IANZ

Measurement Standards Laboratory of New Zealand

Burden or Boon?

Getting the most out of your IANZ assessment

Claire Jongenelen, IANZ and Laurie Christian, MSL

A business of CallaghanInnovation

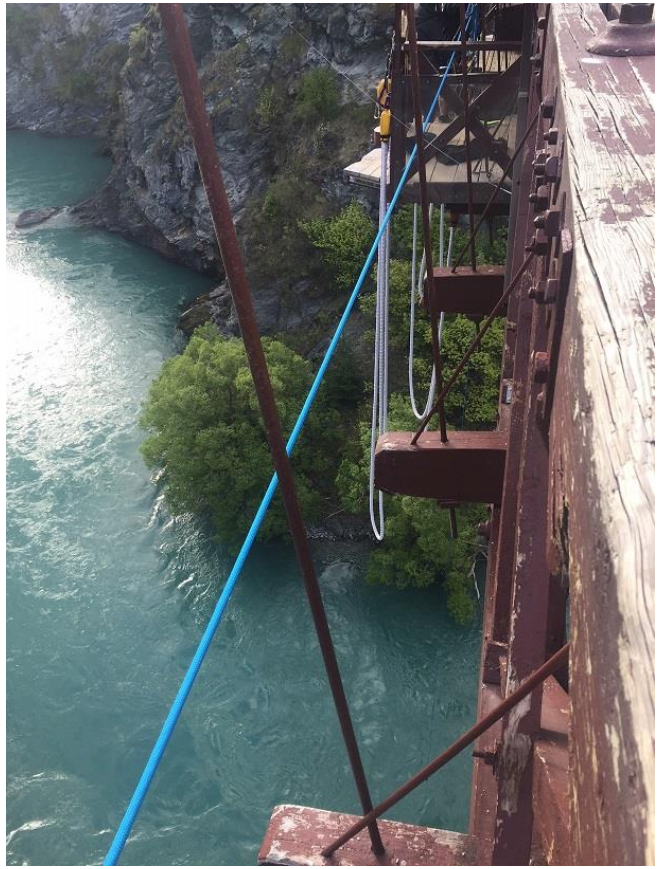
Who are we?

- Laurie:
  - Electrical metrologist with almost 40 years experience
  - IANZ signatory for many types of electrical measurement
  - Contracted by IANZ as a technical expert
  - Has assessed electrical labs in other NMIs
- Claire:
  - IANZ assessor for almost 6 years (testing and calibration)
  - Proficiency testing coordinator
  - Experience as technician in accredited laboratories
  - Standards and policy geek
- Each of us has been on both sides of the IANZ assessment fence

