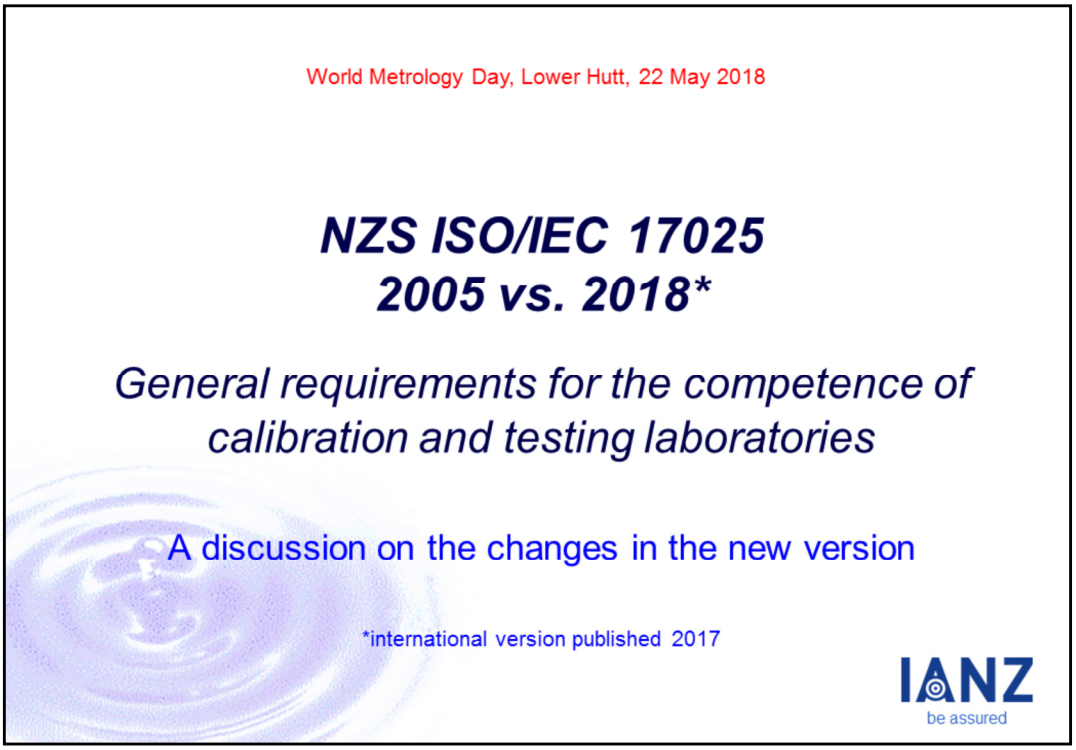


Disclosure:

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!

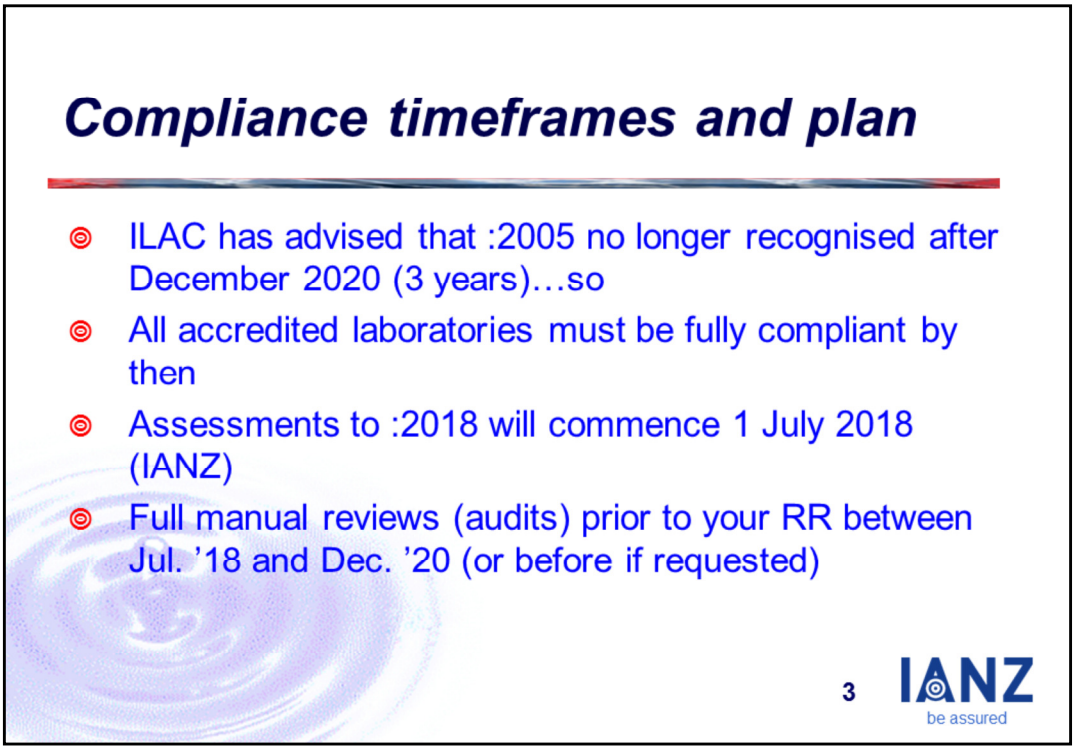
Objective

- To help you feel more comfortable with the transition, new format and **important changes**
- To give an opportunity to ask questions

