

The accreditation experience of clinical laboratories and blood banks in Mexico

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ABSTRACT

The accreditation of clinical laboratories and blood banks based on ISO 15189 is now being consolidated in Mexico, and is coordinated by the Mexican accreditation entity innovative strategies, A.C. (ema) and supported by the activities of the committee of clinical laboratories and blood banks. The active participation in working groups formed by the technical committee of clinical laboratories and blood banks in specific areas, has contributed to the formulation of technical documents and criteria of evaluation that strengthen the current accreditation scheme. The national registry of evaluation (PNE) consists of technical experts and evaluators from different disciplines of clinical laboratory; the evaluators actively participate in accreditation assessment, with an ultimate goal to receive training and feedback for continuous improvement of its own performance.

INTRODUCTION

Accreditation in Mexico under the ISO 15189 standard is being implemented as a culture of quality that seeks the systematization and the reliability of the systems of quality management of clinical laboratories and blood banks, with international requirements of technical competence, recognized and functionally suitable for its operation. Accreditation assessment considers the system of quality management and technical competence as: competence of the personnel, methods validated and verified, traceability of measurements, calibration and maintenance of equipment, environment for carrying out the tests, assurance of the quality of the results, handling and transportation of samples and all the stages of the analytic process¹. Accreditation is the formal and public recognition by an impartial body and third party of the technical competence and reliability of a clinical laboratory and blood bank, to provide services through compliance with the requirements set out in the ISO 15189 standard. In Mexico the responsible organization for evaluation that confers recognition is the Mexican accreditation entity, A.C. (ema)².

PROCESS OF ACCREDITATION IN MEXICO

ema began operating on January 15, 1999, with the permission of 9 units of the Federal Executive, which issued the official Mexican standards of enforcement, as such forming the basis for accreditation by Mexico's privately run, non-profit organization⁴. The main aim of this professional body is to promote reliability and provide expertise on conformity. It emerged when Mexico was negotiating the Treaty of free trade in North America (TLCAM: United States, Canada and Mexico) with subsequent reform of the Federal law of metrology and standardization. Previously this role was carried out by the

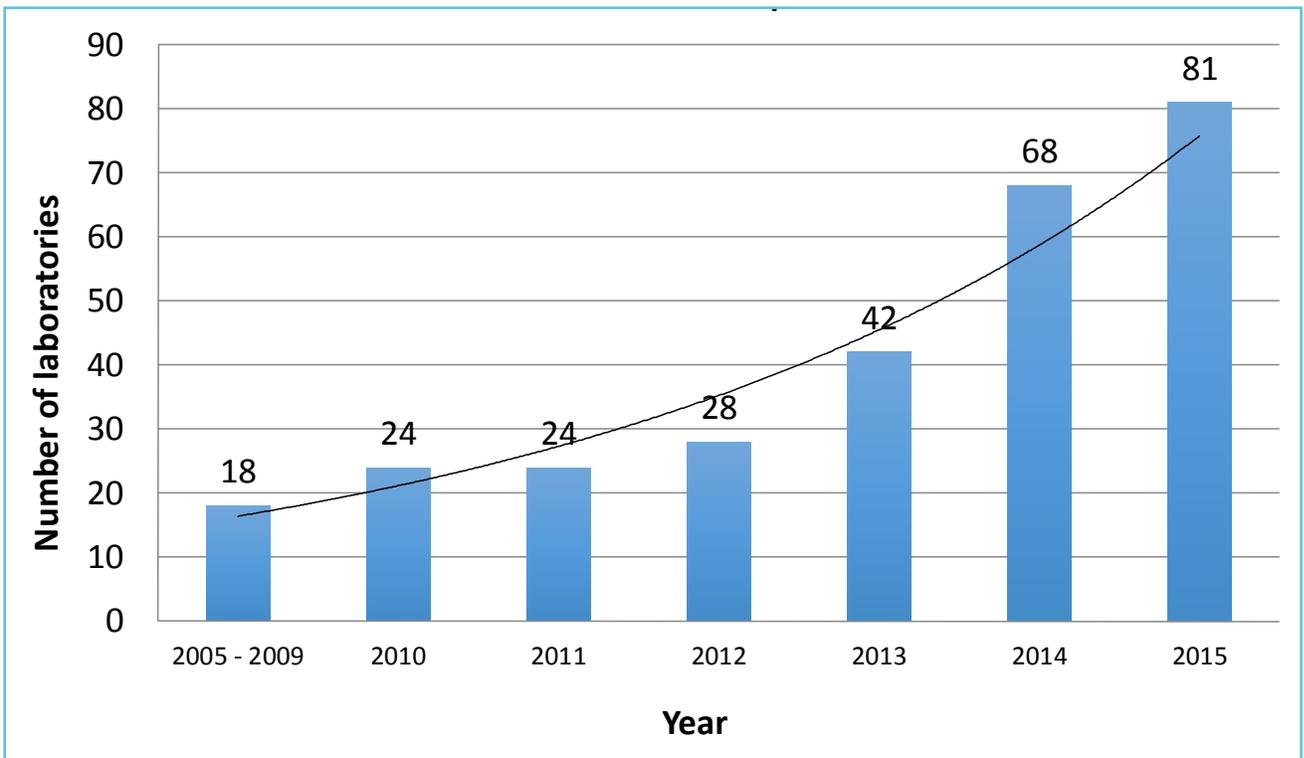
Federal Government through the General direction of rules of the Minister of Economy³.

