



Trends in developments of certified reference materials for chemical analysis - Focus on food, water, soil, and sediment matrices



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ABSTRACT

The growing demand for traceable and reliable results in analytical chemistry can be illustrated with the growth in ISO/IEC 17025 accreditation. Among different technical requirements in this quality system, the use of CRMs is highlighted because of its applications in many operations, such as method validation, proficiency tests, estimation of the uncertainties and quality control.

Over the past several years, there has been an increased need to use different types of CRMs in chemical analysis, new CRM publications about its developments and certification. This paper proposes to show a detailed review considering the development of certified reference materials (CRM) for chemical analysis, focusing on food, water, soil and sediment matrices. An evaluation of the trends and best-applied practices in its development in the last 2 years was performed, to guide new developments for this material that is increasingly necessary to laboratories.

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1. Introduction

Quality has become a critical issue in different fields over the last several decades [1]. In the area of chemistry, there is an increasing demand for traceable and reliable results that can influence the quality of life and cross-border trade [2]. Therefore, it is evident that ensuring the quality of the results is vital for laboratory credibility.

Quality management systems (QMS), as the International Standard ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories), provides tools that allow the management of the administrative and technical operations carried out by a laboratory in a systematic way, which can help ensure the quality of the results [3].

The formal recognition of the implementation of a laboratory quality management system, such as ISO/IEC 17025 or ISO15189 (Medical laboratories - Requirements for quality and competence), is performed by the national accreditation bodies of different countries, which audit and assess these systems. To reach mutual recognition between the assessments of different countries, entities such as ILAC (International Laboratory Accreditation

Cooperation) promote mutual recognition agreements with their full members (actually 91 signatories from 95 economies). For entities from different countries that are ILAC members and associates, there are currently approximately 40.000 testing laboratories and 10.000 calibration laboratories that implement the system and are accredited by the quality management system according to the ISO/IEC 17025 standard, as well as 6.000 accredited clinical laboratories by the ISO 15189 standard. According to Fig. 1, these numbers continue to grow [3,4].

The international standard ISO/IEC 17025 proposes that a laboratory should establish, implement and maintain a quality system that is appropriate to the scope of its activities. The term quality assurance (QA) is directly related to the ability to provide trustworthy results that meet those quality requirements.

Within this context, three technical requirements of the ISO/IEC 17025 can be highlighted as critical operations to ensure the attainment and maintenance of reliable results: method validation, uncertainty estimation and quality control (QC). Those three requirements are part of the analytical quality assurance cycle (AQAC), which is a valuable tool that was developed to help QA in analytical laboratories, as shown in Fig. 2 [5].

As a vital part of the AQAC, QC is important for monitoring and evaluating the validity of the methods and equipment used in the laboratories' activities. Many strategies can be used in QC, such as

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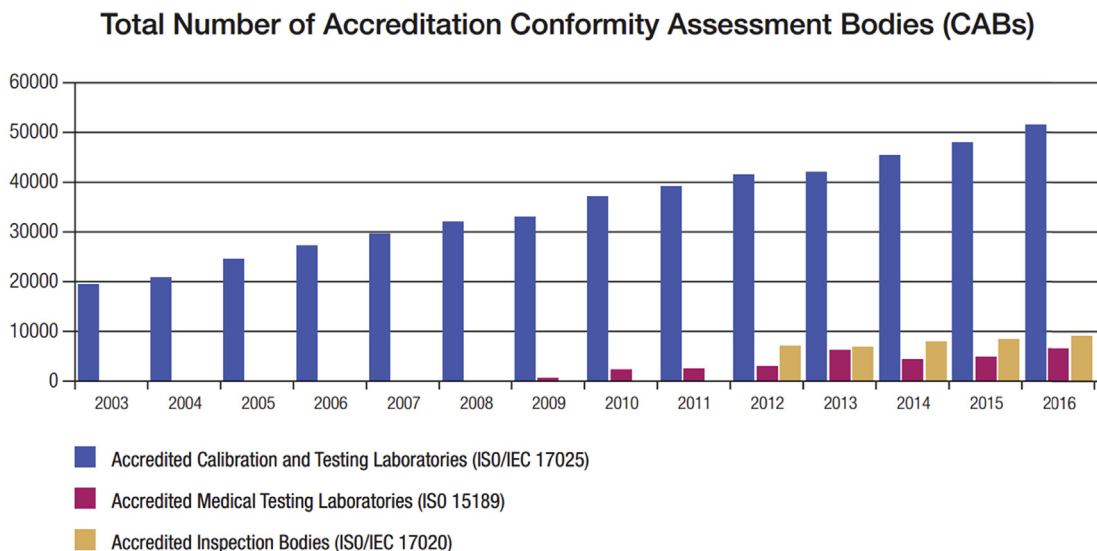


