LEMBAGA ILMU PENGETAHUAN INDONESIA
(INDONESIAN INSTITUTE OF SCIENCES)

LIPI

TIPS & TRICKS in implementing **ISO/IEC 17025:2017** FOR A BETTER LAB COMPETENCY

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The cover

INTERNATIONAL STANDARD

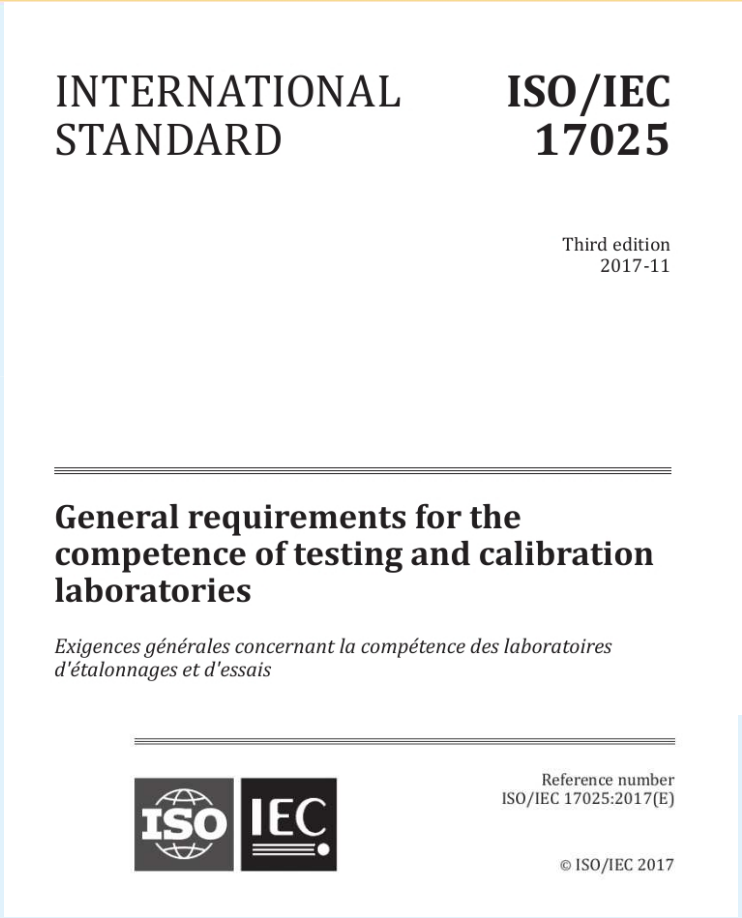
ISO/IEC 17025

Third edition
2017-11

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2017(E)



