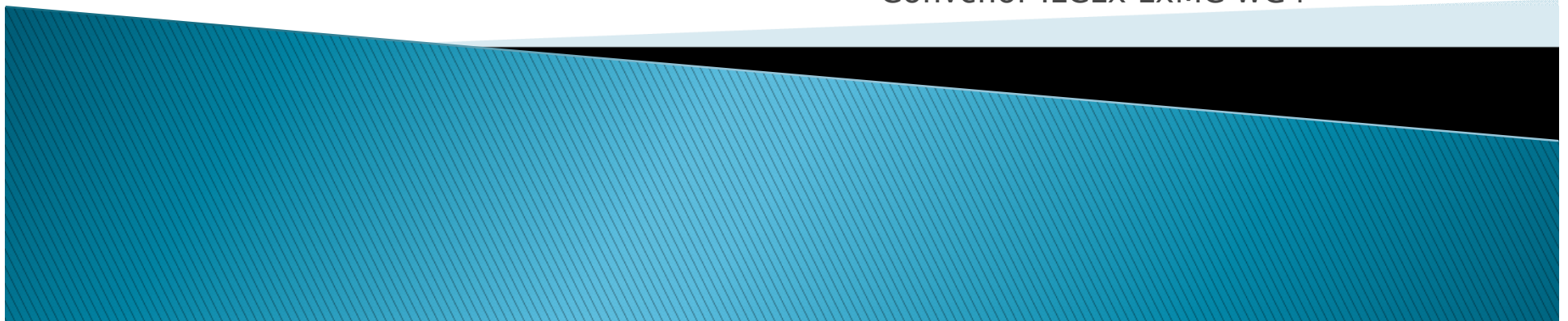


# ISO/IEC 17025

## Third edition (2017-11)

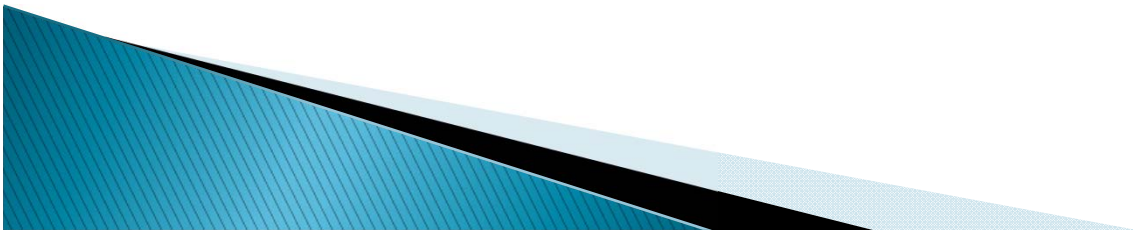
### Requirements, including changes to previous edition

Dr Jim Munro  
Managing Director  
Jim Munro International Compliance Pty Ltd  
Convenor IECEx ExMC WG4



Good news

Bad news

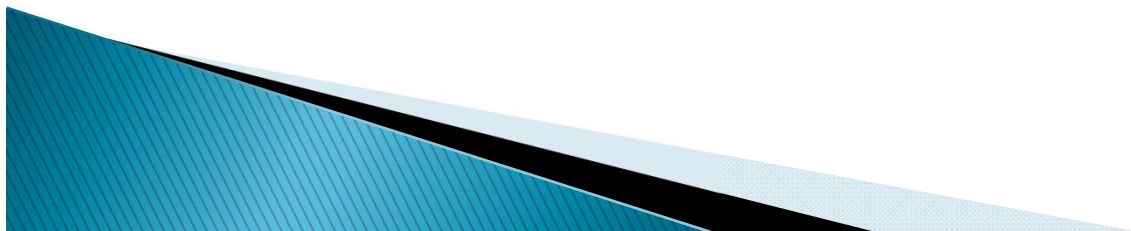






# Major topics for presentation

- ▶ *Overview and background of the Standard*
- ▶ *Changes to the previous edition*
- ▶ *Approaches for use in the IECEx 02 Equipment Scheme*
- ▶ *Transition to the 2017 Edition*



