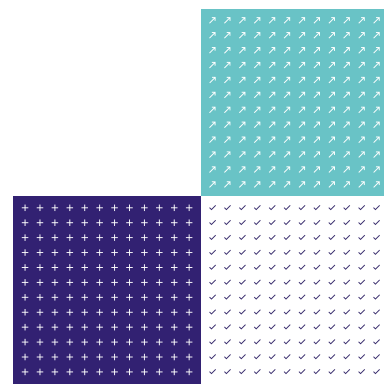


TPS 53

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Management system requirements of laboratories (ISO/IEC 17025 and ISO 15189) and inspection bodies (ISO/IEC 17020)

**- Statements for use on test, examination, calibration
and inspection reports/certificates**



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Changes since last edition

This publication has been revised following an update to the Joint IAF-ILAC-ISO Communiqué relating to ISO/IEC 15189.

1. Background

Following the alignment of ISO/IEC 17025 with ISO 9001:2000 and its publication as ISO/IEC 17025:2005, the joint working group of ISO-ILAC-IAF issued a communiqué concerning the management system requirements of ISO/IEC 17025:2005. The intention was to provide a means by which a laboratory's customers could be informed that the management system of a laboratory accredited to ISO/IEC 17025:2005 met the principles of ISO 9001:2000 and that separate certification (registration) to ISO 9001 was therefore unnecessary. Following the revisions of ISO 9001 in 2008 and 2015 this communiqué was updated by the joint working group and reissued to ensure that the intention was maintained.

In recognition of the benefits of such a communiqué the joint working group of ISO-ILAC-IAF undertook to produce a similar communiqué relating to management system requirements of ISO 15189 to reinforce the fact that medical laboratories also operate a recognised management system. The initial communiqué was issued in 2009, with further revised versions issued in 2015 (following the revision of ISO 15189 in 2012) and 2021 (future-proofing the communiqué by removing the publication year of the standards).

A further Joint IAF-ILAC-ISO Communiqué on ISO/IEC 17020 accreditation was issued in 2013 to reinforce the fact that inspection bodies accredited to ISO/IEC 17020:2012 also operate a recognised management system.

The joint communiqués are available on the UKAS website www.ukas.com but the text from each is given below for convenience.

Joint ISO-ILAC-IAF Communiqué (ISO/IEC 17025)

"A laboratory's fulfilment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001."

Joint ISO-ILAC-IAF Communiqué (ISO 15189)

"A medical laboratory's fulfilment of the requirements of ISO 15189 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 are written in language relevant to a medical laboratory's operations. Medical laboratories that implement ISO 15189 operate generally in accordance with the principles of ISO 9001."

Joint ISO-ILAC-IAF Communiqué (ISO/IEC 17020)

"An inspection body's fulfilment of the requirements of ISO/IEC 17020:2012 means the Inspection body meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid inspection results. The management system requirements in ISO/IEC 17020:2012 (Section 8) are written in language relevant to inspection body operations and are aligned with the pertinent requirements of ISO 9001."

2. Policy

UKAS has defined the following statements that accredited laboratories and inspection bodies may use on test/examination reports, calibration certificates and inspection reports:

Statement on test reports and calibration certificates (ISO/IEC 17025)

“This laboratory is accredited in accordance with the recognised International Standard ISO/IEC 17025. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer joint ISO-ILAC-IAF communiqué dated April 2017).”

Statement on medical test/examination reports (ISO 15189)

“This laboratory is accredited in accordance with the recognised International Standard ISO 15189. This accreditation demonstrates technical competence for a defined scope and the operation of a medical laboratory quality management system (refer joint ISO-ILAC-IAF communiqué dated November 2021).”

Statement on inspection reports (ISO/IEC 17020)

“This inspection body is accredited in accordance with the recognised International Standard ISO/IEC 17020:2012. This accreditation demonstrates technical competence for a defined scope and the operation of an inspection body quality management system (refer joint ISO-ILAC-IAF communiqué dated September 2013).”

The statement above is the only form of words permissible when making reference to the laboratory or inspection body quality management system on reports and certificates.

The relevant Joint ISO-ILAC-IAF communiqué must be supplied to customers when one of the above statements is used; alternatively the customer’s attention must be drawn to a website where the communiqué is available.

The statement may not be used until the accreditation certificate to ISO/IEC 17025, ISO 15189 or ISO/IEC 17020 is issued to the laboratory/inspection body.