

RM accreditation to ISO Guide 34 and ISO/IEC 17025 together

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My musings on the accreditation of RM producers is a topic that should be familiar to regular readers of this column. In 1996 the ISO Committee on Reference Materials (ISO REMCO) produced the basis for an assessment document to address this issue, ISO Guide 34, General Requirements for the Competence of Reference Material Producers, but since then many have debated the "right" approach.

In the absence of a conclusion the United Kingdom Accreditation Service (UKAS) offered accreditation for RM producers to ISO 17025:1999 as Calibration Laboratories and in *Spectroscopy Europe* 14/4, published in August 2002, I wrote about the first group of UK RM producers granted UKAS accreditation as RM producers as Calibration Laboratories.

The complex multi-lateral debate about the "best" way to accredit RM producers continued and involved RM producers, accreditation bodies and many stakeholders in the analytical community including the International Laboratory Accreditation Council (ILAC), the Asia Pacific Laboratory Accreditation Co-operation (APLAC) and the European Cooperation for Accreditation (EA). One problem was that any recognition must be recognised under the ILAC Mutual Recognition Agreement (MRA) so that accreditation by any of the signatories to that Agreement would be able to recognise an accreditation by any of the other bodies. The debate was concluded in 2004 when at the ILAC General Assembly a formal resolution that accreditation of RM producers should be against the requirements of ISO Guide 34 and ISO 17025 in combination was passed. This followed an earlier decision to allow the accreditation of PT produc-

ers to ISO 17025 and ISO Guide 43. It is worth comment that at an ILAC PT Group Meeting held in Madrid, Spain, earlier this year it was announced that ISO Guide 43 and ILAC Guide G13 (Guidelines for the requirements for the competence providers of proficiency testing schemes) would be merged and used to form the basis for a new ISO Standard 17043, allowing PT producers to be accredited to a single ISO Standard. This step is expected to be completed by 2012.

In 2004 UKAS established a working group to consider the best way forward for the UK. The group looked at developments in other parts of the world and took input from UK stakeholders, including the UK RM Working Group before agreeing ISO 17025 + ISO REMCO Guide 34 would be the best solution. A Steering Committee composed of RM stakeholders was assembled to help with developing a robust assessment process that ensured the full process of RM production was assessed in accordance with ISO Guide 34 and the relevant parts of ISO 17025.

A pilot group of five or six existing RM producers was set up as the most efficient way to develop the experience needed and the real work started in 2005. Most of the pilot group of UK RM producers already had key elements of their RM production and certification processes accredited under ISO 17025. With guidance provided by the Steering Committee, the assessment of the five RM producers was completed in April 2006 and, following a review of the process employed, UKAS granted accreditation to the successful organisations on 30 June 2006.

To mark this occasion, and to formally launch UKAS' accreditation service in this area, an event was held at the London

Science Museum on 17 July 2006 where the UKAS Chairman, Lord Lindsay, awarded the five successful producers their certificates.

The successful five are Bureau of Analysed Samples Ltd, Health Protection Agency—Food and Environmental Proficiency Testing Unit, LGC Ltd, National Physical Laboratory and Optiglass Ltd.

Accreditation as a RM producer in accordance with ISO Guide 34 and ISO 17025 provides the user of RMs from these and similarly accredited laboratories, with confidence that the producer is technically competent to produce, characterise and certify RMs according to effective and robust internal processes. The accreditation covers the entire process of RM production, including production planning and control, material preparation, assessment of homogeneity and stability, and post-distribution service: it is the latter areas that were not formally covered by the previous accreditation of RM producers as calibration laboratories to ISO 17025.

It is very much hoped that with this key step completed that not only will all the UK CRM producers follow, but in the USA A2LA will encourage US RM producers to seek accreditation to the same combination of ISO 17025 and ISO Guide 34. This is important as in many sectors RMs and CRMs from the USA are the only option.

In the future I would like to see the distillation of the ISO REMCO Guides 30 to 35 and ILAC Guide G12 (Guidelines for the requirements for the competence of reference materials producers) into a new ISO Standard that will allow RM producers to be accredited in just the same way as ISO 17043 will work for PT producers.