Guidance for Accreditation to ISO/IEC 17025

ILAC-G15:2001

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PREAMBLE

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* sets out the criteria for laboratories wishing to demonstrate that they are technically competent, operate an effective quality system, and are able to generate technically valid calibration and test results. The standard will form the basis for the accreditation of competence of laboratories by accreditation bodies.

A transition period is needed during which laboratories currently operating to the preceding standards ISO/IEC Guide 25 and/or EN45001 change to operating to the requirements of the standard. Similarly, accreditation bodies may need to adapt existing assessment and accreditation practices. The requirements for accreditation bodies on the transition period were discussed and agreed in order to minimize the period during which accreditation to different standards may exist.

In order to harmonise the accreditation of laboratories to ISO/IEC 17025 (hereafter referred to as "the standard") it is expected that accreditation bodies will use this guidance. At the end of the transition period, or sooner if experience with its application indicates the need, this guidance publication will be reviewed to decide if it should be revised or withdrawn.

PURPOSE

To facilitate consistent application and assessment of the requirements of the standard by accreditation bodies that operate in accordance with ISO/IEC Guide 58. To enable internationally consistent operation to the standard by laboratories seeking and maintaining accredited status (hereafter referred to as "laboratories").

AUTHORSHIP

This publication was developed by a working group of the International Laboratory Accreditation Cooperation (ILAC) committee on Technical Accreditation Issues.

1. GENERAL

1.1 Transition Period from ISO/IEC Guide 25 or EN 45001 to ISO/IEC 17025

Accreditation bodies shall require the laboratories for which they grant and maintain accreditation to comply with the requirements of the standard by 31 December 2002. No extra surveillance activities will be required to confirm this but all accredited laboratories must have been through an on-site assessment according to the new standard before this date. After this date all accreditation documents must refer to ISO/IEC 17025.

1.2 Structure of the Guidance

The Heading and Clause number of ISO/IEC 17025 are printed and, where specific guidance is provided it is identified with the letter "G". The text of the clauses of the standard is not included so that copyright is not breached.

Cross-references between the clauses of ISO/IEC 17025, ISO/IEC Guide 25 and EN 45001 are given in Table 1.

2. GUIDANCE TO CLAUSES OF ISO/IEC 17025

Clause 1 Scope

Comment on Scope - Note 1.

Where guidance is established for specific applications additional general requirements are not to be added. Guidance is expressed by use of the word should. If guidance to a requirement is given then by following it the laboratory will meet that requirement. Alternative ways may be used if they are shown to give an equivalent outcome.

ILAC guidance to clause 1.4 (G.1.4)

G.1.4 ILAC's policy on the use of reference to accreditation either in words or by use of an accreditation mark or logo when reporting results, including those from subcontracted work, is contained in document ILAC G14: 2000, *Guidelines for the use of Accreditation Body Logos and for Claims of Accreditation Status.*

ILAC guidance to clause 1.6 (G.1.6)

G.1.6 Accreditation bodies may include on the accreditation documentation they issue to laboratories (e.g. accreditation certificate) the statement: "Testing and calibration laboratories that comply with requirements of this International Standard operate a quality system for their testing and calibration activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and/or develop test programmes combining standard and non-standard test and calibration methods, and ISO 9002 when they only use standard methods."

Clause 2 Normative references

Clause 3 Terms and definitions

Clause 4 Management requirements

Clause 4.1 Organization and management

Clause 4.2 Quality system

ILAC guidance to clause 4.2.2 (G.4.2.2)

G.4.2.2 It is acceptable for the additional areas covered by ISO/IEC 17025 to be incorporated into the laboratory's existing procedures. It is not necessary for the laboratory to rewrite its procedures in the form of ISO/IEC 17025.

Clause 4.3 Document control

Clause 4.4 Review of requests, tenders and contracts

Clause 4.5 Subcontracting of tests and calibrations

ILAC guidance to clause 4.5.1 (G.4.5.1)

G.4.5.1 Accreditation bodies should only grant accreditation to a laboratory for those activities that it is itself competent to carry out. Where accreditation is granted to a community of laboratories that operate as a group operating a common quality

system under the terms of a legally binding agreement, the scope can include all activities for which the group has been accredited. However, an individual laboratory of the group of laboratories may not embark on activities for which it is not competent.

