



**Accreditation of Proficiency Testing  
Providers to ISO/IEC 17043:2010 -  
A Crosswalk to ILAC G13:2007**

**ILAC-G25:01/2012**

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## PREAMBLE

Prior to the publication of ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing, accreditation bodies used ISO/IEC in conjunction with ILAC G13 in order to meet the accreditation needs of proficiency testing providers. While ISO/IEC Guide 43 provided an excellent practical basis for the operation of proficiency testing programs, it had become outdated in terms of both its fundamental approach and statistical treatments. On the other hand, ILAC G13 was an excellent document adopted by many accreditation bodies as a requirements document and with its 2006 update was reasonably consistent with current practice. However, ILAC G13 was only recognized within the laboratory accreditation community and therefore lacked the broad acceptance of an international standard.

As a result of a request from the ILAC Proficiency Testing Consultative Group in 2006, ISO/CASCO formed a Working Group to update ISO/IEC Guide 43 and convert it into an ISO standard. The fundamental charge of the Working Group was to bring Guide 43 up-to-date with current practice and to convert the guide to a Standard. The Working Group approach was to blend ISO/IEC Guide 43 and ILAC G13 into a standard using ISO/CASCO formats and conformity assessment terminology and considering the element of management systems. A key challenge for the Working Group was to balance the needs of competing laboratory interests and at the same time provide a requirements document that would be suitable to the broad audience that had used ISO/IEC Guide 43 for more than ten years.

The resulting Standard, ISO/IEC 17043, provides the basic guidance and detail required by interested parties who have previously used ISO/IEC Guide 43 to support their operation of independent proficiency testing schemes to improve their own data quality. However, the new ISO/IEC 17043 also includes sufficient technical detail and appropriate statistical treatments to be used by calibration laboratory proficiency testing providers as a basis for their operation and accreditation. The Standard recognizes the limitations of testing laboratories in terms of Uncertainty calculation and appropriately reflects the needs of both testing and calibration proficiency testing by addressing the distinctions in separate sections. The underlying philosophy of the Working Group was to recognize the needs of the diverse audience for the Standard and to appropriately balance requirements to achieve a Standard generally useful for each vested interest group.

At the 13th ILAC General Assembly on the 20 October 2009, ILAC Resolution GA13.27 was passed: *Referencing ILAC GA Resolutions GA 9.12 and 9.13, and recognising that ILAC has played a significant role in the creation of a draft International Standard for Proficiency Testing, the General Assembly endorses the use of ISO/IEC 17043, when published, for the accreditation of Proficiency Testing Providers.*

*Effective two years after publication of ISO/IEC 17043, the General Assembly withdraws its endorsement of the use of ILAC G13 and ISO/IEC Guide 43 as referenced in GA Resolution 9.13 and approves the withdrawal of ILAC G13.*

## PURPOSE

This document provides an introduction to the ISO/IEC 17043:2010 standard, and a crosswalk between it and ILAC G13:2007.

## AUTHORSHIP

ILAC-G25:01/2012 was prepared by working group 1 of the Proficiency Testing Consultative Group.

## INTRODUCTION

ISO/IEC Guide 43 was presented in two parts. The first part of the Guide addressed the technical details required to operate proficiency testing programs. The second part of the Guide was addressed specifically to the laboratory accreditation community and provides guidance on the selection of proficiency testing schemes for use in laboratory accreditation. The new ISO/IEC 17043 is presented as a single Standard with three appendices. Appendix A discusses the types of Interlaboratory Comparison (ILC) schemes. The second appendix is a presentation of the basic statistical protocols used in proficiency testing. However, reference is made to ISO 13528 and the revised International Harmonized Protocol for Proficiency Testing that provides more detailed statistical treatments. The final appendix is a broad expansion of ISO/IEC Guide 43 Part 2 and discusses the selection and use of proficiency testing schemes by any interested party.

Of particular importance in the development of ISO/IEC 17043 was a conscious effort by the Working Group to support the needs of developing External Quality Assessment (EQA) schemes in the medical area. EQA schemes are widely used in several areas of medicine and throughout the clinical laboratory sector to improve quality performance. These schemes in many cases develop only semi-quantitative or even qualitative data and therefore assessments must be made using uniquely designed statistical treatments. The design of ISO/IEC 17043 provides support for the inclusion of EQA schemes and provides guidance on the statistical analyses of the resulting data. The inclusion of EQA in ISO/IEC 17043 allows accreditation bodies who wish to accredit EQA scheme providers as proficiency testing providers to use the new Standard as a requirements document.