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

2

IANZ
be assured



ILAC

International laboratory accreditation cooperation

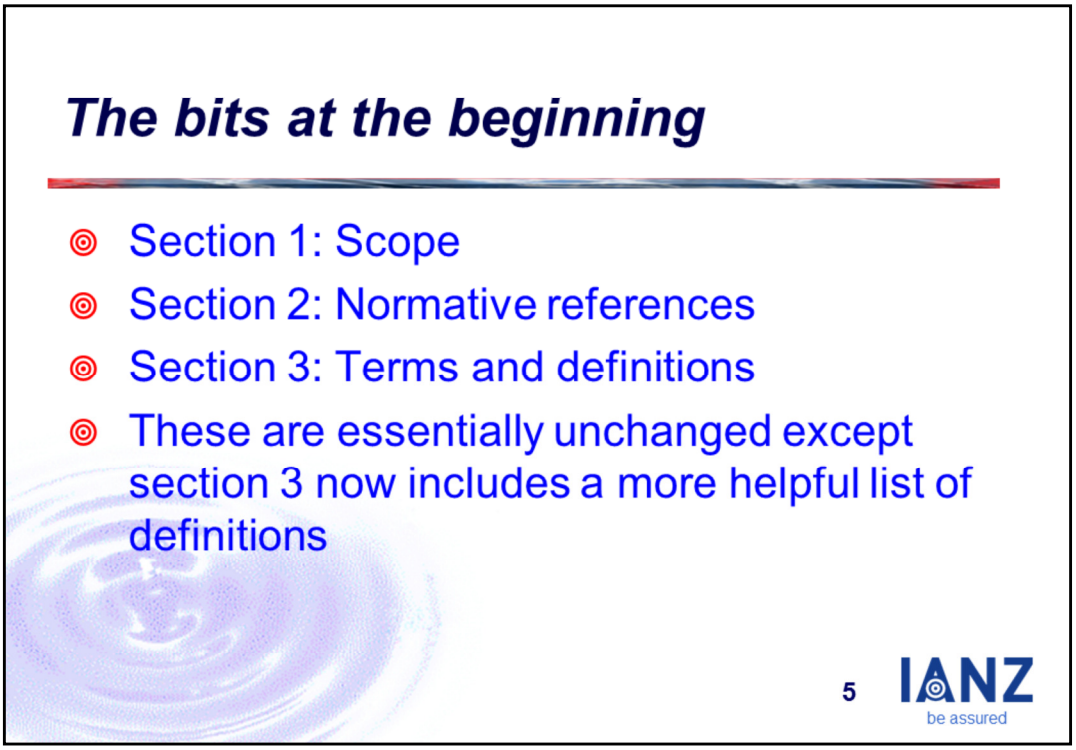
17025:2005

- ***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

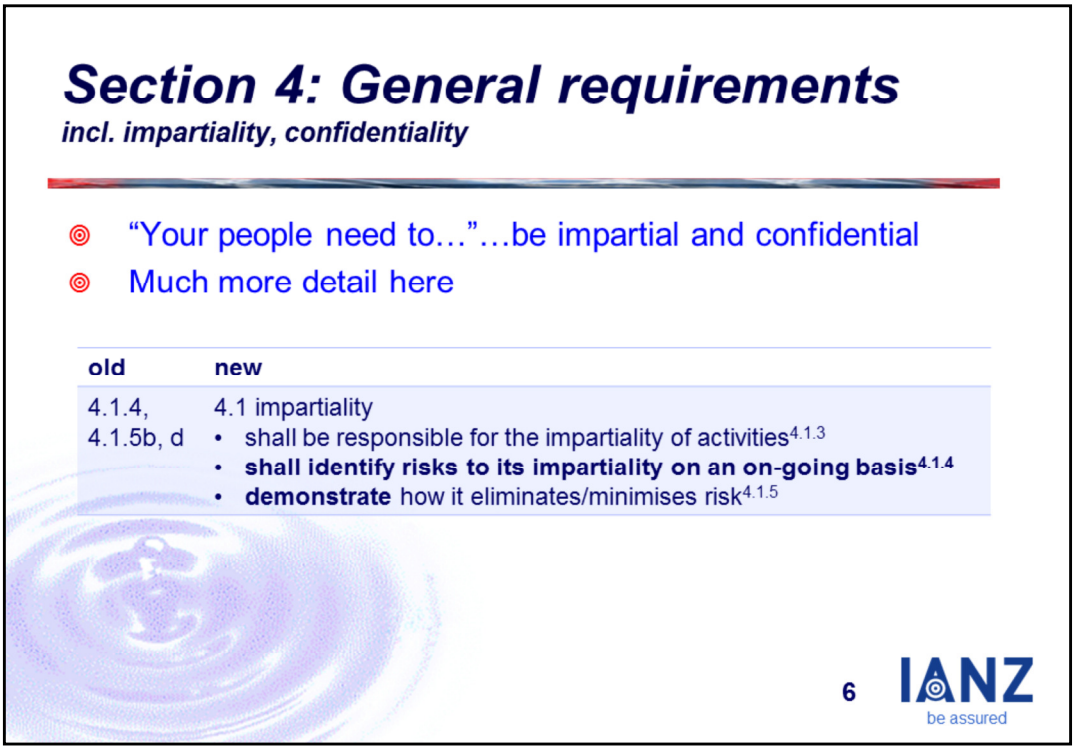


Section 3 examples of definitions include