Fig. 1. Total number of accredited conformity assessment bodies. Data obtained from ILAC [4].

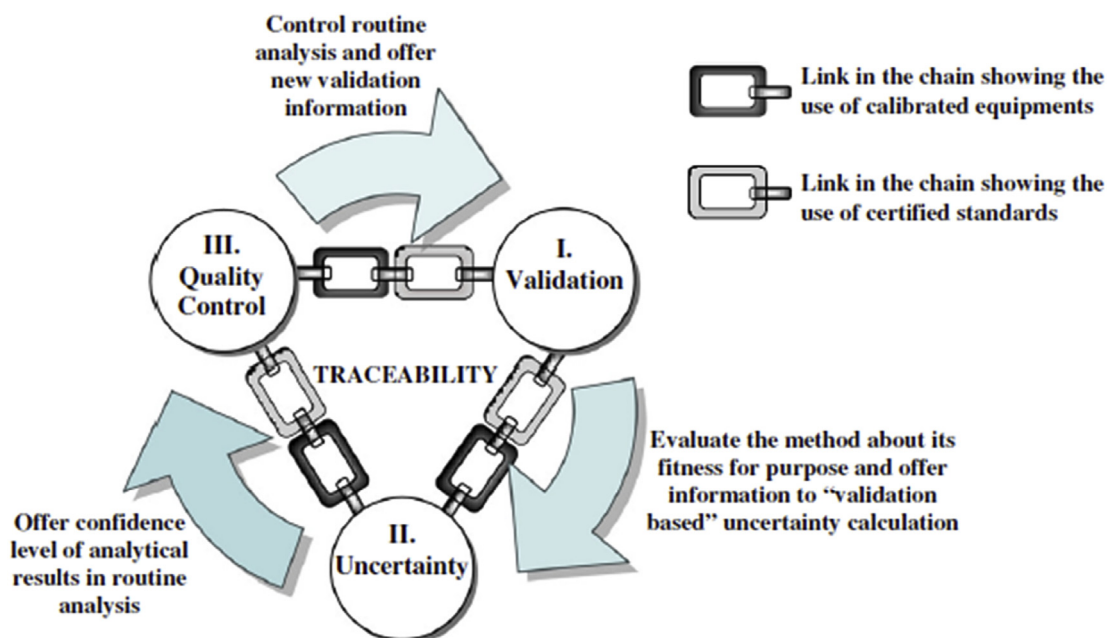


Fig. 2. The three requirements of the analytical quality assurance cycle [5].

the analyses of blanks, spiked samples, proficiency tests (PTs), reference materials (RMs) and certified reference materials (CRMs). Each one of those controls should be evaluated to consider the costs, benefits, and disadvantages.

Reference Material can be defined as a “material, sufficiently homogeneous and stable concerning one or more specified properties, which has been established to be fit for its intended use in a measurement process [6]”. However, it is important to know the values of the specific properties correctly to be used as a reference. This knowledge is very important for the certification of the candidate material to get a CRM, which can be defined as a “reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its

associated uncertainty, and a statement of metrological traceability [6]”.

The importance to developing Reference Materials could be evaluated since the 1970s. In the 1970s, Co-operation for Science and Technology (COST) in Europe was set up, and the European Union's (EU) research agenda was driven forward. This way, in 1973 the European Commission (EC) and the Member States decided to include a programme to organize interlaboratory studies and to develop CRMs as part of the Joint Research Centre (JRC) activities. This small, separate measurement programme was called the Community Bureau of Reference (or BCR). Currently, BCR acronym has achieved wide recognition in the European analytical community and is known to many laboratories worldwide. In the meantime, in the USA, the National Bureau of Standards (NBS),

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