

World Metrology Day, Lower Hutt, 22 May 2018

NZS ISO/IEC 17025 2005 vs. 2018*

*General requirements for the competence of
calibration and testing laboratories*

A discussion on the changes in the new version

*international version published 2017



Disclosure:

This talk is my interpretation of the differences after much reading and highlighting and supported by internal training at IANZ. Also from a calibration person not a testing person!

Objective

- ① To help you feel more comfortable with the transition, new format and **important changes**

- ① To give an opportunity to ask questions

- ① (Time available is not much)
- ① Some detail still to be sorted – and how to assess! (IANZ)
- ① Official [transition document](#) now available at IANZ>Resources>Documents>General
- ① List for cross-reference charts

2



Compliance timeframes and plan

- ⊙ ILAC has advised that :2005 no longer recognised after December 2020 (3 years)...so
- ⊙ All accredited laboratories must be fully compliant by then
- ⊙ Assessments to :2018 will commence 1 July 2018 (IANZ)
- ⊙ Full manual reviews (audits) prior to your RR between Jul. '18 and Dec. '20 (or before if requested)

3



ILAC

International laboratory accreditation cooperation

NZS ISO/IEC 17025:2005	NZS ISO/IEC 17025:2018
Scope/references/terms	Scope/references/terms
Section 4 Management Requirements Incl. documentation, requests, customer service, responsibilities, communication, internal audits, management reviews	Section 4 General Requirements Incl. impartiality and confidentiality
Section 5 Technical Requirements Incl. personnel, environment, equipment, reporting the results	Section 5 Structural Requirements Incl. responsibilities, meeting requirements, communication
	Section 6 Resource Requirements Incl. personnel, environment, equipment
	Section 7 Process Requirements Incl. requests, methods, work, reporting, customer service
Annexes	Section 8 Management Requirements Incl. documentation, improvements, internal audit and mgmt. review (introduces option A and B)
	Annexes

17025:2005

- **A lot of policy/documented procedures needed e.g. uncertainty, corrective action, IAs...**
- **Not in a logical or intuitive order (opinion?)**
- **Requirements referred to in more than one place**

:2018

- **More logically ordered**
- **Introduces risks and opportunities as opposed to preventive action and improvements**
- **Less procedures required and more of 'just doing' - In assessments, ? Maybe don't need to look at procedures, just whether it is happening**
- **Much more detail in the organisational (general and structural) requirements – particularly impartiality and confidentiality**

Discuss option A and option B with reference to standard later

The bits at the beginning

- ① Section 1: Scope
- ① Section 2: Normative references
- ① Section 3: Terms and definitions
- ① These are essentially unchanged except section 3 now includes a more helpful list of definitions



5

IANZ
be assured

Section 3 examples of definitions include

Impartiality

Intralaboratory comparison

Decision rule

Section 4: General requirements

incl. impartiality, confidentiality

- ⊙ “Your people need to...” ...be impartial and confidential
- ⊙ Much more detail here

old	new
4.1.4,	4.1 impartiality
4.1.5b, d	<ul style="list-style-type: none">• shall be responsible for the impartiality of activities^{4.1.3}• shall identify risks to its impartiality on an on-going basis^{4.1.4}• demonstrate how it eliminates/minimises risk^{4.1.5}

6

IANZ
be assured

Old:

4.1.4 – define responsibilities to avoid Cs of I

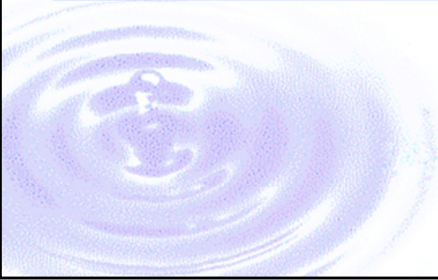
4.1.5b, c, d – internal and external pressures/influences, protection of customers rights and information, avoid activities diminishing impartiality

Definition of impartiality (3.1): presence of objectivity i.e. no conflicts of interest exist or they are resolved. AKA neutrality, fairness, freedom from bias

New: 4.1.4 includes risks arising from activities, its relationships, relationships of its personnel (e.g. ownership, shared resources, marking, sales commissions etc.)

