Joint IAF-ILAC-ISO Communiqué
on the
Management system requirements of ISO 15189:2012 - Medical laboratories - Particular requirements for quality and competence

A medical laboratory's fulfilment of the requirements of ISO 15189:2012 means the laboratory meets both the technical competence requirements and the management system requirements necessary for it to consistently deliver technically valid test results. The management system requirements in ISO 15189 (Section 4) are written in a language relevant to a medical laboratory’s operations and meet the principles of ISO 9001:2008 Quality management systems - Requirements and are aligned with its pertinent requirements.