Impartiality

Intralaboratory comparison

Decision rule



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

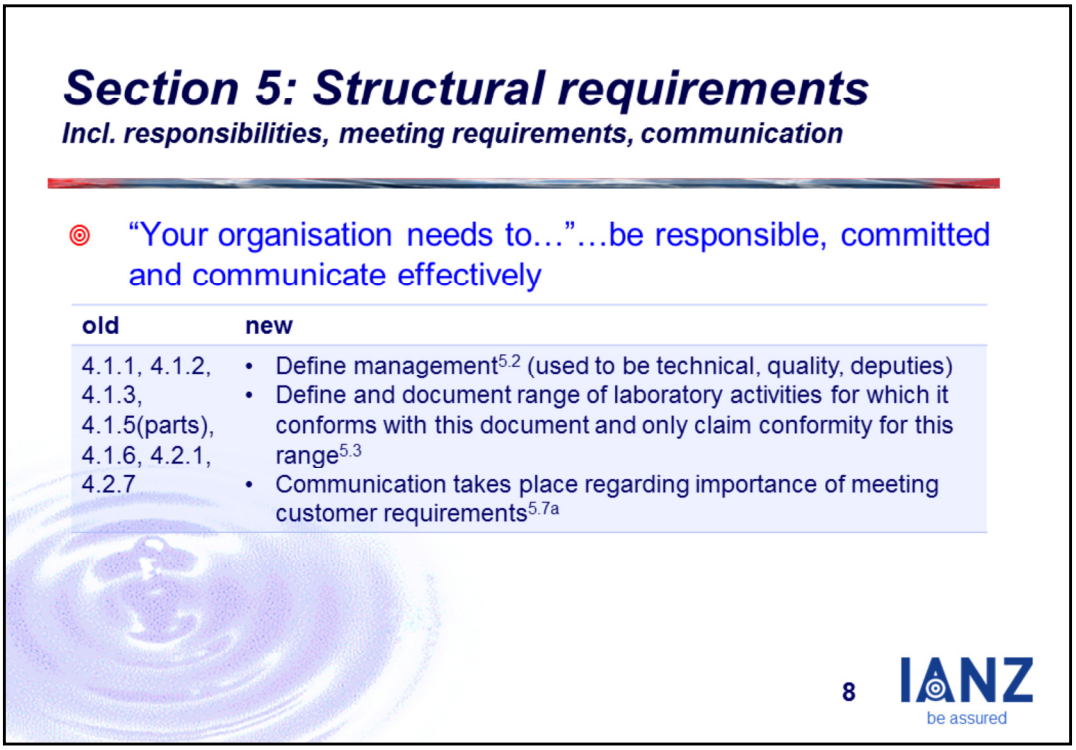
Definition of impartiality (3.1): presence of objectivity i.e. no conflicts of interest exist or they are resolved. AKA neutrality, fairness, freedom from bias