IMPLEMENTATION OF THE MEXICAN VOLUNTARY STANDARD FOR THE ACCREDITATION OF MEDICAL LABORATORIES AND BLOOD BANKS

Services of evaluation and accreditation for clinical laboratories and blood banks under the ISO 15189 standard, approved by the Mexican norm NMX-EC-15189-IMNC, began in 2005, and until 2009 credited 18 clinical laboratories, and by 2012 had another 28 clinical laboratories and 2 accredited blood banks. In search of new strategies for the growth of the sector, it promotes accreditation under this international standard. Currently there are 4 blood banks and 81 accredited clinical laboratories (see Figure 1.) following a second-order polynomial growth, as shown in the equation presented in the same graph. Mexico is ranked second in the Americas, as regards to the number of accredited laboratories: This is in contrast to Canada, which has 184 accredited clinical laboratories, where accreditation is mandatory³.

COMMITTEE ON MEDICAL LABORATORIES AND COMMITTEE OF BLOOD BANK LABORATORIES

The Committee on clinical laboratories and the Committee from blood banks, which are made up of heterogeneous group of stakeholders and experts in the field, was set up to decide upon the evaluation criteria. The committees gather monthly to determine and develop evaluation criteria, furthermore develop guidelines and protocols for verification; currently its working groups have formed: the guideline for the quality control of quantitative methods in the clinical laboratory and the guideline for validation and verification of qualitative methods, furthermore they are involved in updating other documents. In January of this year, they started updating

Figure 1 Number of clinical laboratories accredited in Mexico per year

the guide of traceability metrology of the values assigned to calibrators and control employed by the clinical laboratory. This material was prepared in conjunction with the National Center of Metrology (CENAM), while the guideline for the validation and the verification of the quantitative test used by clinical laboratory procedures is also under review⁶. In Mexico, the labs have guidelines that allow them to understand, implement and comply with accreditation criteria, facilitating the preparation of the accreditation process by the ISO 15189 standard⁷.

NATIONAL REGISTRY OF ASSESSORS

For audit and evaluation purposes a team of evaluators has been conceived. This panel of evaluators is the national registry of appraisers (PNE)⁷, currently consisting of 5 leading evaluators, 8 evaluators, 8 evaluators in training and 44 technical experts. To streamline the accreditation process there is a strategic plan for the

formation of a group of leading technical assessors and technical assessors.

