

ISO/IEC 17025:2017
***General requirements for the competence of
testing and calibration laboratories***

Information Session:
**Changes to the requirements and NATA's
implementation process**

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Session 1

- **Revision of ISO/IEC 17025**
- **Main changes to the standard**
- **Transition period**
- **Transition arrangements**

Revision of ISO/IEC 17025

- Working Group (WG) 44 was established and tasked to review the standard
- Project was to be a three year process from Oct 2014
- Std Aust representatives on WG44
 - John Styzinski & TGA Quality Manager
- Standards review process includes
 - CD = Committee Draft (can include successive versions e.g. CD1, CD2....)
 - DIS = Draft International Standard
 - FDIS = Final DIS (optional stage)
 - each stage includes a commenting and voting process prior to progressing to the next stage

- NATA sought member and AAC feedback at DIS stage in early 2017
 - 9 individuals provided comments, 3 of which were AAC committee members
- Standard was published by ISO on 29 Nov 2017
- Standards Australia adopted the ISO/IEC version of the standard in full and published it on 16 April 2018
 - available from the SAI Global website (www://infostore.saiglobal.com)
- ILAC has specified a 3 year transition from date of publication

Main changes in ISO/IEC 17025:2017

- Mandatory adoption of ISO/CASCO structure
- Scope of the standard covering 'laboratory activities' = testing, calibration, sampling
- Greater emphasis on 'Impartiality'
- Emphasis on result of a process instead of a detailed description of tasks and steps (reflective of risk based thinking approach)
- Reduction in the necessary amount of documentation
- Emphasis on risks and opportunities

- Purchasing and subcontracting combined
- Requirements included for information technology and the validation of such systems (as per ISO 15189)
- Metrological traceability clearer with simplified text
- Decision rules for pass/fail (how MU is to be taken into account when making statements of conformity)
- Two management system options

The look and feel of the revised standard is different to the 2005 version, however, the requirements remain unchanged or better articulated in most cases.

The revision aligns the structure and content of the standard to the ISO/CASCO directives and takes into account the latest revision of ISO 9001; focuses on outcomes rather than prescriptive requirements; and takes into account the latest changes in laboratory environment, work practices and terminology.

New structure

4. General requirements

Impartiality

Confidentiality

5. Structural requirements

6. Resource requirements

General

Personnel

Laboratory facilities & environmental conditions

Equipment

Metrological traceability

Externally provided products & services

7. Process requirements

Review of requests, tenders and contracts

Selection, verification & validation of methods

Sampling

Handling of test or calibration items

Technical records

Evaluation of measurement uncertainty

Assuring the quality of results

Reporting results

Complaints

Management of nonconforming work

Control of data – Information management

8. Management requirements

Options A & B

Management system documentation (Option A)

Control of MS documents (Option A)

Control of records (Option A)

Actions to address risks & opportunities (Option A)

Improvement (Option A)

Corrective action (Option A)

Internal audits (Option A)

Management review (Option A)

Transition period

- NATA being a signatory to the ILAC Mutual Recognition Arrangement (MRA) is required to comply with ILAC policies and resolution
- At the 2016 General Assembly meeting, ILAC past the following resolution

*As the revised version of ISO/IEC 17025 is scheduled for publication in 2017, the General Assembly endorses the recommendation of the Accreditation Committee that a transition period of **3 years from the date of publication** be adopted. At the end of the transition period, accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognised under the ILAC Arrangement*

- The resolution means
 - NATA needs to have all laboratories accredited to ISO/IEC 17025 converted to the new standard by November 2020
 - any laboratory not accredited to the new version of the standard by November 2020 will not be recognised under the MRA

NATA's transition arrangements

- Assessments from 1 August 2018 will be conducted against the new standard
- NATA has prepared
 - Transition Policy incorporating an Implementation Checklist
 - Gap Analysis between the 2005 and 2017 versions of the standard
 - updated NATA's ISO/IEC 17025 Standard Application Document (SAD)
- The three documents are available and packaged together on the NATA website
- The SAD Appendices and Annexes applicable to the various activities / industries are currently in the process of being updated and will be available on the NATA website prior to 1 August

- The updated SAD
 - clauses have been aligned with ISO/IEC 17025:2017
 - the criteria and recommendations included in the previous SAD (January 2018) have been removed where these are now covered in ISO/IEC 17025:2017
 - no new interpretative criteria or recommendations have been included for clauses 4 to 7 other than editorial changes
 - the term ‘subcontractor’ has been replaced by ‘external provider’