# *Overview and background of the Standard*

The following is taken from UKAS training:

- ▶ ISO/IEC 17025 is the international standard used to accredit the competence of testing and calibration laboratories worldwide
- ▶ In the 2017 version the laboratory is left to decide how to achieve any requirement, expressed more in the form of an required outcome. All based on anticipated/perceived risk and opportunity
- ▶ In rewriting the Standard we tried also to modernise it to remove references to paper and to ensure it catered for electronic data presentation, transmission, storage etc and to be relatively future-proof
- ▶ There are very few technical changes to the requirements to be met by the laboratories. Where changes have been made we have included elements from documents previously written to offer interpretation. For example, in traceability and in decision rules
- ▶ In appearance, the biggest change is that of the structure of the document. Completely different!



# Changes to the previous edition

Extract from the Forward:

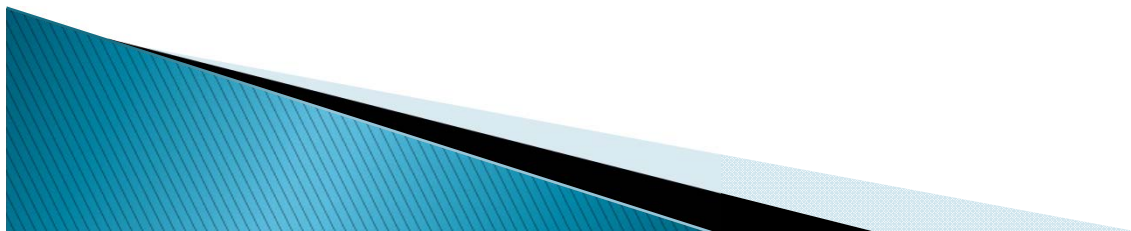
- ▶ This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised.
- ▶ The main changes compared to the previous edition are as follows:
  - the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
  - there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
  - a definition of “laboratory” has been added (see [3.6](#)).



# Changes to the previous edition

Extract from the Introduction:

- ▶ This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.





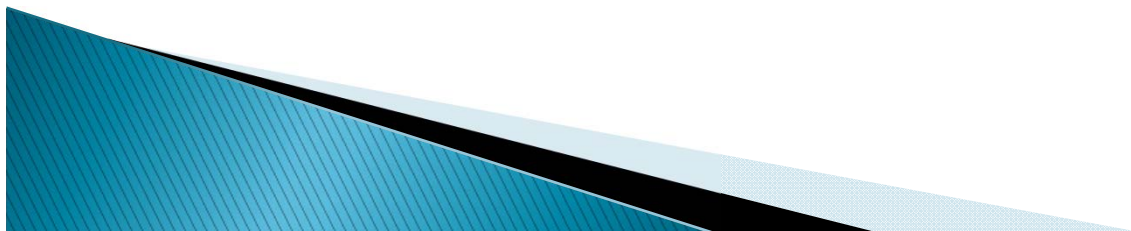
# Changes to previous edition

## Definition of Laboratory

body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.



# Changes to previous edition

## Definition of decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

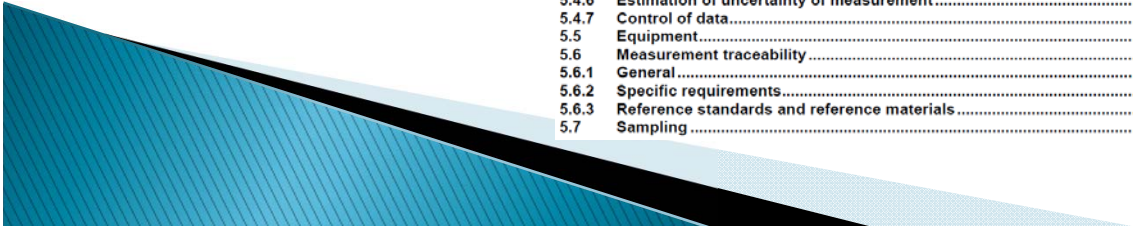
Will we need to revisit measurement uncertainty in IECEx? See also 7.1.3 later.



