



Comparison between ISO 15189:2003 and ISO 15189:2007

The first version of ISO 15189 *Medical laboratories – Particular requirements for quality and competence* was released in 2003. It was subsequently issued as Australian Standard AS 4633 *Medical laboratories – Particular requirements for quality and competence* on 1 December 2004, as prepared by Standards Australia Committee HE-029 *Clinical Laboratory Testing and In Vitro Diagnostic Test Systems*.

In 2005, a revised version of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* was released. ISO 15189 is based on this document and changes were therefore necessary to bring the 2003 version of ISO 15189 into line with the 2005 version of ISO/IEC 17025. Fortunately, the authors of ISO 15189 were aware of some of the changes being mooted for the revision of the 1999 version of ISO/IEC 17025 and incorporated these into the first version of ISO 15189.

The changes between the 2003 and 2007 versions of ISO 15189 are listed in the Table below. The 2007 version was published by Standards Australia in August 2009 as AS ISO 15189:2009.

Section / Clause	ISO 15189:2003	ISO 15189:2007
Introduction	Fourth para: last sentence altered from “ For it is surely preferable that a laboratory seeking accreditation select an accrediting body which operates.....”	To: “If a laboratory seeks accreditation, it should select an accrediting body which operates.....”
	Para 5 details the concurrent revision of ISO/IEC 17025 and ISO 9001	Para 5 omitted
	Para 6 pre-empts the release of a second edition of this document and references the replacement of ISO/IEC Guide 58 by ISO/IEC 17011	Para 6 omitted



Section / Clause	ISO 15189:2003	ISO 15189:2007
Introduction		NEW PARA 5 – specifies that conformity with this Standard does not imply that the laboratory’s quality management system operates to all the requirements of ISO 9001. This Standard is not for use for the purposes of certification.
		NEW PARA 6 – advises that the correlation between the clauses and subclauses of the second edition of ISO 15189 and those of ISO 9001:2000 and ISO/IEC 17025 are detailed in Annex A.
2 Normative References	Altered from: ISO/IEC Guide 2 ISO 31 ISO/IEC Guide 43-1 ISO 9000 ISO 9001:2000 ISO/IEC 17025:1999 <i>International vocabulary of basic and general terms in metrology</i>	To: ISO 31 ISO 9000:2005 ISO 9001:2000 ISO/IEC Guide 43-1 ISO/IEC 17025:2005
3 Terms and definitions	Altered from “For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, VIM and the following apply”	To: “For the purposes of this document, the following terms and definitions apply”



Section / Clause	ISO 15189:2003	ISO 15189:2007
3.1	No definition of “accreditation”	NEW Definition included as 3.1
	Definitions 3.1 – 3.12	Now numbered as 3.2 – 3.13
3.14	No definition of “quality management system”	NEW Definition included as 3.14
	Definitions 3.13 – 3.17	Now numbered as 3.15 – 3.19
4 Management requirements	Heading is Management requirements	Heading is Management requirement
4.1	No subclause 4.1.6	NEW Subclause 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”.
4.4.4	Clients (e.g. clinicians, health care bodies.....	Customers (e.g. clinicians, health care bodies.....
4.6.3	Second sentence altered from “This system should include the recording of lot numbers....”	To : This system shall include the recording of lot numbers
4.8	Reference altered from: (see 4.13.3)	To: [see 4.13.3 i)]
4.9.2	Reference altered from: (see 4.11)	To: (see 4.10)
4.11.2	Second sentence NOTE	Becomes NOTE 1 Becomes NOTE 2



Section / Clause	ISO 15189:2003	ISO 15189:2007
4.14.1	Second half of first sentence moved to:	First half of first sentence
5 Technical requirements		
5.1.3		NOTE includes “Here” as first word
Annex A	Stated to be (normative) Correlation with ISO 9001:2000 and ISO/IEC 17025:1999	Stated to be (Informative) Correlation with ISO 9001:2000 and ISO/IEC 17025:2005 Introduction wording differs
Annex A	Table A1 – Correlation between ISO 9001:2000 and ISO 15189:2003 Table A2 - Correlation between ISO/IEC 17025:1999 and ISO 15189:2003	Table A1 – Correlation between ISO 9001:2000 and ISO 15189:2007 Table A2 - Correlation between ISO/IEC 17025:2005 and ISO 15189:2007
Annex C		
C1	First para, reference at end altered from “For an example, see [17]. <i>NB the actual reference is the same</i>	To: “For an example, see [19] in the Bibliography”.
Bibliography	[1] ISO Guide 30 <i>Terms and definitions used in connection with reference materials</i>	Deleted, replaced by <i>International vocabulary of basic and general terms in metrology</i>
	References [28] and [29] reordered to	References [10] and [11]