- the previous criteria that all reports on results covered by the scope of accreditation must include the accreditation number has been removed
 - criteria for endorsing reports remain unchanged as covered in the *General Accreditation Criteria: Use of the NATA emblem, NATA endorsement and references to accreditation*
- new addition describing a facility's obligations and NATA's processes for assessing an ISO 9001 management system in accordance with Option B described under clause 8



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- ▶ ISO/IEC 17025:2017 Transition Policy, Gap Analysis and Standard Application Document
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- ▶ Healthcare, Pharmaceuticals and Media products Accreditation Criteria Publications Checklist
- ▶ Human Testing for Workplace and/or Community Screening Accreditation Criteria Publications Checklist



Session 2

Clauses 4 to 7 changes

4 General requirements

4.1 Impartiality

- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- New/changed requirements:
 - Identifying risks to impartiality on an on-going basis
 - Addressing risks to impartiality

4.2 Confidentiality

- Language taken from CASCO Procedure document (consistent with other conformity assessment standards)
- New/changed requirements
 - stronger emphasis on customer awareness
 - more detail regarding specific cases where confidentiality could be affected

5 Structural requirements

5 Structural requirements

- Removed terms ‘technical management’ and ‘quality manager’
 - retained same essential functions
- Introduced requirement for laboratory to identify range of laboratory activities for which it conforms with ISO/IEC 17025
 - restricts claims of conformity to the defined range
 - excludes externally provided laboratory activities on an on-going basis

- 5.5 c) requires laboratory to ‘document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results’
 - revised standard consistently uses term ‘procedure’ when the intent is for laboratory to maintain documentation
 - the extent of detail in documentation is up to the laboratory, subject to the conditions in 5.5 c)

6 Resource requirements

6.1 General

- “The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities”

Examples:

- 6.2.1 refers to all personnel, internal or external
[vs 2005 version requiring personnel be employed by or under contract]
- 6.4.1 requires laboratory to have access to equipment
[vs 2005 version requiring laboratory be furnished with all items]

6.2 Personnel

- Terminology and requirements have been updated and reorganised in the revision
- Competence requirements for each function influencing the results of the laboratory activities must be documented (6.2.2)
- It must be ensured that personnel are competent to perform activities for which they are responsible and to evaluate the significance of deviations (6.2.3)
- Procedures and records need to be maintained for personnel covering: determination and competence requirements; selection, training, supervision and authorisation; and monitoring of competence (6.2.5)
- Authorisation of personnel to perform specific activities (6.2.6)

6.3 Facilities and environmental conditions

- Terminology and requirements have been updated and reorganised in the revision
- Measures to control facilities are to be implemented, monitored and periodically reviewed (6.3.4)
- The requirements related to facilities and environmental conditions also apply to activities performed at facilities outside the lab's permanent control (6.3.5)
- Otherwise, no significant changes to this clause compared to the 2005 version

6.4 Equipment

- The laboratory shall have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus that is required for the correct performance of laboratory activities and that can influence the results (6.4.1)
 - description of items considered as equipment is more inclusive than in 2005 version
 - Notes provide more information regarding reference materials
- Equipment shall be capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result (6.4.5)

- Clause 6.4.6 identifies two criteria that determine when calibration of equipment is a requirement
 - the measurement accuracy or measurement uncertainty affects the **validity** of the reported results, or
 - calibration of the equipment is required to establish the **metrological traceability** of the reported result
- A calibration program shall be established, reviewed and adjusted as necessary, to ensure confidence in the status of calibrations (6.4.7)

- All equipment which requires calibration or has a defined period of validity must be labelled or otherwise identified (6.4.8)
 - these criteria apply for all laboratory activities (2005 version had different requirements for calibration and testing)
 - metrological traceability addressed in a separate clause (6.5) (2005 version included calibration in the traceability clause)
- When calibration or reference material data includes reference values or correction factors, it must be ensured the reference values or correction factors are updated and implemented as appropriate to meet specified requirements (6.4.11)

