 2018," he says. "Prior to that, we followed the ISO Guide 34 standard for more than a decade. We make primary reference materials (PRM) under ISO 17034:2016 by following the detailed procedures laid down in ISO 6142-1. The concentration unit is traceable to mass, certified by the National Measurement Institute in Australia. And, their reference mass is at the BIPM in France."

"NATA accredit our quality systems to ensure that we really do what we say we do. It is a completely closed loop process to guarantee international harmonisation of measurement. Here in Australia, we can produce these high-spec products to ensure that scientists in environmental monitoring, production and QC applications can trace their measurements through to the IPK in France. That's how they can be sure that 10 ppm measured here in Sydney is the same as 10 ppm measured in Seoul, Shanghai or Sao Paolo."