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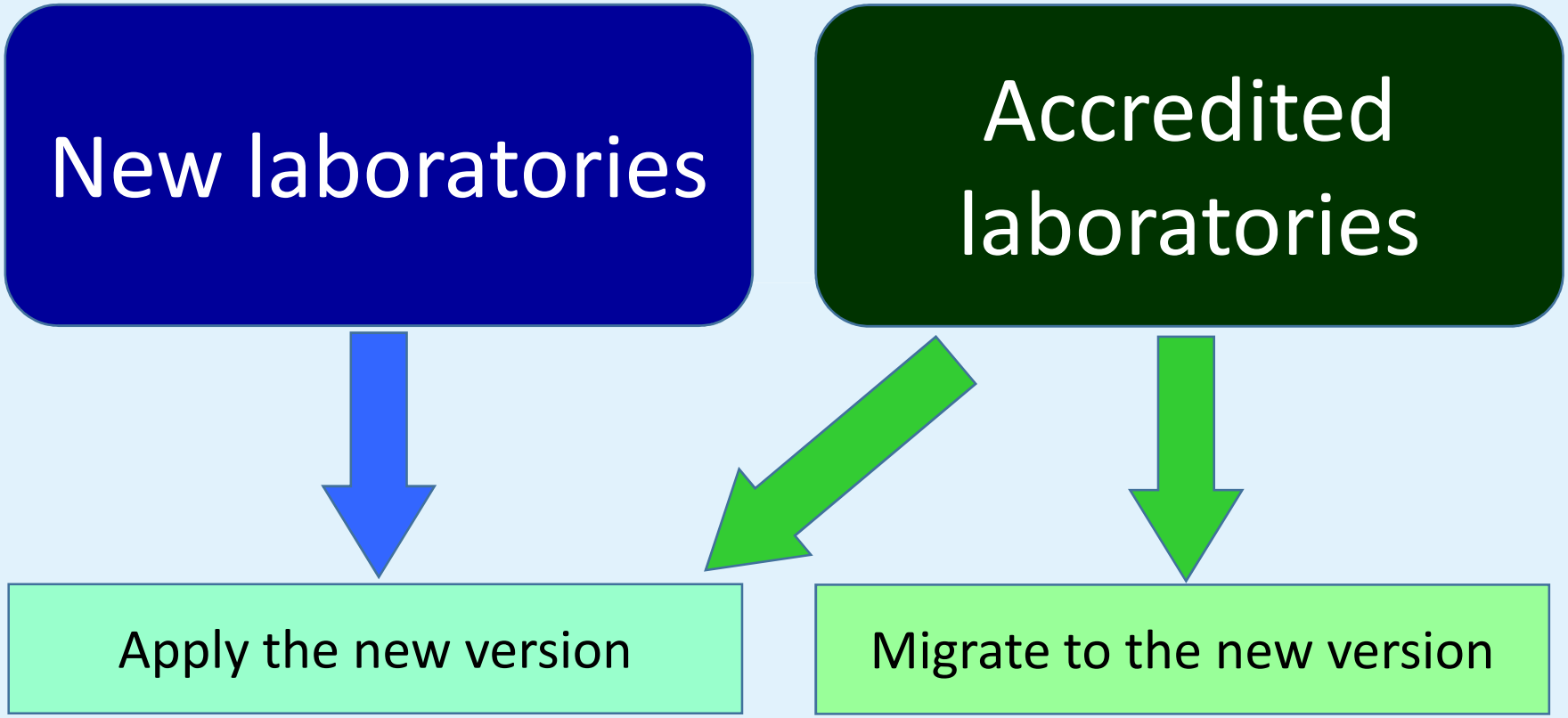
Comparison between the main clauses

2017 VERSION	2005 VERSION
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. General requirements	4. Management requirements
5. Structural requirements	5. Technical requirements
6. Resource requirements	
7. Process requirements	
8. Management system requirements	

What would you like to do?



Migration to ISO/IEC 17025:2017

(*Alternative 1*) ISO/IEC 17025:2017 as the reference:
Listing (sub)clauses in the new version and sorting items in the old version those can be reused in the new version.

(*Alternative 2*) ISO/IEC 17025:2005 as the reference:
Listing (sub)clauses in the old version and sorting items in the new version those can match into each (sub)clause within the old version

Migration to ISO/IEC 17025:2017

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ISO/IEC 17025:2017 as the reference (*alternative 1*):

4. General req
4.1 Impartiality
4.2 Confidentiality
5. Structural req
6. Resource req
6.1 General
6.2 Personnel
6.3 Facilities & env
6.4 Equipment
6.5 Metro traceability
6.6 Ext prov prod & serv

4.4 4.9 5.3 5.9 4.1 5.10 5.7 4.7

ISO/IEC 17025:2005 as the reference (*alternative 2*):

4. Management req
4.1 Organization
4.2 Management sys.
4.3 Doc control
4.4 Rev of req, ten, con
4.5 Subcontracting
5 Technical req
5.1 General
5.2 Personnel
5.3 Accom & env con
5.4 Test & cal method

8.9.2 6.4.12 5.6 7.2.2.4 7.11.4 6.5.3 4.2.2 8.4.1

Sequence of the subclauses
(alternative 1)

ISO/IEC 17025:2017 as the reference:

			Cross-reference ISO/IEC 17025	2017		2005
7			Process Requirement			
	7.1		Review of requests, tenders, and contracts		4.4	Review of requests, tenders and contracts
		7.1.1		Establishment of procedure for review of requests, tenders, and contracts including when external provider is used	4.4.1	(main part) Establishment of procedure for review of requests, tenders, and contracts
					4.4.3	Review for subcontracted works
		7.1.2		Measure needed if method requested by customer is inappropriate or out of date	5.4.2	(par 3) *clear*
		7.1.3		If statement of conformity is requested by customers, the source document shall be clearly defined	5.10.4.2	Part of 5.10.4.2 (par 2) If statement of compliance is made in a calibration certificate, the correlated clauses in the source document shall be identified
		7.1.4		problems arise shall be resolved before commencing the activities	4.4.1	part of 4.4.1 (last part) *clear*
				deviations requested by customers shall not invalidate the results	5.4.1	(par 2, 3rd part) deviations from test and cal method shall only occur if accepted by customers