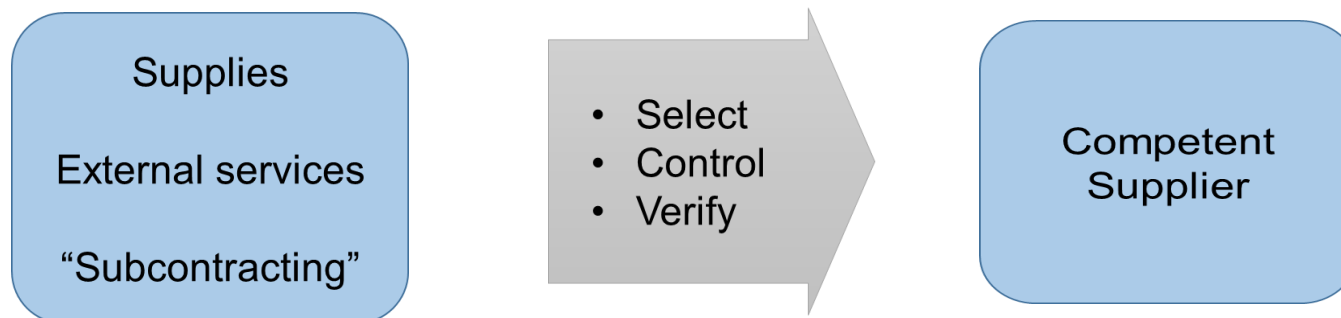
6.5 Metrological traceability

- Terminology and requirements have been updated in the revision to reflect current practice in traceability
- Reduced the number of Notes compared to 2005 version
- Additional explanatory information included in Annex A

6.6 Externally provided products and services

- Combines 4.5 Subcontracting and 4.6 Purchasing Services and Supplies from 2005 version
- The principles of ISO 9001:2015 have been adopted
- Requirements are now clearer, with simplified text
- Emphasis now placed on the laboratory defining its requirements, selecting providers who can meet these and evaluating / monitoring the providers' performance (6.6.2)
- The previous requirement that the laboratory is responsible to the customer for subcontractor's work has been removed

- Emphasis now placed on the laboratory communicating its needs to external providers (6.6.3) including
 - the products and services to be provided
 - the acceptance criteria
 - competence of personnel
 - activities to be performed by the laboratory or its customer at the external provider's premises



7 Process requirements

7.1 Review of requests, tenders and contracts

- The standard or specification and **the decision rule must be clearly defined** when the customer requests a statement of conformity to a specification or standard for a test or calibration. The decision rule must be communicated to and **agreed** with the customer, unless inherent in the requested specification of standard (7.1.3)

More on decisions rules later.....

- Before laboratory activities commence, any differences between the request or tender and the contract must to be resolved. Deviations requested by the customer shall not impact the integrity of the laboratory or validity of results (7.1.4)

7.2 Selection, verification and validation of methods

- Terminology and organisation of clause updated from 2005 version
- Note after 7.2.1.1 clarifies that 'method' as used in this document can be considered synonymous with the term 'measurement procedure' as defined in ISO/IEC Guide 99.
- Method development shall be a planned activity and be performed by qualified personnel equipped with adequate resources. Periodic review as method development proceeds shall occur (7.2.1.6)
- When changes are made to validated methods, the influence of such changes must be determined and validation performed again, if appropriate (7.2.2.2)

7.3 Sampling

- Definition of laboratory (3.6) clarifies that the sampling activity is associated with subsequent testing or calibration
- The sampling method must include (7.3.2)
 - the selection of samples or sites
 - sampling plan
 - preparation and treatment of a sample(s) from a substance, material or product
- Otherwise, no significant changes to this clause compared to the 2005 version

7.4 Handling of test or calibration items

- 7.4.3 includes a new requirement

“When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation”

- Otherwise, no significant changes to this clause compared to the 2005 version

7.5 Technical records

- Technical records now considered process requirements and not management system requirements as in the 2005 version
- General records addressed in Clause 8 (Management System)
- 7.5.2 Amendments to technical records must be traceable to previous versions or to original observations. Original and amended data or files are to be kept, including date of alteration, **an indication of the altered aspects** and the identity of the personnel responsible.
- Otherwise, no significant changes to this clause compared to the 2005 version

7.6 Evaluation of measurement uncertainty

- 7.6.1 requires all significant contributions to measurement uncertainty to be **identified**, including those arising from sampling to be taken into account
- 7.6.2 requires **evaluation** of measurement uncertainty for all calibrations, including those a laboratory performs on its own equipment (i.e. 'in-house' calibrations)
- 7.6.3 In cases for testing where rigorous evaluation of MU is precluded, due to the nature of the method, estimation shall be based on an understanding of the theoretical principles or practical experience of the performance of the methods.