Clause 4.6 Purchasing services and supplies

Clause 4.7 Service to the client

Clause 4.8 Complaints

Clause 4.9 Control of non-conforming testing and/or calibration work

Clause 4.10 Corrective action

Clause 4.11 Preventive action

Clause 4.12 Control of records

Clause 4.13 Internal audits

ILAC guidance to clause 4.13 (G.4.13)

G.4.13 Accreditation bodies should pay particular attention to check the effectiveness of the internal audits where they have been done by personnel not independent of those activities.

Clause 4.14 Management reviews

Clause 5 Technical requirements

Clause 5.1 General

Clause 5.2 Personnel

ILAC guidance to clause 5.2.1 (G.5.2.1-a: 5.2.1-b)

G.5.2.1-a When the scope of accreditation includes standards or in-house procedures that require the reporting of interpretations of test or calibration results the accreditation body and laboratory should pay particular attention to ensure that the additional aspects of competence given in NOTE 2 of clause 5.2.1 of ISO/IEC 17025 are met for the areas for which the laboratory provides opinions and interpretations. This should involve establishing that the laboratory has effective procedures to ensure that the relevant expert personnel have sufficient understanding of the relevant subject(s) and a realistic appreciation of the limits to their own knowledge in the context of the opinions and interpretations reported.

G.5.2.1-b Accreditation bodies should assess the effectiveness of the process for ensuring that only competent staff are involved in the provision of opinions and interpretations. The accreditation body should not assess the adequacy of the opinions or interpretations that the laboratory provides.

Clause 5.3 Accommodation and environmental conditions

Clause 5.4 Test and calibration methods and method validation

Clause 5.4.6 Estimation of uncertainty of measurement

ILAC guidance to clause 5.4.6 (G.5.4.6.)

G.5.4.6 Guidance on this aspect is to be found in the document EA 4/02:1997, *Expression of the Uncertainty of Measurement in Calibration,* and in the EURACHEM/CITAC Guide, *Quantifying Uncertainty in Analytical Measurement*, Second edition 2000.

ILAC guidance to clause 5.4.6.2 (G.5.4.6.2)

G.5.4.6.2 The complexity involved in estimation of uncertainty of measurement in the case of testing varies considerably from one test field to another and also within one field itself. It is also often achieved by a less metrologically rigorous process than that which can be followed for calibration. Clause 5.4.6.2 of ISO/IEC 17025 allows for these factors and accreditation bodies should take them into account during assessments. (ILAC's Laboratory Liaison Committee is developing a strategy for implementation of measurement uncertainty in testing).

Clause 5.5 Equipment

Clause 5.6 Measurement traceability

ILAC guidance to clause 5.6 (G.5.6)

G.5.6 Guidance on this aspect is to be found in the document *ILAC Policy on Traceability of Measurement* (to be published) and in ILAC G2: 1994, *Traceability of Measurements* (under revision).

Clause 5.7 Sampling

Clause 5.8 Handling of test and calibration items

Clause 5.9 Assuring the quality of test and calibration results

ILAC guidance to clause 5.9 (G.5.9)

G.5.9 Accreditation bodies should encourage laboratories to participate in proficiency testing and when justified and appropriate may make such participation a requirement of accreditation in certain fields of testing and calibration unless the laboratory can demonstrate that it has an acceptable alternative. Participation in proficiency testing should be considered as part of the surveillance activities.

Clause 5.10 Reporting the results

Clause 5.10.1 General

ILAC guidance to clause 5.10.1 (G.5.10.1)

G.5.10.1 Laboratories that are accredited by an Accreditation Body which is a signatory of the ILAC Mutual Recognition Arrangement or a regional Multilateral Recognition Agreement in the field of testing or calibration may state this on certificates and reports in the appropriate language; for example:

"XXXXXX *(full name or acronym of accreditation body)* is one of the signatories to the YYYYYY *(full name or acronym of the regional or international organisation)* Multilateral/Mutual Recognition Agreement/Arrangement for the mutual recognition of test reports and/or calibration certificates *(whichever is relevant)*."

Clause 5.10.4 Calibration certificates

ILAC guidance to clause 5.10.4.2 (G.5.10.4.2)

G.5.10.4.2 Accreditation bodies should provide rules for the way in which measurement uncertainty has to be taken into account when statements of compliance are made on calibration certificates. Such rules should follow for example, ILAC G8: 1996, Guidelines on Assessment and Reporting of Compliance with Specification.