# Changes to the previous edition

## Previous edition contents

Foreword .....	v
Introduction .....	vi
1 Scope.....	1
2 Normative references .....	2
3 Terms and definitions.....	2
4 Management requirements .....	2
4.1 Organization .....	2
4.2 Management system.....	3
4.3 Document control .....	4
4.3.1 General .....	4
4.3.2 Document approval and issue .....	4
4.3.3 Document changes .....	5
4.4 Review of requests, tenders and contracts .....	5
4.5 Subcontracting of tests and calibrations .....	6
4.6 Purchasing services and supplies .....	6
4.7 Service to the customer .....	6
4.8 Complaints.....	7
4.9 Control of nonconforming testing and/or calibration work .....	7
4.10 Improvement.....	7
4.11 Corrective action .....	8
4.11.1 General .....	8
4.11.2 Cause analysis .....	8
4.11.3 Selection and implementation of corrective actions .....	8
4.11.4 Monitoring of corrective actions .....	8
4.11.5 Additional audits .....	8
4.12 Preventive action .....	8
4.13 Control of records .....	9
4.13.1 General .....	9
4.13.2 Technical records .....	9
4.14 Internal audits.....	9
4.15 Management reviews .....	10
5 Technical requirements.....	10
5.1 General .....	10
5.2 Personnel .....	11
5.3 Accommodation and environmental conditions .....	12
5.4 Test and calibration methods and method validation.....	12
5.4.1 General .....	12
5.4.2 Selection of methods .....	13
5.4.3 Laboratory-developed methods .....	13
5.4.4 Non-standard methods .....	13
5.4.5 Validation of methods.....	14
5.4.6 Estimation of uncertainty of measurement .....	14
5.4.7 Control of data.....	15
5.5 Equipment.....	15
5.6 Measurement traceability .....	17
5.6.1 General .....	17
5.6.2 Specific requirements.....	17
5.6.3 Reference standards and reference materials .....	18
5.7 Sampling .....	19



# Changes to the previous edition

## Previous edition structure

- ▶ Management requirements
- ▶ Technical requirements



# Changes to the previous edition

## New edition contents

Foreword	v
Introduction	vi
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 General requirements</b>	<b>3</b>
4.1 Impartiality	3
4.2 Confidentiality	3
<b>5 Structural requirements</b>	<b>4</b>
<b>6 Resource requirements</b>	<b>5</b>
6.1 General	5
6.2 Personnel	5
6.3 Facilities and environmental conditions	6
6.4 Equipment	6
6.5 Metrological traceability	8
6.6 Externally provided products and services	8
<b>7 Process requirements</b>	<b>9</b>
7.1 Review of requests, tenders and contracts	9
7.2 Selection, verification and validation of methods	10
7.2.1 Selection and verification of methods	10
7.2.2 Validation of methods	11
7.3 Sampling	12
7.4 Handling of test or calibration items	12
7.5 Technical records	13
7.6 Evaluation of measurement uncertainty	13
7.7 Ensuring the validity of results	13
7.8 Reporting of results	14
7.8.1 General	14
7.8.2 Common requirements for reports (test, calibration or sampling)	15
7.8.3 Specific requirements for test reports	15
7.8.4 Specific requirements for calibration certificates	16
7.8.5 Reporting sampling – specific requirements	16
7.8.6 Reporting statements of conformity	17
7.8.7 Reporting opinions and interpretations	17
7.8.8 Amendments to reports	17
7.9 Complaints	17
7.10 Nonconforming work	18
7.11 Control of data and information management	19
<b>8 Management system requirements</b>	<b>19</b>
8.1 Options	19
8.1.1 General	19
8.1.2 Option A	20
8.1.3 Option B	20
8.2 Management system documentation (Option A)	20
8.3 Control of management system documents (Option A)	20
8.4 Control of records (Option A)	21
8.5 Actions to address risks and opportunities (Option A)	21
8.6 Improvement (Option A)	22
8.7 Corrective actions (Option A)	22
8.8 Internal audits (Option A)	23
8.9 Management reviews (Option A)	23

