Developing an international consensus for reference material production

Department for Business, Energy & Industrial Strategy

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The requirement

Reference materials (RMs) are the cornerstone of accurate and traceable measurements – they are measurement standards which can be used to validate analytical methods, establish traceability and support quality control.

RMs are particularly important for analytical chemistry, where many analyte-matrix combinations exist and emerging new measurement demands must continually be met. These materials can either be a pure substance, e.g. an immunosuppressant certified for purity, or a matrix material, e.g. 'drinking water' containing a range of commonly found compounds.

The development, production, and certification of reference materials are currently underpinned by a number of ISO (International Organization for Standardization) Guides. These guides, adopted by over 160 countries, ensure that materials, products, processes and services are fit for purpose.

ISO Guide 34, which specifies the general requirements for reference material production, was produced to provide non-mandatory technical assistance to those involved in producing and certifying reference materials.

Over time the regulatory environment has changed and accreditation schemes for reference material producers have been introduced by a number of countries, including the UK. These schemes base their assessment on the most recent edition of the Guide (ISO Guide 34:2009) but there are challenges to effectively regulating and performing accreditation against a guide rather than an international standard.

To support the evolving regulatory need, it is essential that Guide 34 be converted in to an international standard.

The solution

ISO Guide 34 has been converted to a conformity assessment standard in the 17000 series: ISO 17034 - General requirements for the competence of reference material producers.

This conversion was performed by a joint working group between ISO's Conformity Assessment Committee (CASCO) and Reference Materials Committee (REMCO). LGC scientists have been instrumental in this process, which has taken two years and significant international effort to achieve.

LGC contributions included leading and coordinating the views of UK reference material stakeholders to inform the international position and providing comments throughout the drafting and production stages. The parallel contributions LGC scientists have been making in writing, editing and commenting on the revisions to ISO Guide 35 (Reference materials - General and statistical principles for certification) have also informed the development of this new standard.

The impact

This new standard represents a global consensus for reference material production.

ISO 17034 describes the mandatory requirements reference material producers must adhere to, such as the need for homogeneity and stability assessments. As an international standard, this will provide a more cohesive framework to support regulation and allow for clearer accreditation requirements.

This will provide greater confidence in RM suppliers and will benefit the UK through increased acceptance of our reference materials overseas.

The degree of input into the production and revision of the ISO Guides for reference material production demonstrates the level of impact LGC has on the best practise in the field, maintaining the position of the UK reference material producers at a global level.

As Dr Steve Ellison, Science Fellow and a UK Representative on the joint ISO CASCO/ISO REMCO Working Group explains:

"LGC's coordination role helped to make sure that our UK representatives were well briefed on the technical problems facing the different reference material producers in the UK. LGC's reference material and international metrology experts were able to contribute strongly to the detailed technical provision of the new Standard. This new Standard provides a very good balance between essential requirement and those that need to be more flexible to allow for the very different kinds of reference materials needed in today's measurements."

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