Once upon a time: a tale of ISO 15189 accreditation

There is no doubting that healthcare professionals gave the initial impetus for establishing hospital and laboratory accreditation systems, the main purpose of which is to improve quality and patient safety, as highlighted by eminent physicians, such as Ernest Amory Codman and Avedis Donabedian [1]. After an initial pioneering stage, essentially based on the peer-review concept, some regulatory activities have inevitably gained a footing in accreditation programs. In recent decades laboratory medicine has become increasingly subject to legislation and regulation, so much so that the voluntary and educational aspects of accreditation seem to have been overlooked and displaced by an emphasis on inspection and compliance. In addition, the mounting relevance of models for quality management may shift the focus of the accreditation from its main goal – particularly in health care and in laboratory medicine – of competently providing specific services. The evolution of the accreditation of clinical laboratories in different countries was once based on distinct models, standards, and accreditation bodies, and this led to confusion and disenchantment in the laboratory community. In particular, two distinct lines of International Standard development were applied to the medical laboratory. One, ISO 9001:2000 (the latest version issued in 2008) [2], focused on the “requirements for quality management systems” applicable to any organization, and the other, ISO 17025:1999 (the latest version issued in 2005) [3], originally designed to assess the technical competence of laboratories, is a generic standard used in the accreditation of any type of testing or calibration laboratory [4]. In 2003, after a long journey, the Working Group 1 of the Technical Committee, ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic systems” (established in 1995), issued the first edition of an International Standard, the ISO 15189 “Medical laboratories – Requirements for quality and competence”, specifically designed for the medical laboratory [5]. ISO 15189 brought together the quality system requirements of ISO 9001 and the competency requirements of ISO/IEC 17025, addressing the specific needs of medical laboratory professionals worldwide. In particular, it incorporated sector specific issues of crucial importance in the provision of medical laboratory services. For example, it emphasizes the quality of not only the measurement but also that of the total service (e.g., consultation, turnaround time and cost-effectiveness), highlights important features of pre- and post-examination issues, focuses on patient outcomes and addresses ethics and the information needs of the medical laboratory [6]. The ISO 15189, developed with a significant contribution from the European Communities Confederation of Clinical Chemistry – EC4 – (now merged with the Federation of European Societies of Clinical Chemistry – FESCC – in the European Federation of Clinical Chemistry and Laboratory Medicine – EFLM), has been recognized by both the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Co-operation (ILAC). However, the standards are only one of the four elements of an accreditation system as both the accreditation body and assessors/inspectors play a relevant role. Moreover, the user laboratory represents the fourth element. It is important to bear in mind that accreditation according to the ISO 15189 International Standard was conceived as a voluntary process, as is clearly highlighted by the inclusion of a specific clause (8.4.3 in the latest revision of the International Standard) on “continual improvement”. The evidence that in some countries, such as France and, at least in part, Belgium, accreditation according to the ISO 15189 is mandatory is further proof of its value and may facilitate the efforts of clinical laboratories to comply with a series of consensually developed and harmonized requirements other than with some national or regional standards. Yet, despite its growing global recognition by the main scientific organizations in the field of laboratory medicine, in many countries only a small number of laboratories are currently accredited [7]. The reasons for the variations between countries include differences in experience, competence, the interests of national...
accreditation bodies (NABs), the availability of trained assessors and the commitment of the national scientific society in stimulating all stakeholders. The problem of harmonization of medical laboratory accreditation in Europe and elsewhere therefore needs to be addressed. In the current issue of the journal, Marc H.M. Thelen and co-workers on behalf of the Quality and Regulations Committee of the EFLM provide the guidance on flexible scopes for ISO 15189 accreditation [8].

According to ILAC and European Accreditation (EA) regulations [9, 10], the description of the scope may be either fixed or flexible. Conventionally, the scope of accreditation is described using a fixed list of all methods/calibration or examination procedures that the laboratory can use when referring to accredited status. This list, usually an annex to the certificate of accreditation, details the scope of accreditation [9]. The inclusion of all tests performed and, in turn, the need for assessors to evaluate and assess any single test, an intriguing issue, has raised concern in laboratories and representing organizations. Therefore, both EA and ILAC have published some position papers and guidelines stressing the need to accept and opt for the approach based on a flexible scope. The IFCC and the EFLM Quality and Regulations Committee have endorsed this view [11]. In particular, the EA-4/17 recognizes that the “flexible” scope of accreditation is preferred [10]. The flexible scope does not mention individual tests or services, but coherent groups of services within a medical field and with similar technical principles with provision of all applicable materials (and matrices such as serum, plasma, urine blood cultures). The laboratory shall maintain a list of all individual examinations (even in a website) that form part of its accreditation. This approach is fully in line with overall EA principles on flexible scopes as published in EA-2/15 [11]. In addition, the same document states that: 1) “for each medical field, mentioned in the scope, it is expected that the laboratory provides a full service, which includes all pre-examination, examination and post-examination aspects that are essential to provide an effective and efficient laboratory service to the patients. Within this, it is expected that a medical laboratory is able to demonstrate its competence in interpreting the results of the examinations performed”; and 2) “at a first level, the scope of accreditation shall be defined as a medical laboratory field, such as for example Clinical Chemistry, Haematology, Immunology, Microbiology, etc.” [7]. The value of the paper by the Quality and Regulations Committee of the EFLM lies in its clarification of the advantages and risks of flexible scopes and the provision of useful information on the Dutch experience of flexible scopes as an example of a pragmatic approach that should be adopted by other countries. In addition, this paper should improve the interest and concern of laboratorians regarding the issue of ISO 15189 accreditation to provide new impetus to the right path to follow. The latest revision of the International Standard [12] and the evidence in the recent literature should encourage scientific societies and laboratory professionals to understand that: 1) the main goal of ISO 15189 accreditation is to improve the quality of laboratory services provided for patients and users not only through the compliance with consensually developed and harmonized requirements but also by adopting the philosophy of continual improvement; 2) the patient-centered view of ISO 15189 accreditation calls for an evaluation of both the quality system and technical competence in delivering laboratory services, thus requiring the appropriate education and training of assessors/inspectors; 3) quality should be evaluated and improved in all steps of the total testing process as the state-of-the-art demonstrates that the pre- and post-analytical phases are more vulnerable to errors than the intra-analytical phase [13]; 4) the flexible scope allows medical laboratories to address their efforts more effectively in order to assure total quality and patient safety; 5) the harmonization of ISO 15189 accreditation in Europe and at an international level calls for close interaction and cooperation between the national accreditation bodies and scientific societies; 6) national accreditation bodies should cooperate with scientific societies to assure the competence of assessors/inspectors and guarantee an appropriate approach for evaluating the competence of a medical laboratory in providing an effective service to its customers and users; and 7) a major role should be played by the harmonization of quality indicators, which are fundamental requirement for medical laboratory accreditation [14, 15]. The journey towards a reliable accreditation system for medical laboratories started two decades ago but the time has come to provide an effective translation of the right principles to effective practice.

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