## Annexes and bibliography

<b>Annex A (informative) Metrological traceability</b>	<b>25</b>
<b>Annex B (informative) Management system options</b>	<b>27</b>
<b>Bibliography</b>	<b>29</b>

# Changes to the previous edition

New ISO/IEC 17025 edition structure

- ▶ General requirements
- ▶ Structural requirements
- ▶ Resource requirements
- ▶ Process requirements
- ▶ Management system requirements

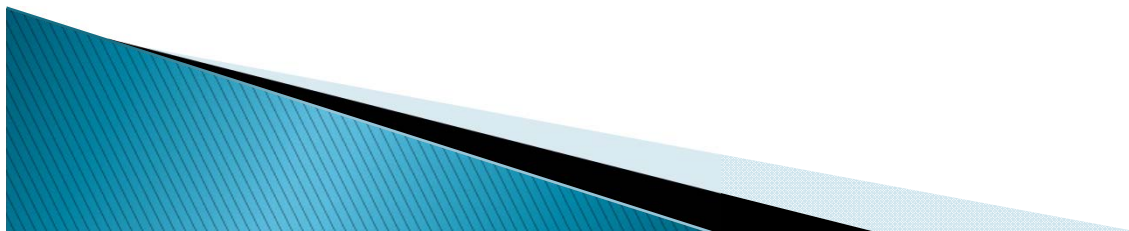


# Changes to the previous edition

ISO/IEC 17065 structure:

- ▶ General requirements
- ▶ Structural requirements
- ▶ Resource requirements
- ▶ Process requirements
- ▶ Management system requirements

LOOK FAMILIAR???



# Changes to the previous edition

## 4 General requirements:

### ▶ 4.1 Impartiality

- Safeguard impartiality
- Commercial etc pressure to compromise impartiality
- Identify risks to impartiality
- Demonstrate how to eliminate or minimise risk
- (reference to 'independence' dropped)

### ▶ 4.2 Confidentiality





# Changes to the previous edition

## 5 Structural requirements:

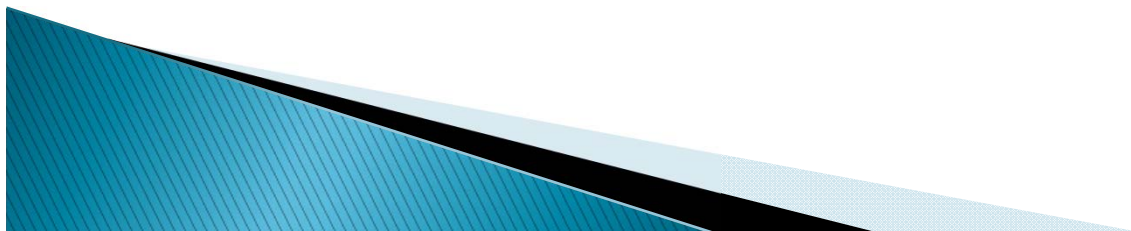
- ▶ Shall be legal entity or defined part of legal entity
- ▶ Identify management with overall responsibility for lab
- ▶ Define and document range of lab activities
- ▶ Carry out activities to meet requirements of this document, customers, regulatory authorities and organizations providing recognition



# Changes to the previous edition

## 5 Structural requirements (continued):

- ▶ Have personnel with authority and resources to carry out:
  - Implementation etc of management system
  - Dealing with deviations from MS
  - Reporting on performance
  - Ensuring effectiveness of lab activities