ISO/IEC Guide 43 failed to address the critically important but technically difficult areas of measurement uncertainty and metrological traceability. ISO/IEC 17043 recognizes the importance of uncertainty and traceability particularly in the calculation and presentation of proficiency testing Assigned Values. However, the Standard also recognized that calibration laboratories and calibration proficiency testing providers handle uncertainty and traceability differently than testing laboratories and their proficiency testing providers. In order to balance the needs of both groups, the Working Group developed separate requirements for calibration proficiency testing providers and those serving testing laboratories. This approach to uncertainty and traceability is similar to that used in ISO/IEC 17025 and is consistent with the current state-of-the-art in the respective sectors.

Section 4 of ISO/IEC 17043 addresses the technical requirements for proficiency testing program providers, while Section 5 addresses the quality systems requirements. This formatting is consistent with ISO/IEC 17025 and users of ISO/IEC 17025 should find the new Standard straightforward. The management quality system requirements of Section 5 are now more consistent with the newer ISO 9000 standards. The technical requirements of Section 4 have been developed from the requirements of ILAC G13 with consideration given to the older ISO/IEC Guide 43 and recognition that the newer International Harmonized Protocol and ISO 13528 may themselves be revised in the future. Section 4 should therefore be reviewed in detail and careful consideration should be given since ISO/IEC 17043 was developed as a stand-alone requirements document.

The attached table is a crosswalk between ILAC G13 and the new ISO/IEC 17043 Standard. It has been provided to allow accreditation bodies to quickly review how ISO/IEC 17043 addresses the individual detailed requirements of the older ILAC G13. Every element of ILAC G13 has been addressed in ISO/IEC 17043. However, some ILAC G13 requirements were revised and ISO/IEC 17043 introduces some new requirements.

When using ISO 17043, particular attention should be paid to the explanatory notes throughout the Standard.

**COMPARISON TABLE**

ISO/IEC 17043:2010	ILAC Guide 13:2007
<b>4 Technical Requirements</b>	<b>3 Technical Requirements</b>
	<b>3.0 General</b>
<b>4.1 General</b>	<b>3.0 General</b> <b>3.1.1</b>
<b>4.2 Personnel</b>	<b>3.1 Personnel</b>
<b>4.2.1</b>	<b>3.1.2</b>
<b>4.2.2</b>	<b>3.1.4</b> <b>3.1.5</b>
<b>4.2.3</b>	<b>3.1.6</b>
<b>4.2.4</b>	
<b>4.2.4 a)</b>	
<b>4.2.4 b)</b>	
<b>4.2.4 c)</b>	
<b>4.2.4 d)</b>	



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4.2.4 e)	
4.2.4 f)	
4.2.4 g)	3.6.1.2
4.2.4 h)	
4.2.4 i)	
4.2.4 j)	
4.2.4 k)	
4.2.5	3.1.7
4.2.6	
4.2.7	3.1.6
4.3 Equipment, accommodation and environment	3.2 Accommodation and environmental
4.3.1	3.2.1
4.3.2	
4.3.3	
4.3.4	
4.3.5	3.2.3
4.3.6	

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<b>4.4 Design of proficiency testing schemes</b>	<b>3.3 Organisation and design logistics</b>
<b>4.4.1 Planning</b>	<b>3.3.1 Planning</b>
<b>4.4.1.1</b>	<b>3.3.1.1</b>
<b>4.4.1.2</b>	
<b>4.4.1.3</b>	<b>3.3.1.2</b> <b>3.3.1.2 c)</b>
<b>4.4.1.3 a)</b>	<b>3.3.1.2 a)</b>
<b>4.4.1.3 b)</b>	<b>3.3.1.2 b)</b>
<b>4.4.1.3 c)</b>	<b>3.3.1.2 e)</b>
<b>4.4.1.3 d)</b>	<b>3.3.1.2 d)</b>
<b>4.4.1.3 e)</b>	<b>3.3.1.2 f)</b>
<b>4.4.1.3 f)</b>	<b>3.3.1.4 c)</b>
<b>4.4.1.3 g)</b>	<b>3.3.1.4 d)</b>
<b>4.4.1.3 h)</b>	<b>3.3.1.2 g)</b>
<b>4.4.1.3 i)</b>	
<b>4.4.1.3 j)</b>	<b>3.9 Collusion and falsification of results</b>
<b>4.4.1.3 k)</b>	<b>3.3.1.2 h)</b> <b>3.6.2.2 b)</b>
<b>4.4.1.3 l)</b>	<b>3.3.1.2 i)</b> <b>3.3.1.2 j)</b>