Note 2 applies to all laboratories, and clarifies that a laboratory is not required to calculate a unique uncertainty every time a test or calibration is performed provided the established and verified conditions are met

7.7 Ensuring the validity of results

- Clause separates requirements for monitoring done within the laboratory (7.7.1) and those involving comparison with other laboratories (7.7.2)
- Data from internal activities (7.7.1) required to be recorded such that trends can be detected and, where practicable, statistical techniques applied
- 7.7.2 Now makes proficiency testing (PT) a requirement
 - 2005 version made it optional despite it being an ILAC requirement, accordingly the requirements for NATA accredited facilities remains unchanged
 - participation in inter-laboratory comparisons may be an option where PT is not available

- Both 7.7.1 and 7.7.2 activities must be analysed, used to control and (if applicable) improve laboratory activities
- Action must be taken when results of analysis of data found to be outside pre-defined criteria

7.8 Reporting of results

- Language reflects current approaches to reporting
- New/updated requirements
 - 7.8.2.2 data provided by a customer
 - 7.8.5 reporting sampling
 - 7.8.6 reporting statements of conformity
- **7.8.2.2 (New)**
 - the laboratory is responsible for all the information in the report, except that provided by the customer which must be clearly identified
 - disclaimer must be included when information is supplied by the customer which can affect the validity of the results
 - when the laboratory is not responsible for sampling e.g. the sample has been supplied by the customer, it must state in the report that the results apply to the sample as received

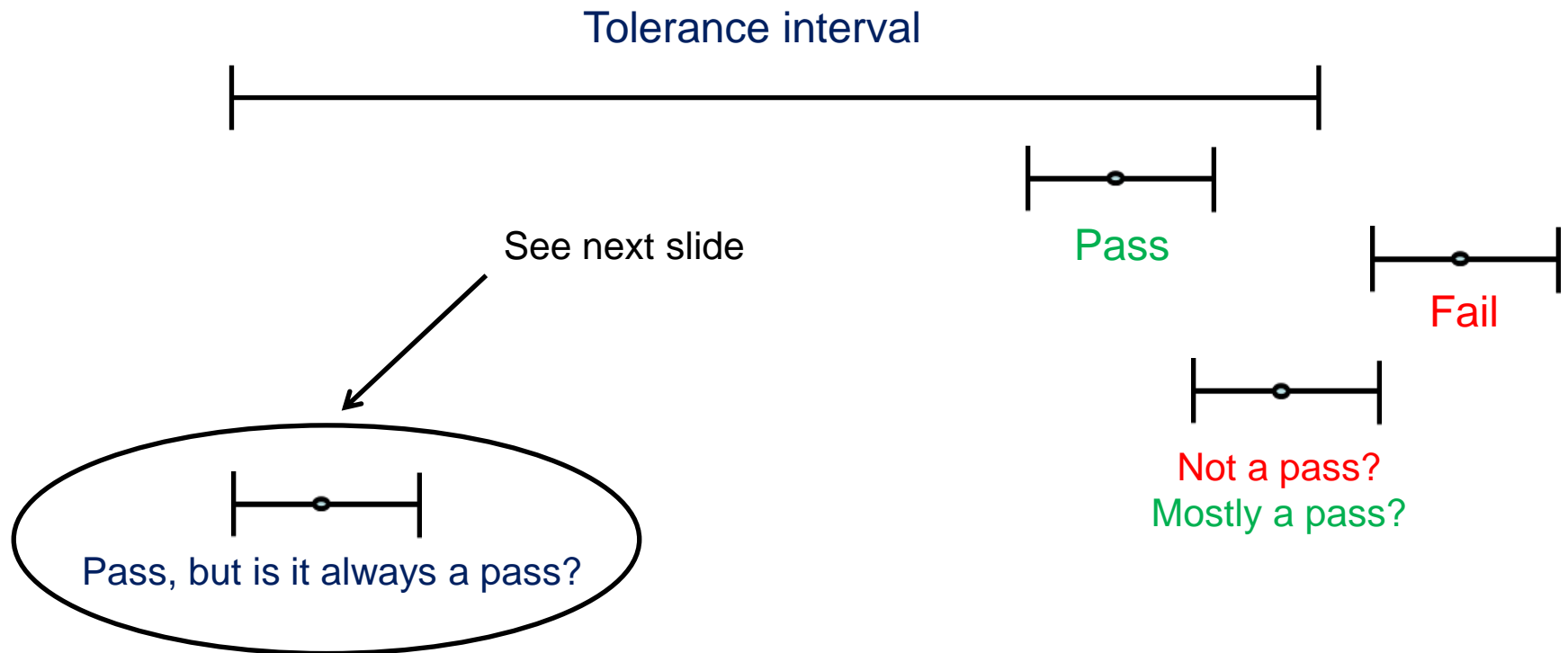
More on decision rules....