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

4.2.1 e.g. contractual agreements

What this might mean

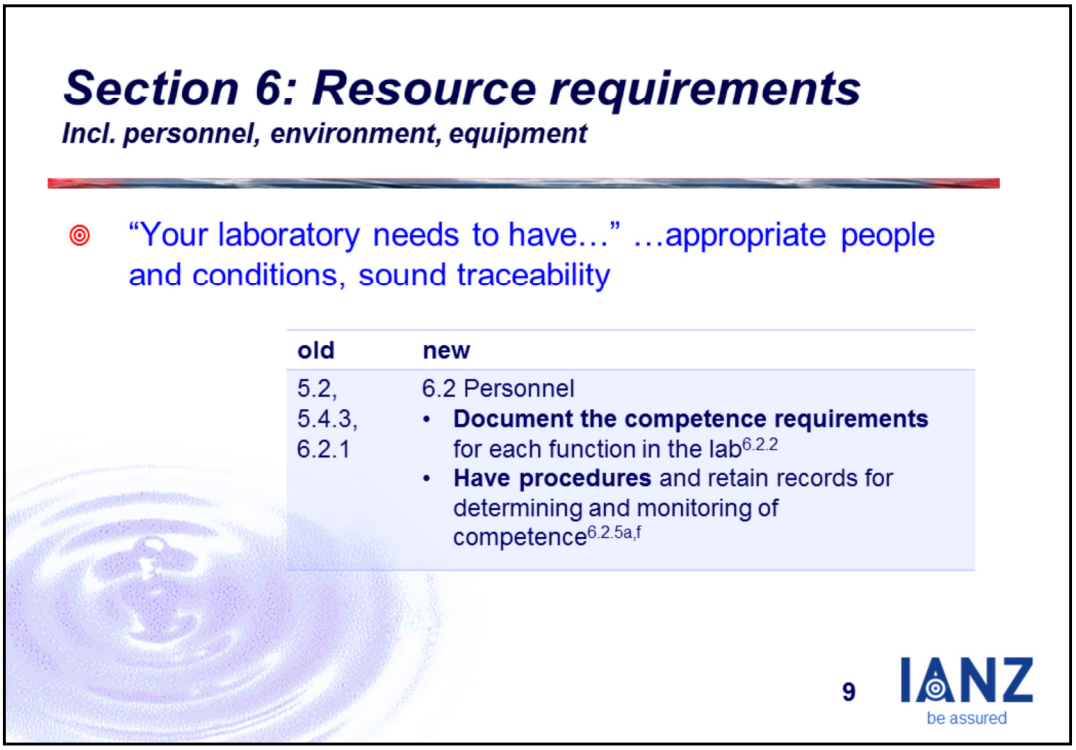
1. *Add clauses to service agreements, terms and conditions, for management of client information? 4.2.1*
2. *Some labs may need to insert standard clauses for information to the public domain e.g. EIPC labs? 4.2.1*
3. *Update complaints procedure 4.2.3*



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



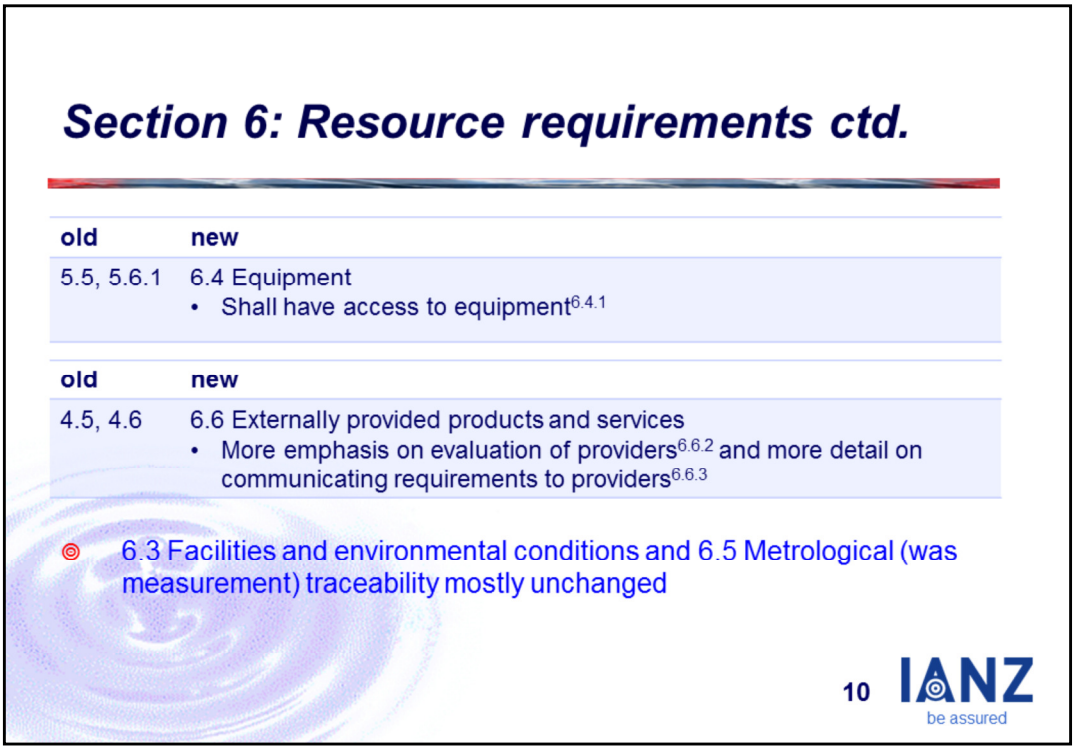
6.2 – used to be 'ensure the competence of'