4.4.1.3 m)	3.3.1.2 k) 3.3.1.4 e)
4.4.1.3 n)	
4.4.1.3 o)	3.3.1.2 m) 3.3.1.4 i)
4.4.1.3 p)	3.3.1.2 l)
4.4.1.3 q)	3.3.1.2 p)
4.4.1.3 r)	3.3.1.2 n) 3.3.1.4 .l)
4.4.1.3 s)	3.3.1.2 m)
4.4.1.3 t)	3.3.1.2 o)
4.4.1.3 u)	
4.4.1.4	3.3.1.3
4.4.1.5	3.3.1.4
	3.3.1.4 a)
	3.3.1.4 f)
4.4.1.5 a)	3.3.1.4 b)
4.4.1.5 b)	3.3.1.4 g)
4.4.1.5 c)	3.3.1.4 h)
4.4.1.5 d)	3.3.1.4 j)

4.4.1.5 e)	3.3.1.4 k)
4.4.1.5 f)	3.3.1.4 m) 3.3.1.4 n)
4.4.1.5 g)	3.3.1.4 o)
4.4.1.5 h)	3.3.1.4 p)
4.4.1.5 i)	
4.4.2 Preparation of proficiency test items	3.3.2 Preparation of proficiency test items
4.4.2.1	3.3.2.1
4.4.2.2	3.3.2.2 3.3.2.5
4.4.2.3	3.3.2.4
4.4.2.4	
4.4.3 Homogeneity and stability	3.3.3 Homogeneity and stability testing
4.4.3.1	3.3.2.3
4.4.3.2	3.3.3.1 3.3.4.2 g)
4.4.3.3	3.3.3.2
4.4.3.4	3.3.3.4
4.4.3.5	3.3.3.3
4.4.3.6	

<b>4.4.4. Statistical design</b>	<b>3.3.4 Statistical design</b>
4.4.4.1	
4.4.4.2	3.3.4.1
4.4.4.3	3.3.4.2
4.4.4.3 a)	3.3.4.2 a)
4.4.4.3 b)	3.3.4.2 b)
4.4.4.3 c)	3.3.1.4 i)
4.4.4.3 d)	3.3.4.2 c)
4.4.4.3 e)	
4.4.4.3 f)	3.3.4.2 e)
4.4.4.3 g)	3.3.4.2 f)
4.4.4.3 h)	3.3.1.4 b)
<b>4.4.5 Assigned values</b>	
4.4.5.1	3.3.4.2 d)
4.4.5.2	
4.4.5.3	
4.4.5.4	

4.4.5.5	3.5.1.6
4.5 Choice of method or procedure	3.4 Choice of method or procedure
4.5.1	3.4.1
4.5.2 a) b)	3.4.2
4.6 Operation of proficiency testing schemes	3.5 Conduct of proficiency testing schemes
4.6.1 Instructions for participants	3.5.3.1 Instructions to participants
4.6.1.1	3.5.1.1
4.6.1.2	3.5.1.2
4.6.1.2 a)	3.5.1.5
4.6.1.2 b)	3.5.1.3
4.6.1.2 c)	
4.6.1.2 d)	
4.6.1.2 e)	
4.6.1.2 f)	3.5.1.4
4.6.1.2 g)	3.5.1.4
4.6.1.2 h)	
4.6.1.2 i)	

<b>4.6.2 Proficiency test items handling and storage</b>	<b>3.5.2 Materials handling and storage</b>
4.6.2.1	3.5.2.1 3.2.3
4.6.2.2	3.5.2.2
4.6.2.3	3.5.2.3
4.6.2.4	3.2.2 3.2.4
<b>4.6.3 Packaging, labeling and distribution of proficiency test items</b>	<b>3.5.3 Packaging, labeling and distribution</b>
4.6.3.1	3.5.3.1
4.6.3.2	
4.6.3.3	3.5.3.2
4.6.3.4	3.5.3.3
4.6.3.5	3.5.3.4
<b>4.7 Data analysis and evaluation of proficiency testing scheme results</b>	<b>3.6 Data analysis and interpretation of scheme results</b>
<b>4.7.1 Data analysis and records</b>	<b>3.6.1 Data analysis and records</b>
4.7.1.1	3.6.1.1 3.6.1.3
4.7.1.2	3.6.1.4
4.7.1.3	3.6.1.5
4.7.1.4	3.6.1.6