Clause 5.10.6 Testing and calibration results obtained from subcontractors

ILAC guidance to clause 5.10.6 (G.5.10.6)

G.5.10.6 Accreditation bodies should ensure that when the laboratory does not take responsibility for the subcontracted work, as provided for in ISO/IEC 17025 Clause 4.5.3, this fact is clearly stated in the report.

Annex A

Annex B

Bibliography

ILAC guidance to Bibliography (G.Bib)

G.Bib As well as the ISO/IEC publications referenced in the standard, there are documents produced by ILAC and regional cooperations of accreditation bodies (e.g. EA, APLAC), and also by professional associations (e.g. EURACHEM/CITAC). Accreditation bodies should encourage laboratories to consult these for guidance for demonstrating competence in specific aspects of laboratory operation for the purpose of accreditation.

TABLE 1
Cross-references* between ISO/IEC 17025 and ISO/IEC Guide 25 and EN 45001

** The cross-references only indicate where clauses from one standard address similar subjects in another. There is no exact equivalence and the topics dealt with in a particular clause may also be partly covered in other clauses. There are often significant differences from one standard to another in the content of related clauses.*

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Scope	1.1	1.1	1
1.2	-	-	
1.3	-	-	
1.4	1.3	1	
1.5	*7.6 Note*	-	
1.6	*Intro*	-	
Normative references	2	2	-
Terms and definitions	3	3	2
Management requirements			
Organisation	4.1.1	4.1	3
	4.1.2	1.2	7 a)
	4.1.3	4.1	-
	4.1.4	-	4
	4.1.5 (a)	4.2 a)	4, 5.1, 5.4.6, 5.4.2
	4.1.5 (b)	4.2. b)	4
	4.1.5 (c)	4.2. i)	5.4.6
	4.1.5 (d)	4.2.c)	4
	4.1.5 (e)	5.2 b), 5.2 c)	5.1
	4.1.5 (f)	4.2.d)	5.1
	4.1.5 (g)	4.2.e)	5.1

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Organisation (cont)	4.1.5 (h)	4.2 f)	5.1
	4.1.5 (i)	4.2.g)	5.4.2
	4.1.5 (j)	4.2 h)	-
Quality system	4.2.1	5.1	5.4.2
	4.2.2	5.1, 5.2 a)	5.4.2
	4.2.2 (a)	5.1	-
	4.2.2 (b)	5.2a)	-
	4.2.2 (c)	5.2 a)	-
	4.2.2 (d)	5.1	5.4.2 c)
	4.2.2 (e)	5.2	-
	4.2.3	5.2 m)	5.4.2 e)
	4.2.4	5.2 e)	5.4.2
Document control	4.3.1	5.2 d)	-
	4.3.2.1	5.2 d)	-
	4.3.2.2 (a)	5.1, 5.2 d)	5.4.1
	4.3.2.2 (b)	5.2 d)	5.4.1
	4.3.2.2 (c)	5.2 d)	-
	4.3.2.2 (d)	5.2 d)	-
	4.3.2.3	5.2 d)	-
	4.3.3.1	5.2 d)	-
	4.3.3.2	5.2 d)	-
	4.3.3.3	5.2 d)	-
	4.3.3.4	5.2 d)	-
Review of requests, tenders and contracts	4.4.1	5.2 i)	-
	4.4.1 (a)	5.2 i)	-
	4.4.1 (b)	5.2 i)	-

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Review of requests, tenders and contracts (cont)	4.4.2	5.2 i)	-
	4.4.3	5.2 i)	5.4.7
	4.4.4	5.2 i)	-
	4.4.5	5.2 i)	-
Subcontracting of tests and calibrations	4.5.1	14.1	5.4.7
	4.5.2	14.1	5.4.7
	4.5.3	-	-
	4.5.4	14.2	5.4.7
Purchasing services and supplies	4.6.1	10.8, 15.2	-
	4.6.2	15.1	-
	4.6.3	-	-
	4.6.4	15.3	-
Service to the client	4.7	-	6.1
Complaints	4.8	16.1	5.4.2 h), 6.1
Control of nonconforming work	4.9.1	5.2 o)	5.4.2 g)
	4.9.1 (a)	5.2 o)	-
	4.9.1 (b)	5.2 o)	-
	4.9.1 (c)	5.2 o)	-
	4.9.1 (d)	5.2 o), 13.6	-
	4.9.1 (e)	5.2 o)	-
	4.9.2	16.2	-
Corrective action	4.10.1	5.2 o)	5.4.2
	4.10.2	5.2 o)	-
	4.10.3	5.2 o)	-