Content and objective

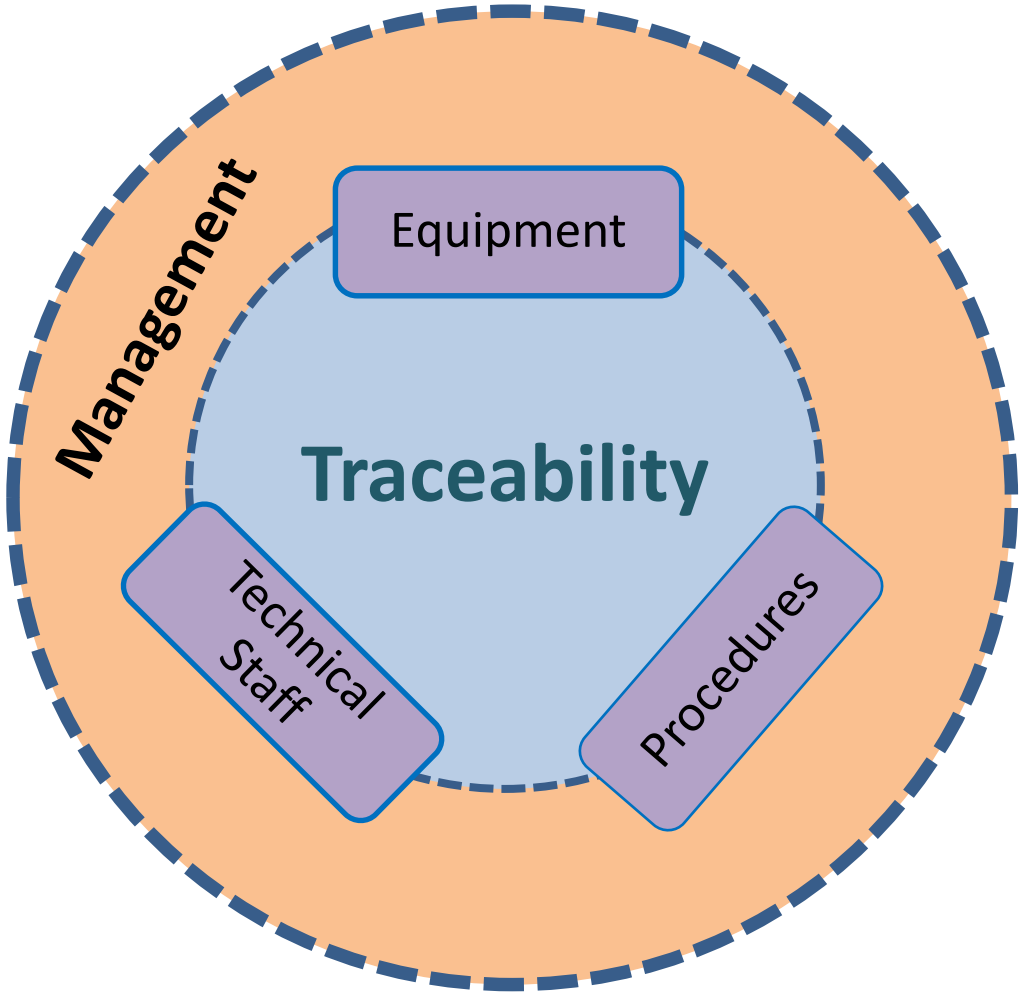
- Intentions and objectives of IANZ accreditation and the assessment
- The assessment process
- Managing expectations regarding the assessment
- Some specific examples of what might be reviewed during your assessment
- View the assessment as a two-way process – we learn and you learn
- Relax (and save time and money!)

Value of traceability – quantifying uncertainty and gaining confidence



“WEIGHT:
Between 35 kg to 235 kg. Weight difference between tandem Jumpers must not exceed 30 kg, Maximum combined weight is 235 kg”

ISO 17025 and test and calibration laboratories



- ISO 17025 (2017) “specifies the general requirements for the competence, impartiality and consistent operation of laboratories.”
- Traceability can be lost if there are failures in any of the elements in the diagram.
- ISO 17025 describes the **minimum** requirements for each of these elements.
- It defines what is required to consistently provide the test and calibration services specified in the laboratory’s scope of accreditation.

The date has been set

- How to make the assessment the most useful experience for the laboratory?
- Expectations
  - What do you want to get out of the assessment?
  - Are there aspects of the assessment you are nervous or unsure about? > Seek clarification.
- Attitude
  - What attitude do technical staff and management have towards the assessment? Is that helping or hindering?
  - If you are a manager, how can you help your staff feel comfortable?
- Preparation
  - Pressures on the business can mean that you may not be as prepared as you would like – we understand that!
  - Remember to acknowledge content of letters and emails regarding the assessment.

Be honest!

Value of the assessment process?

- Is the assessment like having to pay for your vehicle license or more like getting a WOF?
  - The first feels like handing money over just because you have to and the other an activity that could save lives.
- Internal audits and management reviews can help manage ISO 17025 non-conformances but they are not equivalent to an external assessment.
  - Your customers get greater assurance from an independent third-party expert review of your laboratory operations and competence of staff.

Expectations

- What will be a successful outcome for you?
  - Is anything other than zero CARs a failure?
- What about setting the expectation among the staff that the laboratory will be more successful as a result of the assessment?
- We want to help your laboratory improve and thrive – fact-finding, not finger-pointing.

