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Introduction

<i>Fikriye Uras</i>	229	Editorial
<i>Edgard Delvin</i>	231	Editorial

Full Length Articles

<i>W. Greg Miller</i>	232	The role of proficiency testing in achieving standardization and harmonization between laboratories
<i>Mauro Panteghini</i>	236	Traceability as a unique tool to improve standardization in laboratory medicine
<i>HA Morris</i>	241	Traceability and standardization of immunoassays: A major challenge
<i>Paul De Bièvre</i>	246	The 2007 International Vocabulary of Metrology (VIM), JCGM 200:2008 [ISO/IEC Guide 99]: Meeting the need for intercontinentally understood concepts and their associated intercontinentally agreed terms
<i>Hui Li and Khosrow Adeli</i>	249	Laboratory quality regulations and accreditation standards in Canada
<i>Ali S. Qatishat</i>	256	Medical laboratory quality and accreditation in Jordan
<i>Manzoor Ahmad, Farooq Ahmad Khan, and Sadia Atif Ahmad</i>	259	Standardization of pathology laboratories in Pakistan: Problems and prospects
<i>Fikriye Uras</i>	263	Quality regulations and accreditation standards for clinical chemistry in Turkey
<i>Sedef Yenice</i>	266	Implementing a resource management program for accreditation process at the medical laboratory

continued on back cover

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ISO 15189 accreditation in medical laboratories: An institutional experience from Turkey

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Accreditation is defined as a voluntary process by which the organization is certified by an independent body. It confirms the confidence of the performance of the organization. The accreditation process focuses mainly on the technical part of the services provided.

The International Organization for Standardization, ISO, is a non-governmental organization. The main purpose of ISO is to develop internationally recognized standards. It is well known that ISO standards are not product standards. They are in fact, concerned about management and processes. Specific standards have more technical and specific approaches. An example is ISO 15189: 2003—Medical Laboratories, particular requirements for quality and competence is an example of a specific standard.

ISO 15189: 2003 is becoming a widely accepted standard to be used for accreditation of clinical laboratory competence. It usually allows laboratories to organize their operational procedures effectively to fulfill the expectations of clients and to improve the services they provide. The ISO 15189:2003 standard is important for assessing the competence of the medical laboratories in their technical capacity and quality management of a professional service and its staff with or without the aim of accreditation. The ISO 15189:2003 is not a certification standard but an important guide for technical approach.

The ISO 15189: 2003 standard is composed of two parts: first part contains management requirements, which is related to quality management systems, and the second part

contains technical requirements. The first part of ISO 15189 is completely based on the ISO 9001: 2000 requirements. The second part of ISO 15189 presents the technical requirements that are directly applicable to technical accreditation of the clinical laboratory competence. Here, the laboratory world will recognize the terminology more easily, because it is more specific to clinical laboratories; for example, the main steps of the analytical procedures are called pre-examination, examination and post-examination procedures (usually called pre-analytical, analytical and post-analytical procedures by other accreditation standards, respectively).

Our laboratories were established in Turkey in 2002 and provide laboratory services in a central laboratory, 6 different hospitals, 6 out-patient clinics and in 2 regional laboratories, in clinical chemistry, hematology, immunology, microbiology and virology in a multidisciplinary manner. The process of certification started in 2004 after being assessed and certified by SGS, as meeting the requirements of ISO 9001: 2000 Quality Management Systems. We were accredited in the scope of accreditation of Acibadem Healthcare Group according to JCI standards in February 2005. We were successfully audited by Deutsche Akkreditierungsstelle Chemie (DACH) in October 20, 2005 and were honored to be the first clinical laboratory awarded the ISO 15189 accreditation standard in Turkey. External audits were successfully completed in 2006 and 2007. Our quality policy and quality objectives were identified and documented in our quality manual. Together with the quality manual, 22 laboratory procedures, 236 laboratory instructions, 313 follow-up forms and 23 job identifications have been prepared according to standards and communicated to all relevant personnel. In the presentations, the experiences in

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different steps of examination procedures will be evaluated with examples.

As a conclusion, although it is well known, ISO standards are new in healthcare laboratory services. In the last few years, ISO 15189 standard has been becoming more important for

medical laboratories and is now the most used international quality model in medical laboratories. We believe that all countries will use ISO 15189 for the accreditation of all their medical laboratories in the near future in order to be competitive in a global environment.