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Corrective action (cont)	4.10.4	5.2 o)	-
	4.10.5	16.2	-
Preventive action	4.11.1	-	-
	4.11.2	-	-
Control of records	4.12.1.1	12.1	5.4.4
	4.12.1.2	12.2	-
	4.12.1.3	12.2	5.4.4
	4.12.1.4	10.7 e)	-
	4.12.2.1	12.1	5.4.4
	4.12.2.2	-	-
	4.12.2.3	-	-
Internal audits	4.13.1	5.3	5.4.2
	4.13.2	5.3	5.4.2
	4.13.3	5.5	-
	4.13.4	-	-
Management reviews	4.14.1	5.4	5.4.2
	4.14.2	5.5	5.4.2
TECHNICAL REQUIREMENTS			
General	5.1.1	-	-
	5.1.2	-	-
Personnel	5.2.1	6.1	5.2
	5.2.2	6.2	5.2
	5.2.3	-	-
	5.2.4	5.2 e)	-
	5.2.5	6.3	-

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Accommodation and environmental conditions	5.3.1	7.1, 7.2	5.3.2
	5.3.2	7.3	5.3.2
	5.3.3	7.4	5.3.2
	5.3.4	7.5	5.3.2
	5.3.5	7.6	5.3.2
Test and calibration methods and method validation	5.4.1	10.2, 10.1, 10.5	5.4.1
	5.4.2	10.3	5.4.1
	5.4.3	-	-
	5.4.4	10.4	5.4.1
	5.4.5.1	-	-
	5.4.5.2	10.4	-
	5.4.5.3	-	-
	5.4.6.1	10.2	5.4.3 k)
	5.4.6.2	10.2	-
	5.4.6.3	-	-
	5.4.7.1	10.6	5.4.1
	5.4.7.2	10.7	-
	5.4.7.2 (a)	10.7 b)	-
	5.4.7.2 (b)	10.7 c)	-
	5.4.7.2 (c)	10.7 d)	-
Equipment	5.5.1	8.1	5.3.1
	5.5.2	9.1	5.3.3
	5.5.3	10.1	-
	5.5.4	-	5.3.3 b)
	5.5.5 (a)	8.4 a)	5.3.3 b)

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Equipment (cont)	5.5.5 (b)	8.4 b)	5.3.3 b)
	5.5.5 (c)	-	-
	5.5.5 (d)	8.4 d)	5.3.3 d)
	5.5.5 (e)	8.4 f)	-
	5.5.5 (f)	8.4 g)	5.3.3
	5.5.5 (g)	8.4 h)	5.3.3 f)
	5.5.5 (h)	8.4 i)	5.3.3 g)
	5.5.6	8.2	-
	5.5.7	8.2	5.3.3
	5.5.8	8.3	-
	5.5.9	-	-
	5.5.10	-	5.3.3
	5.5.11	-	-
	5.5.12	-	-
Measurement traceability	5.6.1	9.1	5.3.3
	5.6.2.1.1	9.2	5.3.3
	5.6.2.1.2	9.3	5.3.3
	5.6.2.2.1	9.2	5.3.3
	5.6.2.2.2	9.3	5.3.3
	5.6.3.1	9.4, 9.5	5.3.3
	5.6.3.2	9.7	-
	5.6.3.3	9.6	-
	5.6.3.4	-	-
Sampling	5.7.1	10.5	-
	5.7.2	-	-
	5.7.3	-	5.4.4