- 7.8.6.1 When a **statement of conformity** to a specification or standard is provided, the laboratory must document the decision rule it employs, taking into account the level of risk associated with the decision rule, and apply the decision rule
- 7.8.6.2 The laboratory must report on the statement of conformity, with the statement identifying
 - the results to which the statement of conformity applies
 - which specifications, standards or parts thereof that are met or not met
 - the decision rule applied (unless inherent in the requested specification or standard)

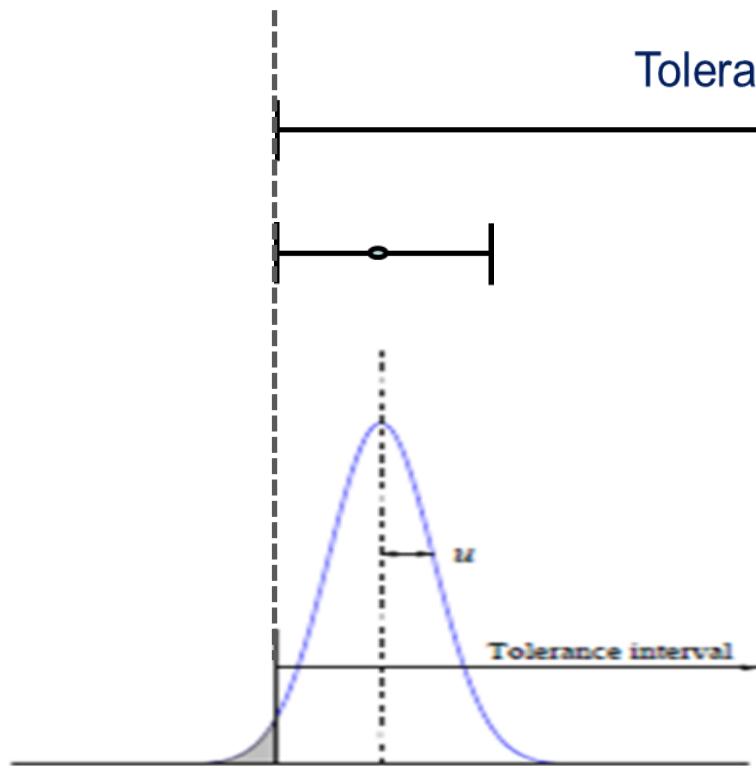
- 3.7 Decision rule = “*Rule that describe how measurement uncertainty is accounted for when stating conformity with a specified requirement*”

So when reporting to a specification, there are two possible outcomes

- 1) the result is reported as conforming
- 2) the result is reported as not conforming



The simple decision rule used globally in the past was generally based on 95% or two standard deviations of the uncertainty