# Changes to the previous edition


## 6 Resource requirements

- ▶ Lab have available personnel, facilities, equipment system and support services to perform lab activities
- ▶ This section is extensive but similar to requirements in previous standard but much of the prescriptive requirements are gone



# Changes to the previous edition

## 7 Process requirements:

- ▶ Review of requests, tenders and contracts
  - ▶ Selection, verification and validation of methods
  - ▶ Sampling
  - ▶ Handling of test or calibration items
  - ▶ Technical records
  - ▶ Evaluation of measurement uncertainty
  - ▶ Ensuring the validity of results
  - ▶ Reporting of results
  - ▶ Complaints
  - ▶ Nonconforming work
  - ▶ Control of data and information management
- 

# Changes to the previous edition

- ▶ 7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.



# Changes to the previous edition

## 8 Management system requirements:

### Option A

- ▶ As a minimum, the management system of the laboratory shall address the following:
  - management system documentation (see 8.2);
  - control of management system documents (see 8.3);
  - control of records (see 8.4);
  - actions to address risks and opportunities (see 8.5);
  - improvement (see 8.6);
  - corrective actions (see 8.7);
  - internal audits (see 8.8);
  - management reviews (see 8.9).



# Changes to the previous edition

## 8 Management system requirements:

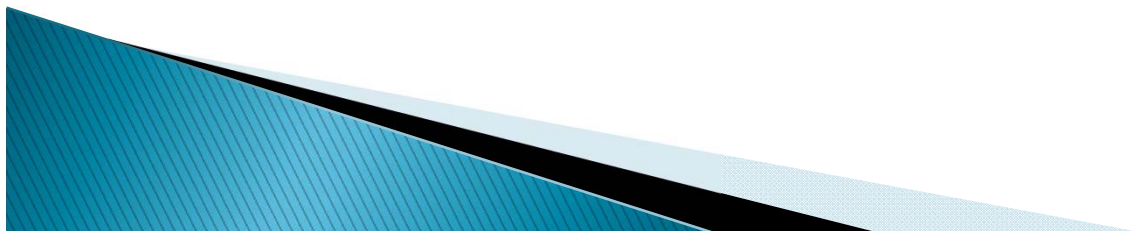
### Option B

- ▶ A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.



# Approaches for use in the IECEx 02 Equipment Scheme

- ▶ We have revised harmonised checklist to be approved at ExMC
- ▶ We will need to think about impact of disappearing prescriptive requirements on consistency in IECEx





# Changes to the previous edition

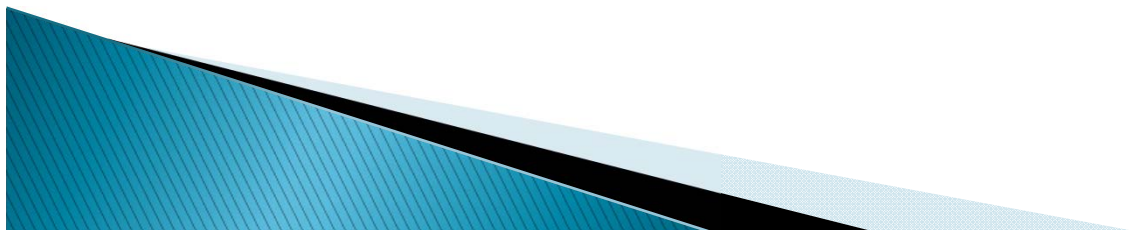
## Example of dropping of prescriptive measure

In technical records, previous edition:

- ▶ When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

In new edition:

- ▶ The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.



# Transition to the 2017 Edition

## Recommendation 4

- ▶ That ExMC decide that IECEx will follow the same timeframe as ILAC with the final date for all ExTL and ATFs to comply with the latest edition of ISO/IEC 17025 being 30 November 2020. Further, that new applications for ExTLs and ATFs after 30 November 2019 must include compliance with the latest edition.