Section 4: General requirements ctd.

old	new
4.1.5c	4.2 confidentiality <ul style="list-style-type: none">• shall be responsible through legally enforceable commitments for the management of all information obtained or created^{4.2.1};• Notification to client of info in public domain^{4.2.1}, info released by law^{4.2.2}• Confidentiality of source in complaints, disputes^{4.2.3}



4.2.1 e.g. contractual agreements

What this might mean

1. *Add clauses to service agreements, terms and conditions, for management of client information? 4.2.1*
2. *Some labs may need to insert standard clauses for information to the public domain e.g. EIPC labs? 4.2.1*
3. *Update complaints procedure 4.2.3*

Section 5: Structural requirements

Incl. responsibilities, meeting requirements, communication

- ① “Your organisation needs to...” ...be responsible, committed and communicate effectively

old	new
4.1.1, 4.1.2, 4.1.3, 4.1.5(parts), 4.1.6, 4.2.1, 4.2.7	<ul style="list-style-type: none">• Define management^{5.2} (used to be technical, quality, deputies)• Define and document range of laboratory activities for which it conforms with this document and only claim conformity for this range^{5.3}• Communication takes place regarding importance of meeting customer requirements^{5.7a}

5.2 – but see also 5.6d req to have *personnel* responsible for reporting to laboratory mgmt. on the performance of the mgmt. system, 5.6e for ensuring the effectiveness of the system

What this might mean

5.3 – FOR ACCREDITED LABORATORIES might mean that some labs document the distinction here between activities in conformance vs. activities accredited

Section 6: Resource requirements

Incl. personnel, environment, equipment

- ① “Your laboratory needs to have...” ...appropriate people and conditions, sound traceability

old	new
5.2, 5.4.3, 6.2.1	6.2 Personnel <ul style="list-style-type: none">• Document the competence requirements for each function in the lab^{6.2.2}• Have procedures and retain records for determining and monitoring of competence^{6.2.5a,f}

9



6.2 – used to be ‘ensure the competence of’

What this might mean

1. 6.2 Each function e.g. technician, signatory, lab manager, needs competency requirements document. For example you might say that a technician needs competency in carrying out a calibration procedure but not in checking a report.
2. 6.2.5 write procedure on how competency is determined and monitored (ref to competence requirements, probably)

This may mean that your competence reviews will be more straightforward

You may be more ready for a signatory to be recommended by IANZ, as opposed to the recommendation for signatory approval being held up because some aspect of competence required was missed

Section 6: Resource requirements ctd.

old	new
5.5, 5.6.1	6.4 Equipment <ul style="list-style-type: none">• Shall have access to equipment^{6.4.1}
old	new
4.5, 4.6	6.6 Externally provided products and services <ul style="list-style-type: none">• More emphasis on evaluation of providers^{6.6.2} and more detail on communicating requirements to providers^{6.6.3}

- ⊙ 6.3 Facilities and environmental conditions and 6.5 Metrological (was measurement) traceability mostly unchanged

6.4 – used to be ‘be furnished with’

6.6 used to be subcontracting of tests and calibrations, purchasing services and supplies

What this might mean

6.4 - ? Appropriate access via other sites? Hired equipment? But need to ensure control of, still

6.6 – more detail in procedures for externally provided products/services

Section 7: Process requirements

Incl. requests, methods, work, reporting, customer service

- ⊙ “Your processes need to...” be carried out with integrity, be technically appropriate and be valid

old	new
4.4, 4.5, 4.7.1	7.1 Review of requests, tenders and contracts <ul style="list-style-type: none">• Decision rule shall be clearly defined and shall be communicated to and agreed with the customer unless inherent in requested spec/standard^{7.1.3}• Deviations requested by the customer shall not impact integrity of lab or validity of results^{7.1.4}

- ⊙ 7.3 was 5.7 Sampling but most metrology laboratories exclude this requirement as no sampling is done (some changes to records required)
- ⊙ 7.5 was 4.13.2 Technical records and 7.6 was 5.4.6 (U of M) no major changes

11



Decision rule definition – discuss more with reporting

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

What might this mean

7.1 – the reqs for review of work are more detailed and strict – probably service requests etc. will have to be made more formal in most cases, even if just the first case for routine clients – and include d.r

7.1.4 – consider what this might mean for clients who ask for sub-standard work e.g. as cost-cutting

Unfortunately in metrology there are not a lot of specifications or standards (and if you do have one it doesn't usually include the decision rule to use)

An example for 7.1.3 where the decision rule is inherent in the requested specification would be in the MSA Test Method 2 for calibration of pressure gauges, which includes the decision rule to use.

Section 7: Process requirements ctd.

old new

- 5.8 7.4 Handling of test and calibration items
- the laboratory shall add a disclaimer in the report indicating which results may be affected by [a deviation from specified conditions requested by customer]^{7.4.3}

old new

- 5.9 7.7 Assuring the validity [was quality] of results
- Shall have a **procedure** for monitoring the validity of results^{7.7.1}
 - Monitoring shall include where appropriate^{7.7.1a-k} (gives more/new examples)
 - Shall monitor its performance **by comparison with other laboratories**^{7.7.2}

12



7.7.1 used to be ‘shall have qc procedures for monitoring the validity of...’

7.7.1a-k includes now review of reported results, intra-lab comparisons

7.7.2 (where available and appropriate)

What this might mean

7.4.3 for example (?) if a function on a multi-function calibrator is not working and the customer wants you to calibrate it anyway, you have to make a disclaimer in the report?