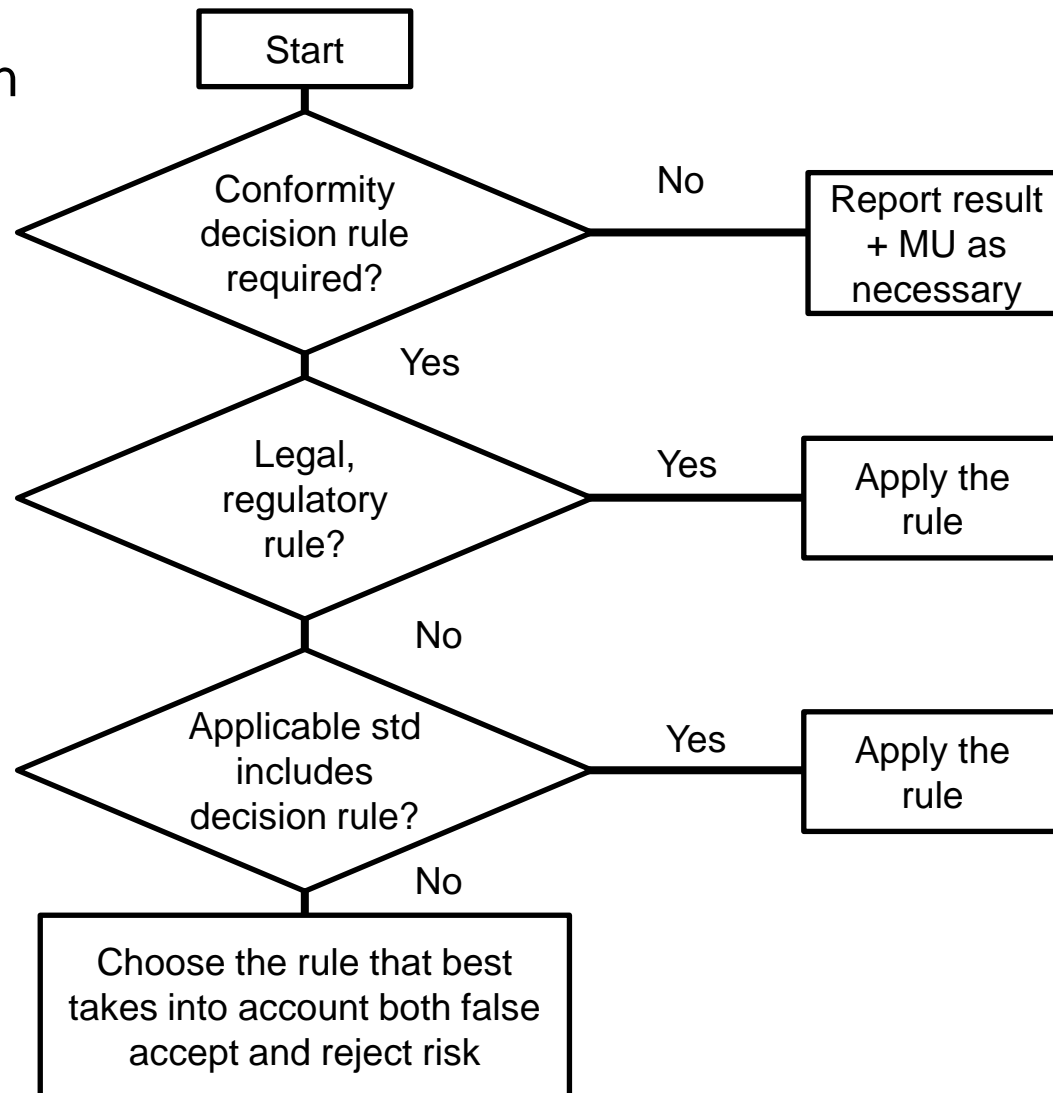


For this example
97.5% probability of a pass
or
2.5% probability of fail
(false acceptance of result)

Laboratory may believe 97.5% is acceptable whereas the customer sees 2.5% fail as unacceptable

- What decision rule to use will be based on the acceptable risk
- ILAC G8 (once revised) together with OIML G19 include examples of decision rules
 - there are many other published papers e.g. Eurachem
- Examples by name include
 - Accuracy Method
 - Consumer's Risk
 - Shared Risk
 - Global Risk
 - Producer's Risk
 - Guard Bands

Example of a decision rule flowchart



7.9 Complaints

- Language has been taken from the CASCO Procedure document (consistent with other conformity assessment standards)
- New/updated requirements
- 7.9.2 requires a description of the complaints handling process be available to any interested party upon request
- 7.9.6 requires the outcomes to be communicated to the complainant be made by, or reviewed and approved by, individual(s) **not involved** in the original laboratory activities in question

7.10 Nonconforming work

- No significant changes to this clause compared to the 2005 version
- 7.10.2 now specifically requires records to be retained of non-conforming work and the actions taken

7.11 Control of data and information management

- Extends and updates 5.4.7 in the 2005 version to address current laboratory practice
- 7.11.2 Note 1 clarifies that use of the term ‘laboratory information management system(s)’ in this document includes both computerised and non-computerised systems
- 7.11.4 requires the laboratory to ensure that off-site or external providers of information management comply with applicable requirements of ISO/IEC 17025

Session 3

Clauses 8 changes

8 Management system requirements

8.1 Options

- The standard now provides two options (A or B) for implementing a management system

Option A

As a minimum the management system of the laboratory shall address the requirements in clauses 8.2 to 8.9