Assessors and technical experts receive ongoing training by *ema*, with online training, through the system of educational administration (SADE), with courses and in-person workshops; some of which are mandatory and essential to the permanence in PNE and the allocation of assessments. The SADE is a tool available to all members of the PNE, as one of the benefits of its services and participation; courses are assigned, according to the area in question, in order to acquire or strengthen their knowledge, either to increase their level of qualification within the PNE, or to use as query or update mechanism. Also included is the assessment of performance, attention to complaints, congratulations and monitoring reports.

In addition, meetings, courses and workshops are organized with providers of clinical laboratories and blood banks, who have offices or

representations in Mexico looking for informed and above all approved criteria based on ISO 15189. This is also done with providers of proficiency testing⁸ of programs accredited on the basis of the ISO 17043.

The accredited laboratory must comply with guidelines related to programs of proficiency testing, which are embodied in a document of the *ema* known as: fitness testing policy. This document requires laboratories to participate in proficiency testing that meet ISO/IEC17043 Guide: 2010 (NMX_EC:17043 - IMNC - 2010). Currently it comprises 5 programs of proficiency tests accredited by the institution in the area of clinical laboratories and blood banks. Also laboratories have the opportunity to participate in any other international programs that are recognized by a mutual recognition agreements in which *ema* is a signatory.

QUALIFYING CLINICAL AND BLOOD BANK LABORATORY DISCIPLINES

The *ema* provides accreditation in the disciplines of: hematology and coagulation, clinical chemistry, immunology and immunochemistry, microbiology, mycology and bacteriology, parasitology, urinalysis, pathology, cytopathology, molecular biology, histocompatibility and genetics, toxicology, flow cytometry and transfusion medicine. Having the largest number of accredited disciplines: clinical chemistry (60), immunology and immunochemistry (55), hematology and coagulation (33) and urinalysis (28)⁹.

WORKING GROUP OF ACCREDITED LABORATORIES AND ACCREDITED BLOOD BANKS

Laboratories accredited periodically receive feedback and update, some of them work in a program known as: adopt a lab, which consists of an accredited laboratory adopting to another that is not, in order to support it with advice,

paving the way for its accreditation. Also participating in some other activities to promote accreditation and the transparency in the process, such as the Organization of the first inter-American Congress for the accreditation of clinical laboratories, blood banks and hematopoietic progenitor cells in August 2015, where the slogan was: “delivering confidence to the sector health and social care”, which highlights the importance of accreditation in the sector health.

In Mexico, the international version of upgraded ISO 15189:2012 was translated and approved by the Instituto Mexicano de normalización y certificación A.C., and it issued the Declaration of validity in the Official Gazette from May of 2015, under the name NMX-EC-15189-IMNC-2015¹⁰.

INTERNATIONAL RECOGNITIONS

The accreditation of clinical laboratories and blood banks under the standard ISO 15189 in Mexico, is supported by all the international players in the field of accreditation¹¹, which are: the International Forum of Accreditation (IAF), the International Laboratory Accreditation Cooperation (ILAC), Inter-American Cooperation of Accreditation (IAAC), the Laboratory Accreditation Cooperation of Asia Pacific (APLAC) and the Cooperation of Accreditation of the Pacific (PAC)¹².

Thus, the function of *ema* is comparable with the entities of Spain (ENAC), Canada (SCC), United States (ANAB), Japan (JAB), Brazil (INMETRO), Argentina (OAA) and France (COFRAC), among others. The *ema* works continuously to improve the technical competence of the accredited staff, evaluators and colleagues, innovating with new evaluation, accreditation and training services.

ACTIVITIES BEYOND EMA

Mexico celebrated, on the 9th of June 2015, the world accreditation day with an academic event where it recognized different sectors and clinical

laboratories for its outstanding contributions to the accreditation of proficiency testing and blood banks. The slogan of the day was “giving confidence to the health sector and social care”.

CONCLUSION

Accreditation in clinical laboratories and blood banks in Mexico is a reality that increasingly attracts a good number of laboratories. Its growth is based on the implementation of a culture of quality for the improvement and continuous training of all stakeholders.

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