

Reference materials and accreditation

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Over the last year or so I've touched on the subject of the accreditation of RM producers. I am delighted that Rob Bettinson, Development Manager at UKAS (United Kingdom Accreditation Service) has offered to set out the position from the UKAS perspective.—P.J.J.

The importance of using reference materials is greatly appreciated by laboratories across a broad range of sectors. They form the cornerstone for the accuracy of data that laboratories produce, from the initial validation and ongoing monitoring of methods to the monitoring of staff competence and calibration of equipment. However, it is not so clear to many people what UKAS' position is with respect to reference materials (RMs) or what its role is with respect to RM producers.

The United Kingdom Accreditation Service (UKAS) is the sole national accreditation body recognised by UK Government for the assessment of organisations undertaking tasks such as testing, calibration, inspection and certification: this recognition is formalised in a memorandum of understanding with the DTI. Many people will be familiar with UKAS' laboratory accreditation service, where it assesses and accredits laboratories to undertake specified testing and calibration methods in accordance with the international standard ISO/IEC 17025.

For many years it was through this involvement with the laboratory community that UKAS' main interest in RMs laid. Important factors in the competence of laboratories include the use of valid methods, the use of calibrated equipment and the use of quality control checks to ensure that the measure-

ment system continues to perform at the required standard. Understandably, therefore, ISO 17025 promotes the use of RMs for each of these factors. In addition, ISO 17025 requires laboratories to evaluate suppliers of "critical consumables" which affect the quality of testing and calibration. In an environment where there is no specific assessment of the competence of RM producers, laboratories could find this latter requirement difficult to implement.

Many RM producers have appreciated the impact that the quality of their products have on their customers and in recognising their customers needs have implemented formal third party assessments to provide greater confidence to the market place. In some cases this has included accreditation by UKAS as a calibration laboratory, demonstrating the competence of the laboratory to measure the property values. Other producers have looked to the management of the production process and registered their management systems to ISO 9001. Previously, in the absence of a more specific standard for the recognition of RM producer competence, such demonstration of conformity was found to be acceptable (in the case of accreditation to ISO 17025 this can still be the case for certain RMs). However, over the past few years the ISO Committee on Reference Materials (ISO REMCO) has been working on a series of standards specifically relating to RM industry. One of these standards (ISO Guide 34) was produced with the intention of setting out the requirements with which a producer should demonstrate that it operates.

The publication of this standard paved the way for formal assessment of RM producers against a clearly defined spec-

ification produced for this purpose. This was taken up in certain parts of the world such as in Australia and the United States where accreditation bodies started to accredit producers directly to ISO Guide 34 in the late 90s.

Developments within Europe were more cautious. Initially concerns were raised as to whether the activities of RM producers were appropriate for accreditation. There was also a long-standing debate as to whether accreditation should be to ISO/IEC 17025, ISO Guide 34 or a combination of both. This issue was finally settled at the International Laboratory Accreditation Cooperation (ILAC) General Assembly in Cape Town during October 2004 which resulted in two key resolutions. First, that RM producers were recognised as undertaking conformity assessment activities and hence were able to be accredited, and second, that accreditation should be based on the harmonised criteria of ISO Guide 34 and ISO/IEC 17025 in combination.

Over the past couple of years UKAS has continued to monitor the international developments within this area, and also to have an input through the EA Laboratory Committee. In November 2002 UKAS prepared a proposal to the UK Department of Trade and Industry (DTI) funded VAM programme for the development of an accreditation service for RM producers. This proposal received support from DTI and funding was eventually secured a year later. UKAS are now in the process of developing an accreditation service for RM producers in line with the ILAC resolutions. This will involve an assessment of the overall process to the requirements of ISO Guide 34, with the more specific requirements of ISO/IEC 17025 being implemented with respect to the measurement of property values.

A project steering committee has been set up to represent the interests of major stakeholders in this area, and UKAS will look to this committee to provide advice and technical expertise as appropriate. UKAS are planning to trial its service in a pilot programme during the first half of 2005 and will look to grant accreditation to successful applicants following its completion.