7.7 a concentrated procedure on monitoring validity of results

Section 7: Process requirements ctd.

old	new
4.5.3, 5.10	<p>7.8 Reporting the results</p> <ul style="list-style-type: none">• Results shall be reviewed and authorised prior to release^{7.8.1.1}• Required: date of issue of report ^{7.8.2.1(j)}• Clear ID of externally provided results ^{7.8.2.1(p)}• Info provided by customer cleared identified and a disclaimer when it may affect validity of results^{7.8.2.2 (also 7.4.3)}• Decision rule^{7.8.6.2(c)} and level of risk documented^{7.8.6.1}• Report reissue: Change of information identified and where appropriate, reason for change included in report^{7.8.8.1}

7.8.2.1(p) – used to be allowed for testing only, but issuing lab still responsible for whole report

7.8.6.2c unless inherent in requested spec or std

7.8.6.1 when a statement of conformity to a specification or standard is provided, the lab shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule. (Note: where the d.r. is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

What it might mean

Changes to policy for reporting templates including reissued reports

Section 7: Process requirements ctd.

old new

- 4.8 7.9 Complaints [much more detailed]
- Description of handling process **shall be available to any interested party** on request^{7.9.2}
 - Acknowledge **receipt, provide progress reports** and outcome^{7.9.5}
 - Outcomes made or reviewed and approved by individual(s) not involved^{7.9.6}

old new

- 5.4.7 7.11 Control of data – information management
- Laboratory information management system(s) shall be validated for functionality by the laboratory before introduction^{7.11.2}
 - More detail on what is required in the system(s)^{7.11.3}

- ⊕ 7.10 Nonconforming work was 4.9 – new focus on wording – actions based on risk, impact analysis on previous results

14



7.9 Used to be 4.8: basically, have a policy and procedure and maintain all records.

7.11 Note to 7.11.2: commercial off-the-shelf software sufficiently validated already.

Section 8: Mgmt system requirements

Incl. documentation, improvements, internal audit and mgmt. review (introduces option A and B)

🎯 “Your management system needs to...”

old **new**

- | | |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ~4.10, | 8.5 Actions to address risks and opportunities |
| ~4.12 | <ul style="list-style-type: none">• The laboratory shall plan actions to address considered risks and opportunities and how to integrate, implement and evaluate the actions^{8.5.2}• (Actions proportional to potential impact on validity of results^{8.5.3}) |

old **new**

- | | |
|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.15 | 8.9 Management review a few new agenda requirements ^{8.9.2} : |
| | <ul style="list-style-type: none">• Changes in internal and external issues relevant to lab• Status of previous MR action items• Personnel feedback• Effectiveness of implemented improvements• Results of risk ID |

15



Mostly the same but with the noted addition of 8.5

***Examples of risks:**

Recurring non-conformances

Staff succession/numbers

Failing or old equipment

***Examples of opportunities:**

External training

Considerations IANZ recommendations

Staff suggestions

4.10 IMPROVEMENT and 4.12 preventive action

What this might mean:

Updates to improvement procedures/policies, Addition of risk assessment procedures/policies

Section 8: Management system requirements – new Options

- ⊙ New options A and B
 - ⊙ Option A is the same as how we do it now
 - ⊙ Option B – need to ensure the ISO 9001 system appropriately covers the accredited laboratory's processes and requirements from ISO 17025
 - ⊙ IANZ will still need to assess outcomes of the 9001 system *related to the scope* covering requirements of 17025 (e.g. internal audit, document control etc.)



Re option A

“as a minimum the laboratory shall address clauses 8.2-8.9 [this section]” (basically, section 4 of :2005)

Option A is normal assessment process as we have been doing it so far

Re option B

“if the lab maintains an ISO 9001 system capable of supporting the requirements of clauses 4 – 7 of 17025 then the lab FULFILLS AT LEAST THE INTENT of clauses 8.2 to 8.9”

Goes on to say in annex

“conformity with 9001 does not demonstrate competence to produce valid results – this is accomplished through compliance with clauses 4 to 7”

How will you comply – next steps

- ⊙ Get your copy, if you haven't already (SNZ, login for IANZ-accredited laboratories)
- ⊙ Cross-reference charts, IANZ transition paper may help
- ⊙ NZQC training courses (**June**, Aug Chch, **Sept Akl**, Oct Akl)
- ⊙ You don't *need* to re-write your documented system!
- ⊙ Interim/regular internal audits to check progress and/or
- ⊙ Option for early review of your quality manual if you feel it would help

Bolded courses are update only (others LQM)

*Official transition document download (pdf) at
<https://go.promapp.com/ianz/Documents/Minimode/Permalink?crypto=tXf5qrDpzE4adeZOjkK3G>*