

Implementation of ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence

Background and Rationale for this ISO 15189 amendment, published 19 April 2007.

ISO TC212 WG1 gave an undertaking to make the necessary changes to ISO 15189 to preserve alignment with *ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories*.

The main changes introduced into the 2003 version of 15189 are as follows:

Introduction:

- 1) New fifth paragraph, copied with minor changes from ISO/IEC 17025:2005.

NOTE: The statement that this standard is not intended to be used for certification is included here, rather than in the Scope, as in ISO/IEC 17025:2005. This is in accordance with the strong preference expressed by WG1 members at the Mexico meeting that this statement should be part of informative rather than normative text.

- 2) New sixth paragraph stating the reason for the changes
- 3) Deletion of text no longer needed in the new edition.

Scope:

New subclause added, with wording modified from ISO/IEC 17025:2005.

Normative references:

Deletion of Guide 2 (no longer relevant).

ISO 9000 and 9001 moved to the Bibliography, as in ISO/IEC 17025:2005.

Addition of ISO/IEC 17025:2005.

Terms and definitions:

Addition of a definition of “accreditation” corresponding to the definition given in ISO/IEC Guide2:1996.

NOTE: This is needed because the old ISO/IEC Guide 2:1996 has been replaced by Guide 2:2004 which no longer includes this definition. There is a new definition of “accreditation” in ISO/IEC 17000, but this refers only to accreditation of conformity assessment bodies.

Clause 4:

Addition of new subclause 4.1.6 adapted from subclause 4.1.6 of ISO/IEC 17025:2005.

In subclause 4.4.4, replacement of “Clients” by “Customers”

NOTE: the term “client” or “clients” only appears once in the existing ISO 15189 texts.

In subclauses 4.11.1 and 4.14.2, replacement of “quality system” by “quality management system” for consistency with the rest of the document.

Annex A:

Changed to Informative, as in ISO/IEC 17025:2005, rather than Normative.

New Table A2.

Bibliography:

Insertion of references to ISO 9000:2000 and ISO 9001:2000.

Updating title of ISO/IEC 17011.

General:

Minor editorial amendments following from the above changes.

ARC discussed the implementation of the new standard and proposed a transition period of two years.