Wordings may have slightly different meaning
(alternative 1)

ISO/IEC 17025:2017 as the reference:

			Cross-reference ISO/IEC 17025	2017		2005
7			Process Requirement			
	7.1		Review of requests, tenders, and contracts		4.4	Review of requests, tenders and contracts
		7.1.1		Establishment of procedure for review of requests, tenders, and contracts including when external provider is used	4.4.1	(main part) Establishment of procedure for review of requests, tenders, and contracts
					4.4.3	Review for subcontracted works
		7.1.2		Measure needed if method requested by customer is inappropriate or out of date	5.4.2	(par 3) *clear*
		7.1.3		If statement of conformity is requested by customers, the source document shall be clearly defined	5.10.4.2	Part of 5.10.4.2 (par 2) If statement of compliance is made in a calibration certificate, the correlated clauses in the source document shall be identified
		7.1.4		problems arise shall be resolved before commencing the activities	4.4.1	part of 4.4.1 (last part) *clear*
				deviations requested by customers shall not invalidate the results	5.4.1	(par 2, 3rd part) deviations from test and cal method shall only occur if accepted by customers

Comparison may not always be 1 to 1
(alternative 1)

ISO/IEC 17025:2017 as the reference:

			Cross-reference ISO/IEC 17025	2017		2005
7			Process Requirement			
	7.1		Review of requests, tenders, and contracts		4.4	Review of requests, tenders and contracts
		7.1.1		Establishment of procedure for review of requests, tenders, and contracts including when external provider is used	4.4.1	(main part) Establishment of procedure for review of requests, tenders, and contracts
					4.4.3	Review for subcontracted works
		7.1.2		Measure needed if method requested by customer is inappropriate or out of date	5.4.2	(par 3) *clear*
		7.1.3		If statement of conformity is requested by customers, the source document shall be clearly defined	5.10.4.2	Part of 5.10.4.2 (par 2) If statement of compliance is made in a calibration certificate, the correlated clauses in the source document shall be identified
		7.1.4		problems arise shall be resolved before commencing the activities	4.4.1	part of 4.4.1 (last part) *clear*
				deviations requested by customers shall not invalidate the results	5.4.1	(par 2, 3rd part) deviations from test and cal method shall only occur if accepted by customers

The same findings when refering to version 2005
(alernative 2)

ISO/IEC 17025:2005 as the reference:

Cross-reference ISO/IEC 17025		2017		2005
5.1		*clear*	4.1.1	laboratory as a legal entity or part of legal entity
			4.1.2	Lab activities shall be carried out to meet the requirements of docs, customer, etc
5.4		*clear*	4.1.3	The management system shall cover the work carried out in laboratory's permanent facilities or other specified locations
	4.1.1.	**laboratory activites** shall be undertaken impartially	4.1.4	**personnel**: identification of conflict of interest
5.6	a	Lab has personel who implement, maintain, and develop the management system	4.1.5.a	Lab has personnel to implement, maintain, and develop management system; to identify departures from the management system, and to prevent or minimize such departures
	b	Lab has personnel who identify the deviation from management system		
	c	Lab has personnel to prevent or minimize such deviations		
		laboratory management shall be		

Notes become subclauses and vice versa

	Cross-reference ISO/IEC 17025	2017		2005
6.3.1	NOTE	examples on factors adversely affecting the results	5.3.2	(middle part) examples on factors adversely affecting the results
8.6.1	NOTE	the bases for the improvement	4.10	remaining fraction of 4.10
	7.2.1.6	method development; development plan shall be approved and authorized	5.4.5.3	NOTE 2 development plan shall be approved and authorized
	7.2.2.2	measure that shall be carried out when changes to validated methos are made	5.4.5.2	NOTE 3 *clear*
7.3.2		contain of sampling method	5.7.1	NOTE 2 contain of sampling procedure
	7.8.7.3	a record of dialogue with customer	5.10.5	NOTE 3 dialogue with customer should be written down

