

# Chapter 37

## Accreditation of Medical Laboratories: Challenges and Opportunities

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### ABSTRACT

*Quality test results generated by medical laboratories across the globe are critical for patient diagnosis and treatment. In addition, this is an area of healthcare that requires standardization. Accreditation is the formal recognition by an authoritative body noting that the clinical laboratory has an established quality*

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*management system and is competent to carry out specific tasks related to testing. The Strengthening Laboratory Management Toward Accreditation (SLMTA) program was established to strengthen national laboratory systems and to drive improvements that are immediate and measurable in developing countries, particularly those in Sub-Saharan Africa. This review seeks to look at opportunities that can be garnered by accredited medical laboratories and challenges in seeking accreditation during the implementation and operational states of the criteria of ISO 15189:2012. It also examines the progress toward clinical laboratories becoming accredited due to the enactment of the SLMTA in resource-limited settings.*

## **INTRODUCTION**

Services offered by clinical laboratories are critical to patient care in the healthcare sector. Therefore, they should satisfy the needs of patients and all stakeholders, including physicians. These services are a fundamental part of clinical decision making; laboratory results are the keystone for diagnosis, monitoring, and treatment of diseases. It is reported that approximately 60% to 80% of clinical decisions regarding patient management involve the use of laboratory data (Forsman, 1996). Such investigations are frequently more specific and sensitive than those limited to criteria related to clinical decisions (Mee, Fielding, Charalambous, Churchyard, & Grant, 2008).

Accreditation, as a valued tool for medical laboratories, is recognized worldwide as an effective means of validating the competence of the laboratory. This offers the highest standard of test results and services to clients, including patients and healthcare providers (Kawai, 2010). While accreditation of medical laboratories is mandatory in most countries, it remains voluntary in other countries (Handoo & Sood, 2012). Accreditation involves an independent or authoritative body that certifies that the applicant laboratory meets management and technical requirements and demonstrates competence to successfully complete specific tasks (Kawai, 2010).

International Organization for Standardization (ISO) 15189, based upon ISO 9001 and ISO 17025 standards, affords requirements for quality and competence of medical laboratories (Guzel & Guner, 2009). Many countries have adopted ISO 15189 for their accreditation of medical laboratories, particularly for improving the quality management system, technical competence of staff, and patient safety (Akyar, 2009). There is widespread use of the standard among medical laboratories as a self-assessment tool and by accreditation bodies for both certification and regulation (Handoo & Sood, 2012).

Medical laboratories seeking accreditation using ISO 15189 are faced with many challenges, including insufficient infrastructure, low management support, and increased documentation. Accredited medical laboratories enhance the credibility and competency of their testing services (Peter et al., 2010). On the other hand, medical laboratories that are accredited are known to improve the accuracy of their test results, facilitate rapid diagnostics, and decrease errors at the preanalytical, analytical, and postanalytical stages thus improving quality and safety of patients (Gough & Reynolds, 2000).

This article seeks to examine opportunities that can be garnered by accredited medical laboratories and challenges in seeking accreditation during the implementation and operational states of the ISO

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