

Increasing the reliability and value of analytical results

Sigma-Aldrich achieves “Gold Standard” double accreditation according to both ISO/IEC 17025 and ISO Guide 34, and now offers a unique class of CRM

Jürg Wüthrich, Senior Scientist R&D Europe, Sigma-Aldrich Switzerland juerg.wuethrich@sial.com
Michael Weber, Manager R&D Europe, Sigma-Aldrich Switzerland michael.weber@sial.com

Produced in double accredited
laboratory fulfilling
ISO/IEC 17025 and
ISO Guide 34

Following long-lasting cooperation with different metrological institutes, such as Switzerland’s EMPA and Germany’s BAM, Sigma-Aldrich has built-up a broad knowledge base in the field of CRM production. In the newly-built laboratories equipped with specialized instruments at our Buchs, Switzerland site, we developed a series of CRMs for the analytical market. After two years of continuous development, our Buchs facility was ready to be audited by the Swiss Accreditation Service (SAS) and receive the highest achievable quality assurance level for CRM producers: the double accreditation as both a testing lab (ISO/IEC 17025) and a CRM producer (ISO Guide 34). This combination is also called the „Gold Standard“ accreditation for CRM producers.

Accreditation vs. Certification

Confusion often arises over the proper meaning and differences between the terms accreditation and certification. Accreditation means that an authoritative body formally recognizes that an organization or individual is competent to execute a specific service as described in the scope of accreditation. Certification, on the other hand, means that an independent third party has confirmed in writing that a product, procedure or service fulfils the prescribed requirements.

The difference between the two seemingly similar definitions lies in the fact that with accreditation, the formal recognition of competence is based on proven technical knowledge and therefore requires the consultation of a technical expert for the scope to be accredited, while certification primarily involves ensuring conformity to a given norm. For example, certification according to ISO 9001 targets the general management, processes and data-handling within a company. Therefore, ISO 9001

certification is not linked to a technical competence. Although both ISO 9001 certification and ISO/IEC 17025 accreditation do have some overlap, they are more-or-less independent [1].

ISO/IEC 17025 for testing labs

The particular aspects of this type of accreditation are described in ISO/IEC 17025 „General requirements for the competence of testing and calibration laboratories [1].“ In addition to the basic management requirements of ISO 9001, the following topics are crucial for ISO/IEC 17025 compliance:



- Instrument qualification
- Validation of analytical methods
- Traceability statements
- Evaluation of measurement uncertainty
- Ongoing education of personnel
- Periodic participation in proficiency tests to demonstrate technical capability

Analytical results produced in laboratories fulfilling ISO/IEC 17025 can be labeled with a special quality logo that confirms the reliability of the results. In every country there is at least one official body that is responsible for accreditation, and each has its own design for their quality logos. In Switzerland, it is the Swiss Accreditation Service (SAS) that gives the permission to the accredited laboratories to use the „Swiss Testing“ logo. This logo and the individual registration number of the laboratory must appear on the certificate. Furthermore, the scope of each accredited laboratory is published on the web sites of the responsible accreditation bodies.

In most cases, ISO/IEC 17025 is associated with a well-defined analytical technique and a stated measurement range comprising analyte, matrix and concentration range. This is called the scope of the accreditation. For example, Laboratory A is accredited to perform ICP-OES measurements of lead in plastics in the range of 0.1 up to 1000 mg/kg with a stated relative uncertainty of 2 up to 5%. Due to the wide variety of analytical techniques and analytes, there are many laboratories worldwide already having an ISO/IEC 17025 accreditation, each for a very specific analytical scope. Since this accreditation is an assignment of a technical competence, it goes without saying that it is strictly linked to the specified staff and

infrastructure of the accredited laboratory and can not be moved from one location to another.

ISO Guide 34 as the relevant guide for CRM producers

A CRM producer is defined as a “technically competent body that is fully responsible for the supply of the CRM and authorizes the property values assigned to the CRM.” The most appropriate document dealing with CRM production is ISO Guide 34 “General requirements for the competence of reference materials producers [2].”



This guide outlines the quality system requirements under which reference materials can be produced. It is intended to be used as part of the reference material producer's general quality assurance procedures.

The organization and management requirements, for example quality system, documentation, services and supplies, preventative and corrective actions, audits and reviews, are usually covered when the laboratory already is certified according to ISO 9001 or accredited under ISO/IEC 17025. In ISO Guide 34, there are a few additional requirements that deal with the production of CRMs:

- Production planning and maintenance of a suitable environment
- Starting materials selection and pre-treatment
- Assignment of a CRM's property values, uncertainty and traceability
- Assessment of CRM homogeneity and stability
- Assurance of adequate packaging and storage
- Certificates that include detailed information

Because many aspects of CRM production require precise measurements, for example homogeneity and stability testing, and proper data evaluation is an integral part of the certification process, a CRM producer under ISO Guide 34 must also comply with ISO Guide 31 (contents of certificates and labels) and ISO Guide 35 (general and statistical principles for certification) [4, 5].