Preparation

1. Take ISO/IEC 17025:2017 as the reference

pros: Good structure

pros: Keep nothing left out

cons: Remake documents

Restructuring 1/2

see details

2.A Make the cross reference

2017	2005	2017	2005	2017	2005	2017	2005
4.1	4.1	6.1	5.1	7.1	4.4 4.7 5.4 5.10	8.1	---
4.2	4.1 4.7	6.2	4.1 5.2	7.2	5.4	8.2	4.2
5.1	4.1	6.3	5.3	7.3	5.7	8.3	4.3
5.2	4.1	6.4	5.5	7.4	5.8	8.4	4.13
5.3	4.2	6.5	5.6	7.5	4.13	8.5	*4.12*
5.4	4.1	6.6	4.6	7.6	5.4	8.6	4.7 4.10
5.5	4.1 4.2			7.7	5.9	8.7	4.11
5.6	4.1 4.2			7.8	5.10	8.8	4.14
5.7	4.1 4.2			7.9	4.8	8.9	4.15
				7.10	4.9		
				7.11	5.4 5.5		

Restructuring 2/2

see details

2.B Make the cross reference in detail

2017	2005	
4.1.1	4.1.4	4.1.5.d
4.1.2	4.1.5.b	
4.1.3	4.1.5.b	
4.1.4	---	
4.1.5	---	
4.2.1	4.1.5.c	
4.2.2	---	
4.2.3	4.7.1	
4.2.4	4.1.5.c	

2017	2005		
5.1	4.1.1		
5.2	4.1.5.h		
5.3	4.2.1		
5.4	4.1.2	4.1.3	
5.5	4.1.5.e	4.1.5.f	4.2.1
5.6	4.1.5.a	4.2.2.e	4.2.3
5.7	4.1.6	4.2.4	4.2.7

6.1 – 6.6.3

7.1.1 – 7.11.6

8.1.1 – 8.9.3

Addition

3. What's new in 2017 version?

4.1.4 The laboratory shall identify risks to its impartiality

4.1.5 The lab shall eliminate or minimize risks to impartiality

4.2.2 Notification to customers arrangement if conf. info released

6.6.2.a Deciding requirmt. for extern. provided prod. & services

6.6.2.d Actions to follow up examining results of external providers

6.6.3 Communication between lab and external providers

+ 10 more

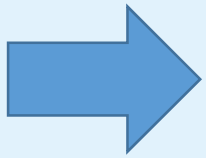
Revising your documents 1/2

hardcopy 2005 version

4.1.1 (2005) - 5.1
4.1.2 (2005) - 5.4
.....
.....
4.1.6 (2005) - 5.7.a
6.2.4

4.1.4 (2017)
4.1.5 (2017)

4.2.1 (2005) - 5.3
5.5.c
4.2.2 (2005) dst



Quality Document

Test/ Calibration Laboratory

on the basis of ISO/IEC 17025

COVER

CROSS-REFERENCE

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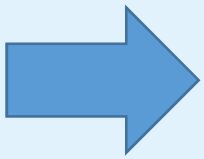
Revising your documents 2/2

softcopy / rearranged h/c

4.1.1 (2017) - 4.1.4
4.1.5.d
4.1.2 (2017) - 4.1.5.b
4.1.3 (2017) - 4.1.5.b
4.1.4 (2017) - addition
4.1.5 (2017) - addition
4.2.1 (2017) - 4.1.5.c
4.2.2 (2017) – addition
dst



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COVER

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Do we have to change the rest of our quality documents?

The new version of ISO/IEC 17025 has very little or no effect on the lower levels of quality documents, i.e.:
Work Instructions
Records and Forms

Note: document numbers or reference numbers may change

Do we have to change our room conditions?

No

Room conditions such as temperature, humidity, content of carbon dioxide, etc refers to other standards.

Do we have to change our master equipment?

Again, master equipment follows other documentary standards for their traceability to the SI. So the answer to most cases is

No

(6.4.5) but there is an emphasis concerning the importance of achieving accuracy **and/or uncertainty**

Do we have to change our human resources?

Requirements for human resources are mainly the same

(6.2.1) But there is an emphasis that **internal personnel** (also) be competent and work in accordance with the laboratory's management system.

Thank you

Please address your questions, comments, or suggestions to:
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jimmy.pusaka@gmail.com