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Handling of test and calibration items	5.8.1	11.4	5.4.5
	5.8.2	11.1	5.4.5
	5.8.3	11.2	-
	5.8.4	11.3	5.4.5
Assuring the quality of test and calibration results	5.9 -	5.6, 5.6 a)	
	5.9 (a)	5.6 c)	-
	5.9 (b)	5.6 b)	6.2 d), 6.3
	5.9 (c)	5.6 d)	-
	5.9 (d)	5.6 e)	-
	5.9 (e)	5.6 f)	-
Reporting the results	5.10.1	13.1	5.4.3
	5.10.2.(a)	13.2 a)	-
	5.10.2. (b)	13.2 b)	5.4.3 a)
	5.10.2. (c)	13.2 c)	5.4.3 b)
	5.10.2. (d)	13.2 d)	5.4.3 c)
	5.10.2 (e)	13.2 h)	5.4.3 f)
	5.10.2. (f)	13.2 e), 13.2 f)	5.4.3 d)
	5.10.2. (g)	13.2 g)	5.4.3 e)
	5.10.2. (h)	13.2 i)	5.4.3 g)
	5.10.2. (i)	13.2 k)	5.4.3
	5.10.2. (j)	13.2 m)	5.4.3 l)
	5.10.2 (k)	13.2 n)	5.4.3 m)
	5.10.3.1 (a)	13.2 j)	5.4.3 h)
	5.10.3.1 (b)	-	-

Item from contents list of ISO/IEC 17025	ISO/IEC 17025 Clause	ISO/IEC Guide25	EN 45001
Reporting the results (cont)	5.10.3.1 (c)	13.2 l)	5.4.3 k)
	5.10.3.1 (d)	-	-
	5.10.3.1 (e)	-	5.4.3 j)
	5.10.3.2 (a)	-	-
	5.10.3.2 (b)	-	-
	5.10.3.2 (c)	-	-
	5.10.3.2 (d)	-	5.4.3 g)
	5.10.3.2 (e)	-	-
	5.10.3.2 (f)	-	-
	5.10.4.1 (a)	13.2 j)	-
	5.10.4.1 (b)	13.2 l)	5.4.3
	5.10.4.1 (c)	-	-
	5.10.4.2	-	-
	5.10.4.3	-	-
	5.10.4.4.	-	-
	5.10.5	-	5.4.3
	5.10.6	13.3	-
	5.10.7	13.7	-
	5.10.8	13.4	5.4.3
	5.10.9	13.5	5.4.3

The International Laboratory Accreditation Cooperation (ILAC) is the principal international forum for the exchange of ideas and information on laboratory accreditation.

Established in the late 1970s, ILAC membership has grown rapidly and includes representatives from the world's major laboratory accreditation systems in Europe, Asia, North America, Australia and the Pacific. Countries that are developing their own laboratory accreditation systems are also welcome to participate and contribute.

ILAC operates a series of committees which investigate issues such as the harmonisation of international laboratory accreditation practices, the effectiveness of mutual recognition agreements in facilitating trade and the promotion of the aims and awareness of laboratory accreditation around the world.

There are regular meetings of individual ILAC committees as well as a major plenary meeting of all ILAC members.

The activities of ILAC affect a diverse range of areas including standardisation, accreditation, certification, testing, calibration, and regulation in both the public and private sectors.

ILAC Publications Currently Available

Information Documents (I Series)

ILAC-I1:1994	Legal Liability in Testing
ILAC-I2:1994	Testing, Quality Assurance, Certification and Accreditation
ILAC-I3:1996	The Role of Testing and Laboratory Accreditation in International Trade
ILAC-I4:1996	Guidance Documents for the Preparation of Laboratory Quality Manuals

Guidance Documents (G Series)

ILAC-G2:1994	Traceability of Measurement
ILAC-G3:1994	Guidelines for Training Courses for Assessors
ILAC-G4:1994	Guidelines on Scopes of Accreditation
ILAC-G7:1996	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC-G8:1996	Guidelines on Assessment and Reporting of Compliance with Specification
ILAC-G9:1996	Guidelines for the Selection and Use of Certified Reference Materials
ILAC-G10:1996	Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
ILAC-G11:1998	Guidelines on Assessor Qualification and Competence
ILAC-G12:2000	Guidelines for the Requirements for the Competence of Reference Material Producers
ILAC-G13:2000	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
ILAC-G14:2000	Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status
ILAC-G15:2001	Guidance for Accreditation to ISO/IEC 17025

Secretariat Documents (S Series)

ILAC-S1:2000	Guidelines for the Preparation, Layout and Numbering of ILAC Publications
ILAC-S2:1998	Rules

Procedural Documents (P Series)

ILAC-P1:2000	ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies
ILAC-P2: 2000	ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition