

ISO, ILAC and IAF streamline quality management requirements for medical laboratories

Medical laboratories accredited to ISO 15189:2012 (a sector-specific technical competence and management system standard) are recognized as meeting the management system principles of ISO 9001:2008.

The move was announced in a joint communiqué by ISO (the International Organization for Standardization), ILAC (the International Laboratory Accreditation Cooperation) and the IAF (the International Accreditation Forum) in September 2009 and updated in January 2015 as a result of the revision of ISO15189 in 2012.

The ISO-IAF-ILAC communiqué was issued to address the misconception in the market that medical laboratories accredited to ISO 15189:2012 do not operate a recognized management system.

Until now, accredited medical laboratories were often requested by their customers to undertake the additional step of obtaining certification to ISO 9001:2008 to demonstrate that they are in full control of their processes.

Medical laboratories accredited to ISO 15189 have demonstrated that they also meet the management systems principles of ISO 9001:2008. Accredited medical laboratories that are included in the scope of a larger organization's certification to ISO 9001 should only need to be assessed according to ISO 15189, and these results will be accepted as meeting the principles of the management system requirements (ISO 9001:2008).

This recognition will improve the efficiency of audits and enable medical laboratories to better meet their customers' needs.

NOTE to editors: ISO is the developer and publisher of ISO 15189 and ISO 9001, but does not itself carry out auditing/assessing, accreditation and certification. These services are performed independently of ISO by accreditation and certification bodies. ISO does not control such bodies, but does develop voluntary International Standards to encourage good practice in their activities on a worldwide basis.

ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures and the promotion of calibration and testing laboratory and inspection accreditation. This accreditation ensures that decisions on international trade, public health and environmental issues are based on reliable, reproducible and accurate data. As well as working in other fields, national accreditation bodies that are members of ILAC assess and declare the competence of medical laboratories against the requirements of ISO 15189.

IAF is the world association of accreditation bodies and other bodies interested in the accreditation of conformity assessment bodies providing certification services. Its primary function is to develop world wide programs of accreditation that promote the elimination of non tariff barriers to trade. Accreditation bodies declare the competence of conformity assessment bodies in the fields of management systems, products, services, personnel and other similar programs of conformity assessment.