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Laboratory accreditation in Argentina

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ABSTRACT

Laboratory accreditation is an essential element in the healthcare system since it contributes substantially to decision-making, in the prevention, diagnosis, treatment and follow-up of the health status of the patients, as well as in the organization and management of public healthcare. Therefore, the clinical biochemistry professional works continuously to provide reliable results and contributes to the optimization of operational logistics and integration of a laboratory into the health system. ISO 15189 accreditation, ensures compliance of the laboratory to minimize instances of error through the planning, prevention, implementation, evaluation and improvement of its procedures, which provides skill areas that involve both training undergraduate and graduate professionals in clinical biochemistry.

INTRODUCTION

Historically the clinical laboratory has concentrated on implementing analytical quality by craftsmanship and industriousness of manual measurement procedures. Technological developments and the modular installation of automated equipment and robotics require adaptations and new tools for designing and implementation of internal and external quality control and quality assurance. At the same time, the general biomedical breakthrough of the health status and diseases have also required the clinical analysis laboratory to develop strategies to control the processes involved in the preanalytical and postanalytical stages[1]. Altogether, the three stages make up the laboratory processing and its product is the report and interpretation of results with clinical relevance. Thus, each stage requires to be monitored and controlled, and eventually would deliver reliable results that have positive impact on the care of the patient and the efficiency of the health system. There arises the concept of total quality, which views the clinical laboratory: as a comprehensive organization, where "quality is assured in all parts of the laboratory".

The standard to implement in the clinical laboratory, is the international standard ISO 15189 – Medical laboratories - particular requirements for quality and competence[2], in their latest improved version 2012, is the product of discussion and consensus of the international scientific community whose guidelines are based on management and technical requirements that ensure the compliance with the laboratory to minimize instances of error through the planning prevention, implementation, evaluation and improvement of its processes. The independent assessment of conformity of their requirements is subject to accreditation bodies around the world that guarantee through the granting of accreditation, that the medical laboratory meets the requirements of technical competence as well as the management system of quality, which ensure results technically valid, reliable, and timely analyses under the accredited scope.

ARGENTINIAN ACCREDITATION AGENCY

In Argentina, the Argentine accreditation organization - OAA[3], as signatory of the multilateral recognition agreements in the field of ILAC (International Laboratory Accreditation Cooperation) and IAAC (inter-American accreditation cooperation), implemented this international recognition to accredited medical laboratories[4]. The OAA was created by a Presidential Decree (1474/94)[5] and, it is a central element in the development of Argentina. Within the process of accreditation and numerous rules of accreditation, the OAA considered essential that medical laboratories were accredited under standard IRAM ISO 15189:2014[6] (equivalent to the ISO 15189:2012 translated by the Standardization Organization of Argentina), then allows that such laboratories, demonstrating compliance in the analytical quality management system, constitute a group of reference laboratories and laboratories of derivation for the medical laboratories in the country. Pharmaceutical industry requires accredited laboratories for clinical drug trials, clinical follow-up of patients involved in their protocols. Accredited laboratories play a key role, contributing with their results in the monitoring of these patients. Similarly, they also make available this information to the IVD (in vitro diagnostic) and medical technology industry.

Within its activities, OAA collaborates in the development of the model of accreditation for clinical laboratories of other American agencies through training and assessments of training of assessors to strengthen the accreditation of laboratories in the region. In this sense, an

accredited clinical laboratory has an organizational structure in which it is defined the direction and responsibility of staff attending, highlighting the figure of the technical supervisor or quality manager; facilitating the effective and efficient communication of staff within the organization; the availability of resources that allow the optimal development of the preanalytical, analytical and postanalytical activities including procedures pertaining to hygiene and occupational safety. Also, compliance by a medical laboratory of the 10 points of technical requirements (5.1 to 5.10) of the current version of the IRAM ISO 15189, are backed by 15 points developed in the management requirements, these laboratories allow access to a level of performance where the position of the profession through the full implementation of the quality is the daily dynamics of developed actions.

LABORATORY ACCREDITATION PROCESS

In Argentina, laboratory accreditation is a voluntary field unlike in other countries where accreditation is mandatory for the entire scope of laboratory or some of its disciplines. This, along with the challenge to overcome preconceived concepts of quality costs, results in a reduced number of accredited laboratories in relation to the total number of laboratories in the country. In contrast to this, most of the professionals are looking for the reliability of its services having already started in implementing quality in their laboratories, with management standards or progressive compliance of quality programs supported by the IRAM ISO 15189.

However, the application of the IRAM ISO 15189 standard requires, at least in Argentina, to promote areas of skills that involve both, undergraduate and graduate professionals in clinical biochemistry to create a "culture of total quality" led within the conceptual framework of the own standard. In this sense, the Republic of Argentina within the framework of the law on higher education (Law 24.521; Decree 268/95)[7] in its article 43 establishes that titles defining the profession regulated by the State "which might compromise the public interest by putting at risk in a direct way the health, safety,... require in addition to the daily work load, what the preceding article is referring; then the following requirements should be addressed: (a) the curricula should take into account the basic curricular contents and criteria about the intensity of the practical training that establishes the Ministry of culture and education, in agreement with the Council of universities; (b) the respective careers shall be credited periodically by the National Commission for University evaluation and accreditation or by private entities established to that end duly recognized." In this sense, Biochemistry or Clinical Biochemistry titles issued by Argentine universities are included in the article 43 of the Act. To do this, this career must meet certain standards established by the National Ministry of education based on five dimensions; one of these dimensions is the own study plan of the university career [8]. In this strategy, one of those core curricular aspects are in analytical chemistry and clinical analysis content, addressing other aspects of metrology, traceability, uncertainty, method verification, quality and quality assurance, requirements which are referred to the technical requirements within the standard IRAM ISO 15189.

UNDERGRADUATE AND GRADUATE PROGRAMS

At the Faculty of Chemical Sciences of the National University of Cordoba (FCQ-UNC), that issued the title of Biochemist, these contents are taught and developed in the subjects of chemical biological analytical and preparatory decision as part of the professional cycle and applied during the fulfillment of the professional practice [9]. In addition to this training, similar

contents are taught and developed in different courses of specialization in clinical biochemistry, hematology, clinical chemistry, immunology, among others[10]. The center of Applied Chemistry (CEQUIMAP) of the FCQ-UNC[11] was also one of the first laboratories accrediting standards of quality in the country according to IRAM 301 (equivalent to ISO/IEC 17025). Also, the implementation of the standards ISO 15189 and IRAM 301 in the laboratory, resulted in the training of teaching and scientific criteria of quality, both as technical management, which is translated in an efficient manner at the academic level to the students of undergraduate and graduate levels at this faculty.

CONCLUSION

In Argentina, without a doubt, this formal training developed by the universities of the country would result in naturalization in the implementation of total quality and continuous assurance of quality in clinical laboratories. This would benefit the public health and the society in general. It is undisputed that the first step is already implemented in several laboratories; this is the beginning of the paradigm of transformation of clinical laboratories in Argentina.

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