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



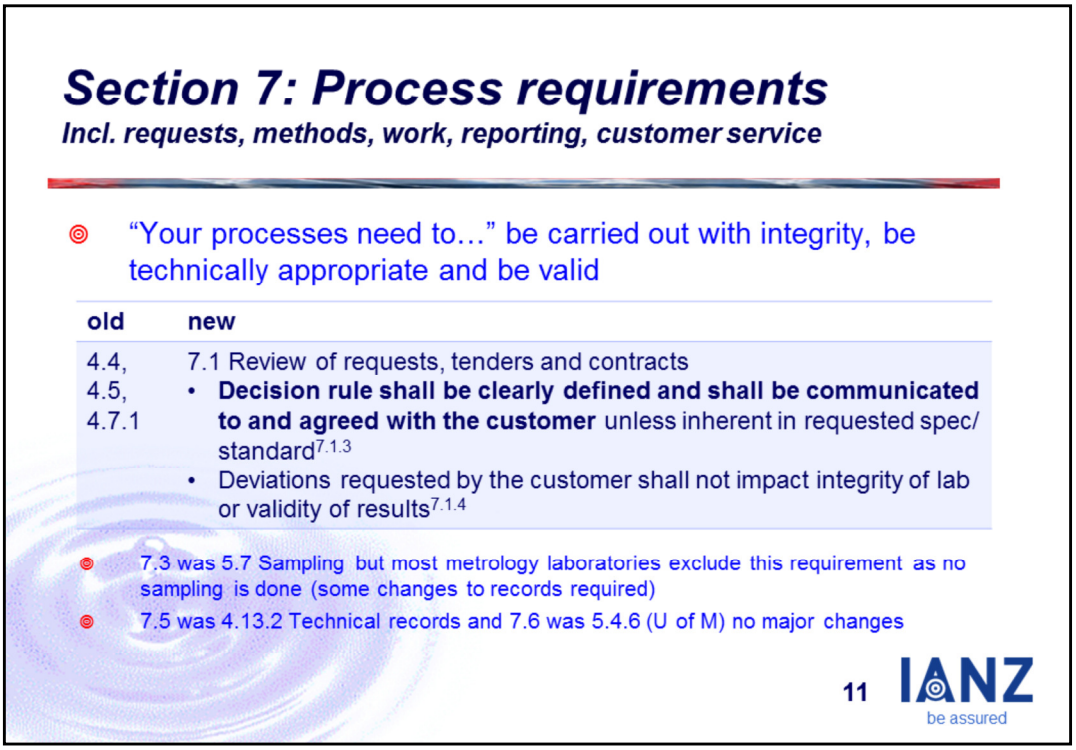
6.4 – used to be 'be furnished with'