4.7.1.5	3.6.1.7
4.7.1.6	3.6.1.8
4.7.2 Evaluation of performance	3.6.2 Evaluation of performance
4.7.2.1	3.6.2.1
4.7.2.2	3.6.2.2
4.7.2.2 a)	3.6.2.2 a)
4.7.2.2 b)	3.6.2.2 c)
4.7.2.2 c)	3.6.2.2 d)
4.7.2.2 d)	3.6.2.2 e)
4.7.2.2 e)	3.6.2.2 f)
4.7.2.2 f)	3.6.2.2 g)
4.7.2.2 g)	3.6.2.2 h)
4.7.2.2 h)	3.6.2.2 i)
4.8 Reports	3.6.3 Reports
4.8.1	3.6.3.1
4.8.2	3.6.3.2
4.8.2 a)	3.6.3.2 a)

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4.8.2 b)	3.6.3.2 b)
4.8.2 c)	
4.8.2 d)	2.5.2
4.8.2 e)	3.6.3.2 c)
4.8.2 f)	3.6.3.2 d)
4.8.2 g)	3.6.3.2 e)
4.8.2 h)	3.6.3.2 f)
4.8.2 i)	3.6.3.2 g)
4.8.2 j)	3.6.3.2 h)
4.8.2 k)	3.6.3.2 i)
4.8.2 l)	3.6.3.2 j)
4.8.2 m)	3.6.3.2 k)
4.8.2 n)	
4.8.2 o)	3.6.3.2 l)
4.8.2 p)	3.6.3.2 m)
4.8.2 q)	3.6.3.2 n)
4.8.2 r)	3.6.3.2 o)

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4.8.2 s)	3.6.3.2 p)
4.8.2 t)	3.6.3.2 q)
4.8.3	3.6.3.3 3.5.1.6 Paragraph 2
4.8.4	
4.8.5	
4.8.5 a)	
4.8.5 b)	
4.8.5 c)	
4.9 Communication with participants	3.7 Communication with participants
4.9.1	3.7.1
4.9.1 a)	
4.9.1 b)	
4.9.1 c)	
4.9.1 d)	
4.9.1 e)	
4.9.2	3.7.2
4.9.3	3.7.3.

<b>4.9.4</b>	<b>3.7.4</b>
<b>4.9.5</b>	
<b>4.10 Confidentiality</b>	<b>3.7 Confidentiality</b>
<b>4.10.1</b>	<b>3.8.1</b>
<b>4.10.2</b>	<b>3.8.2</b>
<b>4.10.3</b>	<b>3.8.3</b>
<b>4.10.4</b>	<b>3.8.4</b>
<b>5 Management Requirements</b>	<b>2 Management Requirements</b>
<b>5.1 Organization</b>	<b>2.1 Organisation</b>
<b>5.1.1</b>	<b>2.1.1</b>
<b>5.1.2</b>	<b>2.1.2</b>
<b>5.1.3</b>	<b>2.1.3</b>
<b>5.1.4</b>	<b>2.1.4</b>
<b>5.1.5</b>	<b>2.1.5</b>
<b>5.1.5 a)</b>	<b>2.1.5 a)</b>
<b>5.1.5 b)</b>	<b>2.1.5 b)</b>
<b>5.1.5 c)</b>	<b>2.1.5 c)</b>

5.1.5 d)	2.1.5 d)
5.1.5 e)	2.1.5 e)
5.1.5 f)	2.1.5 f)
5.1.5 g)	2.1.5 k)
5.1.5 h)	2.1.5 g)
5.1.5 i)	2.1.5 h)
5.1.5 j)	2.1.5 i)
5.1.5 k)	2.1.5 j)
5.1.6	2.1.6
5.2 Management system	2.2 Management system
5.2.1	2.2.1
5.2.2	2.2.2
5.2.3	2.2.3
5.2.3 a)	2.2.3 a)
5.2.3 b)	2.2.3 b)
5.2.3 c)	2.2.3 c)
5.2.3 d)	2.2.3 d)

5.2.3 e)	2.2.3 e)
5.2.4	2.2.4
5.2.5	2.2.5
5.2.6	2.2.6
5.2.7	2.2.7
5.2.8	2.2.8
5.3 Document control	2.3 Document control
5.3.1 General	2.3.1 General
5.3.2 Document approval and issue	2.3.2 Document approval and issue
5.3.2.1	2.3.2.1
5.3.2.2	2.3.2.2
5.3.2.2 a)	2.3.2.2 a)
5.3.2.2 b)	2.3.2.2 b)
5.3.2.2 c)	2.3.2.2 c)
5.3.2.2 d)	2.3.2.2 d)
5.3.2.3	2.3.2.3
5.3.3 Document changes	2.3.3 Document changes