- this is in line with facilities complying with clause 4 of the 2005 version of the standard

Option B

Establish and maintain a management system in accordance with the requirements of ISO 9001

- Both options require that the management system is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025 clauses 4 to 7 and assuring the quality of the laboratory results
- Facilities need only conform to one of the options (not both)

8.1.2 Option A

As a minimum the management system shall address the following:

- Similar to 2005 version
 - management system documentation (see 8.2)
 - control of management system documents (see 8.3)
 - control of records (see 8.4)
- Aligned with ISO 9001:2015
 - **actions to address risks and opportunities (see 8.5) (new)**
 - improvement (see 8.6)
 - corrective action (see 8.7)
 - internal audits (see 8.8)
 - management review (see 8.9)

8.2 Management system documentation (Option A)

- A number of prescriptive requirements have been removed in this clause
 - for example, the standard no longer prescribes a quality policy or specifically a quality manual, 'top management' changed to 'laboratory management'
- The laboratory must
 - establish and implement, document and maintain policies and objectives to fulfil the requirements of the standard
 - have policies and objectives that address the competence, impartiality and consistent operation of the laboratory

- ensure management provides evidence of commitment to implementation of the management system and its continual improvement
- ensure that all documentation, processes and records are included, referenced or linked to the management system
- ensure all personnel have access to the relevant parts of the management system documentation applicable to them

8.3 Control of management system documentation (Option A)

- The requirements are now less prescriptive in this clause
 - for example, 'Masterlist' of documents is no longer specified
- Facilities must ensure that
 - documents are approved prior to issue by authorised personnel
 - documents are periodically reviewed and updated
 - changes and the current revision status of documents are identified
 - relevant versions of documents are available and their distribution is controlled
 - documents are uniquely identified
 - unintended use of obsolete documents is prevented

8.4 Control of records (Option A)

- Changes for this clause are essentially editorial
- Facilities must retain records and implement controls for
 - confidentiality obligations
 - identification
 - storage
 - protection
 - archive
 - retrieval
 - retention times
 - disposal

8.5 Actions to address risks and opportunities (Option A)

- This clause covers new requirements and introduces the concept of **'risk based thinking'** (inherent throughout the whole standard)
 - the concept in the standard may be new, however, facilities already consider risk without necessarily referring to it as such
- Facilities must **consider** the risks and opportunities associated with laboratory activities in order to
 - provide assurance that the management system achieves the intended outcomes
 - enhance opportunities to achieve the laboratory's objectives
 - prevent / reduce undesired impacts and failures
 - achieve improvement

- Actions to address risks and opportunities must be planned and implemented into the management system and their effectiveness evaluated
 - action taken must be proportional to the potential impact on the validity of results
- The Note after 8.5.2 includes two important points
 - there is **no requirement** for formal methods for risk management or a documented risk management process
 - the facility is responsible for deciding which risks and opportunities need to be addressed

- Risks and opportunities should be addressed throughout the facility’s processes and the action taken or planned reflected in the records. For example, consider the following

Activity / issue	Actions / plans to account for risk
Personnel	Training plans
Equipment	Calibration programs, including intermediate checks on calibration status
Records	Maintenance and safeguarding
Measurement uncertainty	Documented methods describing the significant inputs to take into account
Method validation	Documentation to describe how to perform (what to consider) and the acceptance criteria
Quality control	Described for each method, performed as necessary, reviewed and monitored

- Consider the following opportunity and the associated risks

A laboratory tests for X. A customer approaches the company to test additionally for Y for a two year period. This opportunity will provide a 25% growth in the laboratory's activities during this time and require the purchase of new equipment.

- Risks which may need to be accounted for include, but are not limited to
 - capital outlay (equipment including consumables)
 - profit or loss making
 - staff numbers and experience required (including training)

8.6 Improvement (Option A)

- Clauses 4.7, 4.10 and 4.12 in ISO/IEC 17025:2005 have been combined and simplified
- The facility must
 - identify and select opportunities for improvement and implement any necessary actions
 - seek feedback from customers, analyse this and use it to improve the management system and laboratory activities

8.7 Corrective action (Option A)

- The principles of corrective action remain the same in the standard, however, the prescriptive nature of the requirements in ISO/IEC 17025:2005 have been simplified
- A key change is that risks and opportunities, which have been determined, must be updated if necessary when a nonconformity occurs