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



Decision rule definition – discuss more with reporting

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

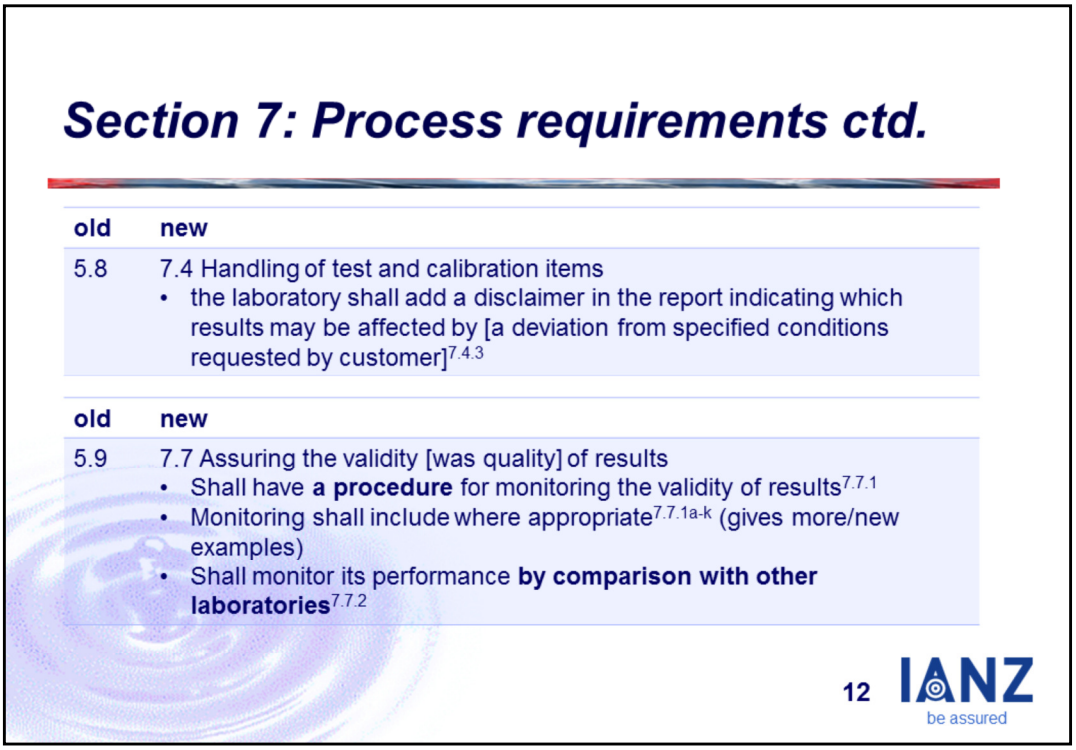
What might this mean

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.



7.7.1 used to be 'shall have qc procedures for monitoring the validity of…'

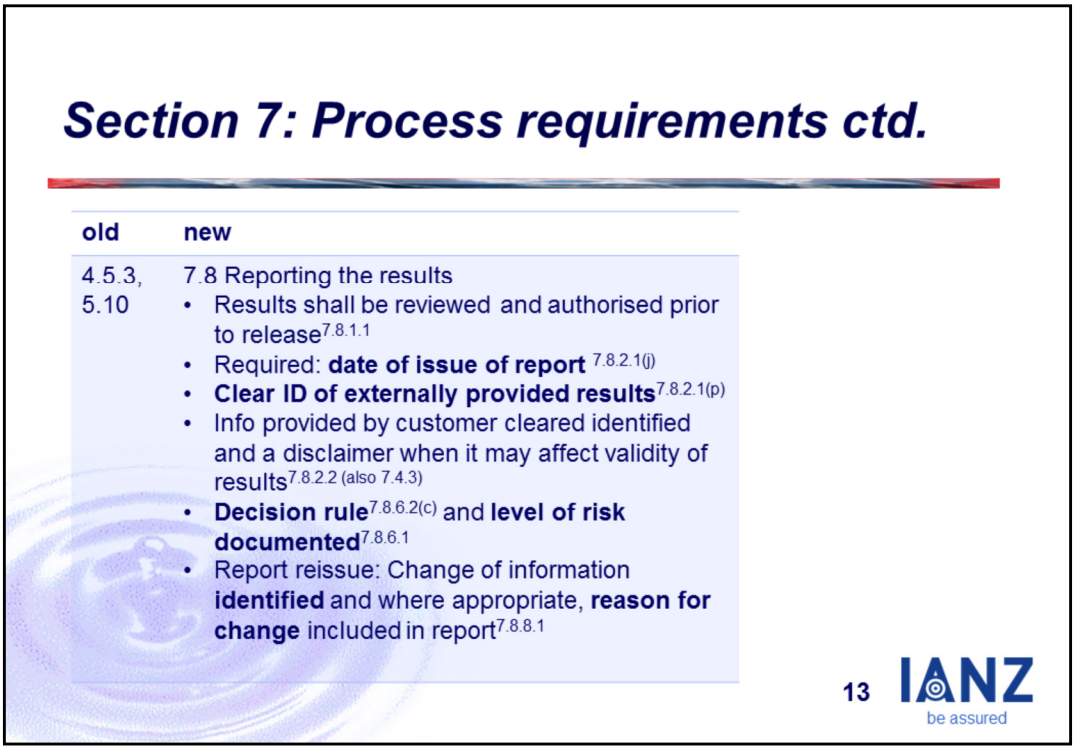
7.7.1a-k includes now review of reported results, intra-lab comparisons