5.3.3.1	2.3.3.1
5.3.3.2	2.3.3.2
5.3.3.3	2.3.3.3
5.3.3.4	2.3.3.4
<b>5.4 Review of requests, tenders and contracts</b>	<b>2.4 Review of requests, tenders and contracts</b>
5.4.1	2.4.1
5.4.1 a)	2.4.1 a)
5.4.1 b)	2.4.1 b)
5.4.1 c)	2.4.1 c)
5.4.2	2.4.2
5.4.3	2.4.3
5.4.4	2.4.4
5.4.5	2.4.5
<b>5.5 Subcontracting services</b>	<b>2.5 Subcontracted services</b>
5.5.1	2.5.1.
5.5.2	
5.5.3	2.5.2

5.5.4	2.5.3
5.5.5	2.5.4
<b>5.6 Purchasing services and supplies</b>	<b>2.6 Purchasing services and supplies</b>
5.6.1	2.6.1
5.6.2	2.6.2
5.6.3	2.6.3
5.6.4	2.6.4
<b>5.7 Service to the customer</b>	<b>2.7 Service to customer</b>
5.7.1	2.7.1
5.7.2	2.7.2
<b>5.8 Complaints and Appeals</b>	<b>2.8 Complaints</b>
<b>5.9 Control of nonconforming work</b>	<b>2.9 Control of nonconforming activities</b>
5.9.1	2.9.1
5.9.1 a)	2.9.1 a)
5.9.1 b)	2.9.1 b)
5.9.1 c)	2.9.1 c)
5.9.1 d)	2.9.1 d)

5.9.1 e)	2.9.1 e)
5.9.2	2.9.2
5.10 Improvement	2.10 Improvements
5.11 Corrective actions	2.11 Corrective actions
5.11.1 General	2.11.1 General
5.11.2 Cause analysis	2.11.2 Cause analysis
5.11.3 Selection and implementation of corrective actions	2.11.3 Selection and implementation of corrective actions
5.11.3.1	2.11.3 Paragraph 1
5.11.3.2	2.11.3 Paragraph 2
5.11.3.3	2.11.3 Paragraph 3
5.11.4 Monitoring of corrective actions	2.11.4 Monitoring of corrective actions
5.11.5 Additional audits	2.11.5 Additional audits
5.12 Preventive actions	2.12 Preventive actions
5.12.1	2.12.1
5.12.2	2.12.2
5.13 Control of records	2.13 Control of records
5.13.1 General	2.13.1 General

5.13.1.1	2.13.1.1
5.13.1.2	2.13.1.2
5.13.1.3	2.13.1.3
5.13.1.4	2.13.1.4
5.13.2 Technical records	2.13.2 Technical records
5.13.2.1	2.13.2.1
5.13.2.1 a)	
5.13.2.1 b)	2.13.2.1 a)
5.13.2.1 c)	2.13.2.1 b)
5.13.2.1 d)	2.13.2.1 c)
5.13.2.1 e)	
5.13.2.1 f)	2.13.2.1 d)
5.13.2.2	2.13.2.2
5.13.2.3	2.13.2.3
5.14 Internal audits	2.14 Internal audits
5.14.1	2.14.1
5.14.2	2.14.2

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<b>5.14.3</b>	<b>2.14.3</b>
<b>5.14.4</b>	<b>2.14.4</b>
<b>5.15 Management reviews</b>	<b>2.15 Management reviews</b>
<b>5.15.1</b>	<b>2.15.1</b>
<b>5.15.1 a)</b>	<b>2.15.1 a)</b>
<b>5.15.1 b)</b>	<b>2.15.1 b)</b>
<b>5.15.1 c)</b>	<b>2.15.1 c)</b>
<b>5.15.1 d)</b>	<b>2.15.1 d)</b>
<b>5.15.1 e)</b>	<b>2.15.1 e)</b>
<b>5.15.1 f)</b>	<b>2.15.1 f)</b>
<b>5.15.1 g)</b>	<b>2.15.1 g)</b>
<b>5.15.1 h)</b>	<b>2.15.1 h)</b>
<b>5.15.1 i)</b>	<b>2.15.1 i)</b>
<b>5.15.1 j)</b>	<b>2.15.1 j)</b>
<b>5.15.2</b>	<b>2.15.2</b>