

Transition to ISO 15189:2007

In April 2007, the second edition of ISO 15189 “Medical laboratories – Particular requirements for quality and competence” was published. Changes made in this edition aimed at preserving alignment with ISO/IEC 17025 by taking into account the changes made in the 2005 edition of ISO/IEC 17025.

HKAS Executive has decided to allow a two-year transition period to the new version. This article summarizes the changes and up-dates in the 2007 edition of ISO 15189 and provides details of the transitional arrangements. A new edition of HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories), which incorporates the changes in ISO 15189:2007, is now being printed and will be provided to applicant and accredited medical laboratories when available. Laboratories confirmed to be compliant with ISO 15189:2007 will be issued new certificates of accreditation referring to the new version of ISO 15189 to replace existing certificates referring to the old version.

Summary of changes

The added and amended clauses deal primarily with how laboratory management ensures effective communication. A new clause 4.1.6 concerning effective communication within the laboratory has been added.

Another change that may affect laboratories is the change of “should” to “shall” for records to be kept in the inventory control system (Clause 4.6.3).

Generic Changes: Terminology

To align with ISO/IEC 17025:2005, the term “client” used in the old version has been replaced by “customer”. Although, ISO/IEC 17025:2005 also replaced “quality system” by “management system”, the ISO Technical Committee 212 responsible for writing ISO 15189, however, has decided to retain the term “quality management system” to upkeep with the principle that ISO 15189 should use language and terms familiar to medical laboratory professionals.

Specific Changes

Details of the changes are given in Annex I.

Transition Plan

With immediate effect, HKAS starts to accept applications for initial accreditation and extension of accreditation in accordance with ISO 15189:2007.

For assessments or reassessment to be conducted before 31 Dec 2007, the laboratory may choose to be

assessed against the requirements of ISO 15189:2003 or ISO 15189:2007. For laboratories elected to be assessed against the new standard, if they are found to be not fully compliant with the new/amended requirements of ISO 15189:2007, accreditation will still be reconfirmed/granted based on ISO 15189:2003. Laboratories not yet compliant with the 2007 version when they are being assessed before 31 Dec 2007 will be reassessed against the 2007 version on HKAS's next visit in 2008 or 2009 (whether it is a surveillance, reassessment, assessment for extension of scope of accreditation or a follow-up visit). These laboratories shall fully comply with the requirements of ISO 15189:2007 before March 2009. Laboratories must provide sufficient evidence of conformity with the new version before the said date. Where necessary, an on-site assessment or surveillance visit will be arranged to confirm conformity with the new version. Accredited laboratories which have not provided sufficient evidence of conformity with the new version to HKAS Executive by 1 April 2009 may have their accreditation suspended.

Laboratories to be assessed or reassessed after 31 Dec 2007 will be assessed against the requirements of ISO 15189:2007. Initial applications for accreditation or applications for extension of scope of accreditation based on ISO 15189:2003 will not be accepted after 30 September 2007.

Before 30 September 2008, for laboratories electing to continue to use the old version, the NCs against the new requirements will be raised as recommendations, and such recommendations will automatically turn into NCs after that day. Initial accreditation or extensions of scope of accreditation based on ISO 15189:2003 will no longer be granted after the same date.

Laboratories seeking extension of scope of accreditation based on the new version will only be granted such accreditation after conformity with the new version for all tests already accredited has been confirmed.

Important dates for this transition plan are summarized in the following table:

Important date	Event
1 July 2007	HKAS Executive starts to accept initial applications for accreditation and applications for extension of accreditation based on ISO 15189:2007
30 September 2007	HKAS Executive stops to accept initial applications for accreditation and applications for extension of accreditation based on ISO 15189:2003
1 January 2008	Starting from this date, all assessments will be based on ISO 15189:2007
30 September 2008	<ol style="list-style-type: none"> 1. Non-conformities against new requirements of ISO 15189:2007 raised as recommendations previously will become non-conformities 2. HKAS Executive stops granting initial accreditation or extension of accreditation based on ISO 15189:2003
31 March 2009	All accredited laboratories shall fully comply with the requirements of ISO 15189:2007.

Annex
Summary of changes in ISO 15189:2007

Note: The page numbers listed below are those of HOKLAS 015 (Second edition).

Page 7, Clause 3 and sub-clause 3.1

Introduction sentence amended and new definition for “accreditation” added as new sub-clause 3.1. Sub-clause numbers changed accordingly.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 accreditation

procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

Page 7, para 3.2, Note 2, End of sentence

“See [13] in the Bibliography” instead of “See [11]”.

Page 9, between definition for “quantity” and “referral laboratory”

New definition for Quality management system added.

3.14 Quality management system

Management system to direct and control an organization with regard to quality

[ISO 9000:2005, definition 3.2.3]

NOTE For the purposes of this International standard, the “quality” referred to in this definition relates to matters of both management and technical competence.

Page 10, title

“Management requirements” becomes “Management requirement”.

Page 11, new clause 4.1.6 added

4.1.6 Laboratory management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the quality management system.

Page 13 Clause 4.2.4, second paragraph, last sentence

[see 4.1.5 i)] moved to the end of the sentence.

Page 15 Clause 4.2.5, first sentence

“which” replaced with “that”.

Page 16 Clause 4.3.2 g)

“and” at the end of g) deleted.

Page 17 Clause 4.3.3 d)

“and” at the end of d) deleted.

Page 18 Clause 4.4.4 and 4.4H

“Clients” changed to “Customers” in Clause 4.4.4 and in first paragraph of 4.4H.

Page 19 Clause 4.5.2 c)

“and” at the end of c) deleted.

Page 19 Clause 4.5.4

The word “NOTE” before “National, regional and local regulations may apply.” deleted.

Page 21 Clause 4.6.3, 4th row

“should” changed to “shall”.

This system shall include the recording of lot numbers of all relevant reagents, control materials and calibrators, the date of receipt in the laboratory and the date the material is placed in service.

Page 26 Clause 4.10.1

Last sentence amended.

Corrective action shall be appropriate to the magnitude of the problem and commensurate with the possible risks.

Page 27 Clause 4.11.1, first sentence

“quality system” replaced with “quality management system”.

Page 27 Clause 4.11.2

Second sentence became Note 1 under Clause 4.11.2; and original NOTE became NOTE 2.

NOTE 1 Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance.

NOTE 2 Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

Page 32 Clause 4.14.2

Last sentence of paragraph 1 – “agreed-upon time” became “agreed upon time”;
Second paragraph – “quality system” replaced with “quality management system”.

Page 33 Clause 4.15.1, first sentence

Sentence restructured.

4.15.1 In order to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements, laboratory management shall review the laboratory’s quality management system and all its medical services, including examination and advisory activities. The results of the review shall.....

Page 35 Clause 5.1.3 NOTE

Sentence restructured.

NOTE Here, competence is understood as the product of basic academic, postgraduate and continuing education, as well as training and experience of several years in a medical laboratory.

Page 45, Clause 5.2.4, second paragraph, first sentence

“permit” replaced “allow”

Laboratory facilities for examination should permit correct performance of examinations.

Page 53, Clause 5.4.3 b)2); c) 8); d) 3)

“and” at the end of b)2); c) 8); and d) 3) deleted.

Page 58, Clause 5.5.6

Sentence restructured.

5.5.6 Upon request, the laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to users of laboratory services.

Page 59, Clause 5.6.3 e)

“upon” added between “agreed” and “by”.

e) mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned;

Page 65, Clause 5.8.3

“,” added after “but not be limited to”.