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



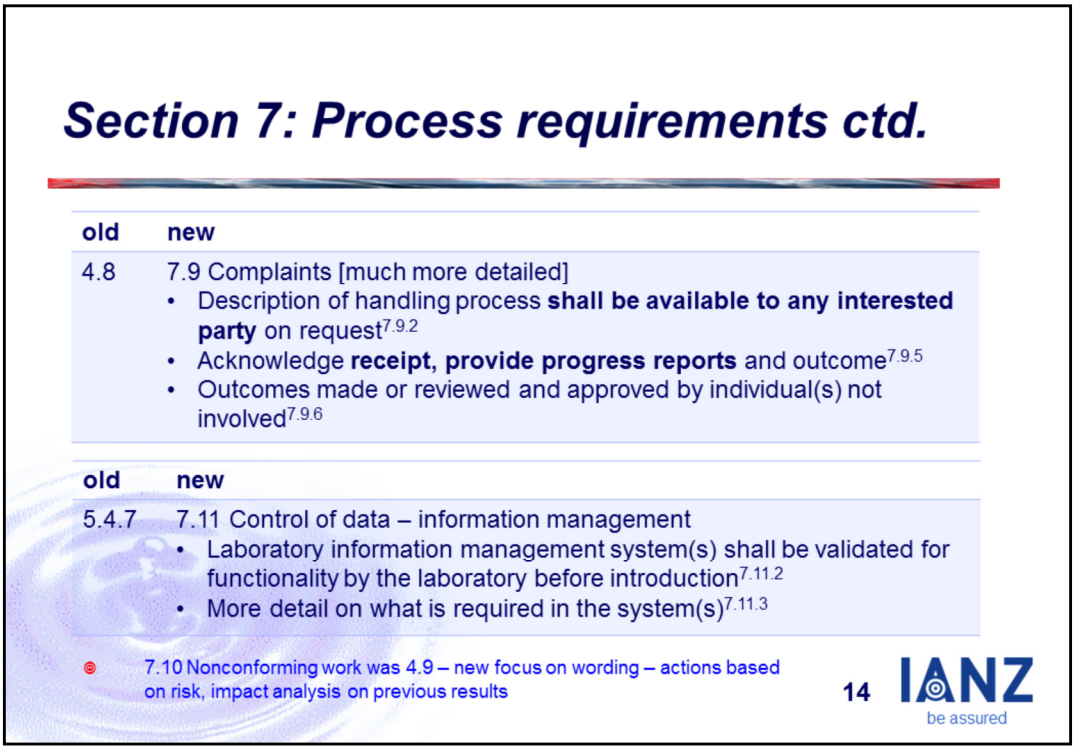
7.8.2.1(p) – used to be allowed for testing only, but issuing lab still responsible for whole report

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.*

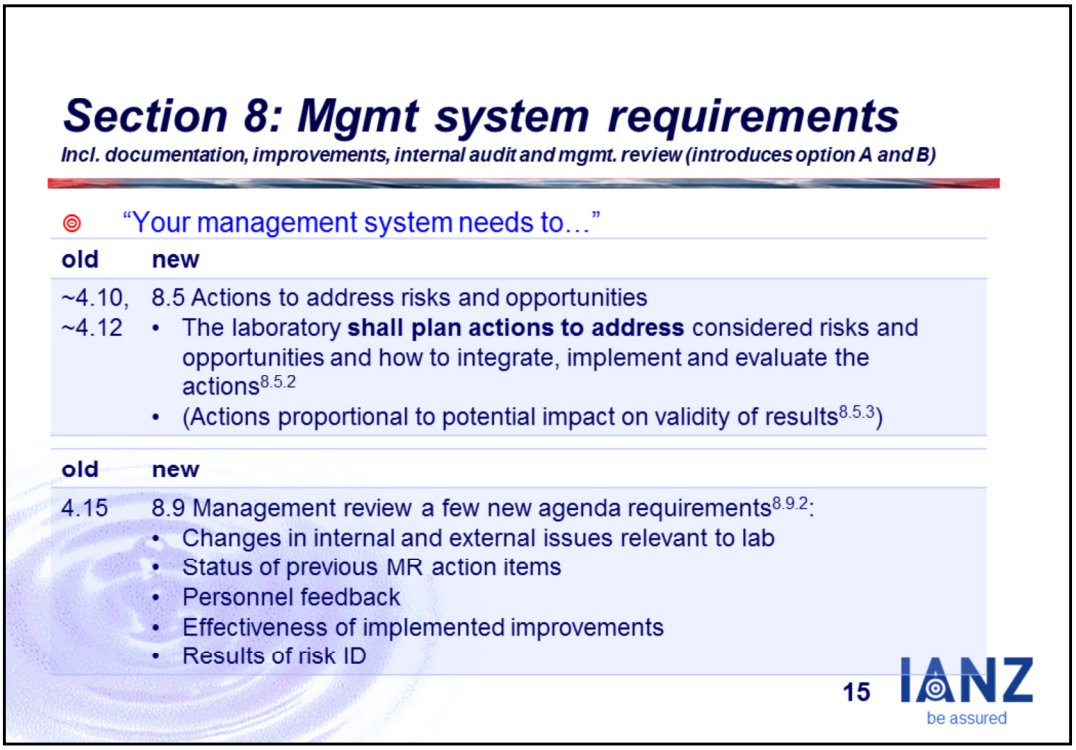
What it might mean

Changes to policy for reporting templates including reissued reports



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.