- When a nonconformity occurs, the laboratory must
 - react and take appropriate actions to control and correct the nonconformity
 - evaluate the need for action to eliminate the cause(s) of nonconformity in order that it does not recur
 - implement any action needed
 - review the effectiveness of any corrective action taken
 - update risks and opportunities if necessary
 - make changes to the management system, if required

8.8 Internal audits (Option A)

- The principles of internal audits remain the same
- ISO/IEC 17025:2005 specified that internal audits were the responsibility of the quality manager, however, the new standard no longer specifies this and simply requires personnel to be authorised for given tasks
- The standard now requires the results of previous audits to be taken into account and that the criteria and scope for each audit be defined

8.9 Management review (Option A)

- The management review requirements are essentially the same, however the elements to review have been expanded including
 - changes in relevant internal and external issues
 - fulfilment of objectives
 - status of actions from previous management reviews
 - effectiveness of any implemented improvements
 - results of risk identification

- The standard now specifies that decisions, in addition to actions, need to be recorded including
 - the effectiveness of the management system and its processes
 - improvement of the laboratory activities related to the fulfilment of the requirements of the standard
 - provision of required resources
 - any need for change

Session 4

- **Transition process**
- **Availability of the standard to Technical Assessors**
- **Assessment process**
- **Assessment of the management system**

Transition

- Facilities must
 - obtain a copy of the revised standard (either from a supplier of ISO or Australian standards)
 - obtain from the NATA website a copy of the Transition Policy and familiarise themselves with it
 - update their NATA Accreditation Criteria (NAC) package by obtaining copies from the NATA website the revised ISO/IEC 17025 Standard Application Document (SAD) and where relevant, the associated Appendices and Annexes

Availability of the standard to Technical Assessors

- The standard will only be distributed to a Technical Assessor at the time that they participate in a reassessment from 1 August 2018

Assessment Process

- For accredited facilities, assessment to the new standard can occur either
 - at the time of the next scheduled NATA visit (whether a reassessment or surveillance visit) after 1 August 2018; or
 - upon request from the facility for a chargeable variation visit
- For applicant facilities, initial assessment from 1 August 2018 will be conducted against the new standard

- Prior to the assessment, facilities will need to complete the pre-assessment questionnaire (*Assessment Information Document*) as is now the case, in addition to completing the *ISO/IEC 17025 Implementation Checklist*
 - supporting evidence (policies, procedures and/or records as necessary) must be supplied with the completed *Implementation Checklist* demonstrating compliance with the new standard
- On-site assessment will be conducted as per current processes

- Any areas of non-compliance identified at the on-site assessment will be detailed in the assessment report as conditions (either 'C' or 'M') as per the current NATA process
 - facilities will need to respond to the conditions in the usual manner prior to accreditation being continued and granted to the new standard
- The scope of accreditation will be updated to reference the new standard following confirmation of compliance, or where conditions have been raised, following a satisfactory response to these

- Conversion to the new standard following a request from the facility outside of a scheduled visit will be conducted as a chargeable activity
 - the facility will need to complete the *ISO/IEC 17025 Implementation Checklist* and provide supporting evidence as necessary
 - the completed checklist and evidence will be reviewed by a NATA Lead Assessor
 - if compliance cannot be established then further evidence may be requested or an on-site visit conducted
 - the facility will need to respond to any areas of non-compliance identified prior to accreditation being granted to the new standard and the scope of accreditation updated

Assessment of the management system

Option A

- Assessment will follow the same process as currently occurs for assessing clause 4 of ISO/IEC 17025:2005

Option B

- The system may not be assessed in full by NATA subject to
 - 1) the management system being certified by a certification body accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).

The certification body must be accredited to certify management system schemes to ISO 9001.

NATA may request the facility to provide evidence of the certification body's scope of accreditation.

- 2) copies of the most recent certification audit reports being made available to NATA for review, including confirmation from the certification body of the close out of any non-conformities raised
- 3) the management system allows the fulfillment of the requirements of clauses 4 to 7 of ISO/IEC 17025 for the activities covered by the facility's NATA scope of accreditation

- The required extent of assessment will depend on the evidence provided
- The facility must notify NATA within 14 days when a change occurs in its ISO 9001 certification status
- Where the ISO 9001 management system is not certified by a certification body recognised under the International IAF MLA NATA will assess the management system in full against the requirements of Option A
- The SAD describes NATA's process for assessing the Option B management system