Double accreditation: The „Gold Standard“

As mentioned previously, ISO/IEC 17025 is the common standard in analytical chemistry, while ISO Guide 34 is more relevant to CRM producers. Nevertheless, the quality of most CRMs also depends on analytical measurement capabilities. Therefore, the double accreditation achieved by following both of these guidelines is the highest achievable quality and confidence level for CRM producers. It is therefore also called the “Gold Standard” for CRM producers. In 2004, the International Laboratory Accreditation Cooperation (ILAC) began recommending this double accreditation for all CRM producers. However, only a very small group of institutes and companies worldwide are working at this level of certified quality today.

Accreditation @ Sigma-Aldrich

After receiving ISO 9001 certification in 1994, we have systematically improved and expanded our quality management systems and skills. The technical competence for CRM production at Sigma-Aldrich Switzerland is a consequence of the long-standing cooperation between our R&D group and various metrological institutes.

In mid-2007, we achieved ISO/IEC 17025 accreditation for the two scopes „mass determination through high-precision weighing“ and “gravimetric preparation of homogeneous solutions from high-purity starting materials.” By the end of 2007, we attained our second accreditation as “Producer of Certified Reference Materials” according to ISO Guide 34 in combination with ISO/IEC 17025. The scope is specified for homogeneous solutions in the concentration range of 0.5 mg/kg to 20,000 mg/kg using gravimetric preparation.

Figure 1 When climbing up the “quality ladder,” only with ISO Guide 34 (in combination with ISO/IEC 17025) can CRM producers achieve the highest level of reliability.



(continued on page 6)

TraceCERT® CRM launched

The first products developed and produced under these doubly-accredited conditions are our recently-launched *TraceCERT* calibration standards for spectrometry and ion chromatography. The name *TraceCERT* stands for Traceability and CERTified, and means that these CRMs are suitable for even the most challenging analytical applications. They also fulfill all the needs of our customers who work in regulated environments. Key characteristics of these new CRMs are:

- Unique level of accuracy and lot-specific values
- Produced in our doubly-accredited laboratory that fulfils ISO/IEC 17025 and ISO Guide 34
- Traceable to at least two independent references (NIST, BAM or SI unit kg)
- Sophisticated packaging and comprehensive documentation, including proper uncertainty calculation, expiration date and storage information

The quality of a CRM strongly depends on the quality of the starting materials and, therefore, their characterization is very important. *TraceCERT* starting materials are characterized by two different approaches: the direct measurement of the purity by the most accurate method (e.g. titrimetry) and the purity assignment by the „100% minus impurities“ approach. The combination of these two purity assignments leads to two independent traceability chains, and results in higher reliability of the CRM.

Figure 2 Only well-characterized and high-purity starting materials are used for *TraceCERT* calibration standards (clockwise from upper left: copper, zinc, nickel and gold).



More information on issues related to CRM quality and production can be obtained by reading the series of Analytix articles we published in 2006 and 2007 [6]. This series covered traceability and uncertainty assignment, handling of high-purity starting materials, production, packaging and stability studies.

References

- 1] ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, 2005.
- 2] ISO Guide 34, General requirements for the competence of reference material producers.
- 3] ISO Guide 30, Terms and definitions in connection with reference materials, 2nd Ed., 1992.
- 4] ISO Guide 31, Reference materials — Contents of certificates and labels, 2nd Ed., 2000.
- 5] ISO Guide 35, Reference materials — General and statistical principles for certification, 3rd Ed., 2006.
- 6] *TraceCERT*® – Traceable Certified Reference Materials. Part 1: Analytix, Vol. 5, 2006 and Part 2-5: Analytix, Vol. 1-4, 2007, available at www.sigmaaldrich.com/analytix.

Get your **NEW** unique microbiology database on CD (4th edition):

More than 750 microbiology products!

The CD contains a lot of new features!

- Advanced search engine – search by application, organisms, names and many other features
- Print your detailed product information
- Application information
- Directions for use
- Required additives
- Test strains
- Test principle
- References, literature

This excellent tool is free of charge!*

Just tick the box on the overleaf BRC or order online

www.sigma-aldrich.com/microbiology_cd



* The stock of this CD is limited! You will receive your Microbiology CD (code: IBG) as long as it is available.