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

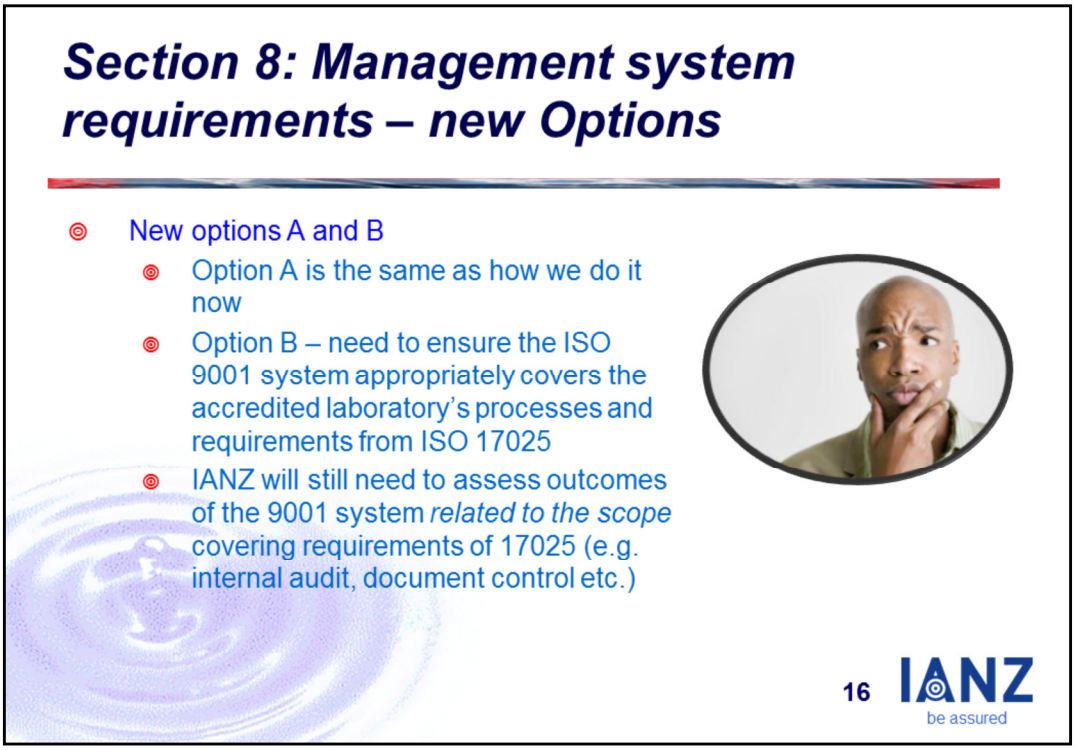
Considerations IANZ recommendations

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



Re option A

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

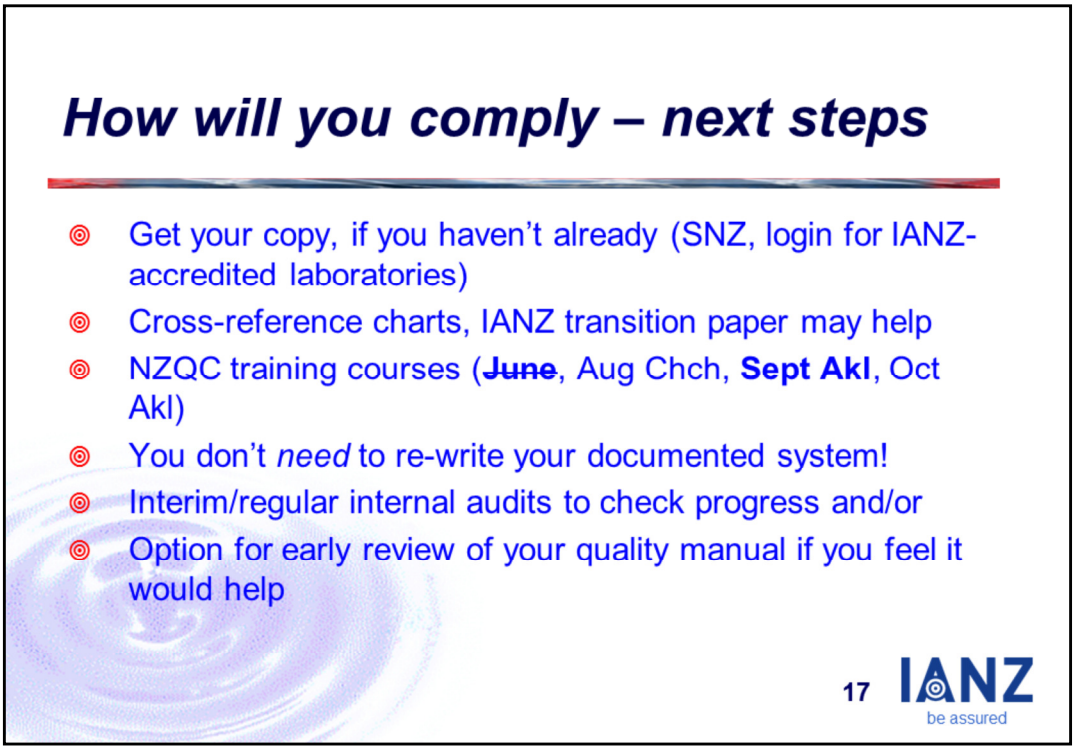
Option A is normal assessment process as we have been doing it so far

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"



Bolded courses are update only (others LQM)

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