(a) Corrective Action Requests are actions that the organisation must carry out before accreditation can be granted. CARs usually relate to non-compliance with the General or Specific Criteria;

(b) Strong Recommendations (where used) are actions that may represent actual minor nonconformities, or potential nonconformities with accreditation criteria;

(c) Recommendations are actions that the organisation is urged to carry out in the interests of good practice, but are not considered CARs.

Loss of reputation

- Loss of reputation is very expensive to a laboratory.
- A CAR raised before reputation damage is done is a really good thing!

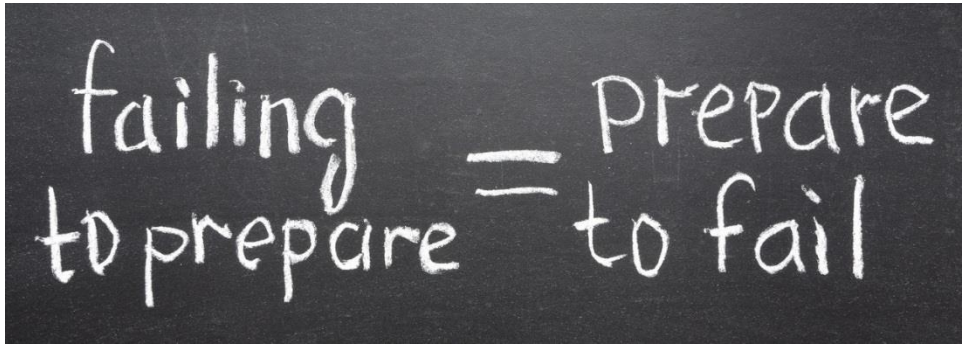
Attitude of management

- Management thinking: is the assessment being a nuisance and a threat, or is it a helpful and positive exercise?
  - It is helpful if all staff, especially the less experienced ones, think of it as positive.
- ISO 17025 is actually a minimum set of requirements.
  - The recommendations are worth reviewing to see if they will improve your laboratory operation either through efficiency gains or reduction of risk.

Attitude of the technical staff

- Almost invariably the technical staff take pride in their work (and are very good at it).
  - Newer staff might be intimidated.
  - Assessment team try hard to make the process comfortable and act professionally.
  - Staff not expected to know everything (but should know who to ask or where to look).
- Encourage staff to be open and engaged.
  - They stand to learn a great deal if they approach the assessment that way.
  - Ask questions!

Taking time to prepare



- It can be difficult when the lab has to keep operating before and during the assessment.
  - But it is obvious to the assessment team when the lab is not prepared.
  - Time is then wasted and the added-value aspects are not realised.
  - The follow-up will likely take longer than if you had prepared anyway (and cost more).
- New staff will benefit most from adequate preparation.
  - They can then really engage with the process and learn from the experience.
  - Important that they have time to understand the kind of questions they will be asked.
  - Particularly important for signatory applicants.

Added-value: fresh and experienced eyes

- The IANZ lead assessor and the technical expert have seen many labs like yours.
  - Useful suggestions for correcting non-conformances and recommendations.
  - Technical experts are picked by IANZ to best fit your laboratory.
  - You are allowed to ask questions especially over lunch!
  - Feedback about your assessment to the team > better services in the future.

And now some specific things we will look at

IANZ lead assessor

- Quality Manual
- QM ‘core’ activities – management review, internal audits etc.
- Participation in PTs/other QA
- Review of issued reports, use of endorsement symbols
- Equipment management and QC checks
- Technical aspects but at varying depths.

Technical expert

- Calibration reports for critical equipment (traceability of equipment)
- Sample of endorsed reports
- Uncertainty calculations supporting CMCs
- Technical procedures
- Staff competence in carrying out these procedures
- Completeness of technical training records
- Competence of Signatories
- Records of laboratory environmental conditions

Quality manual and core activities

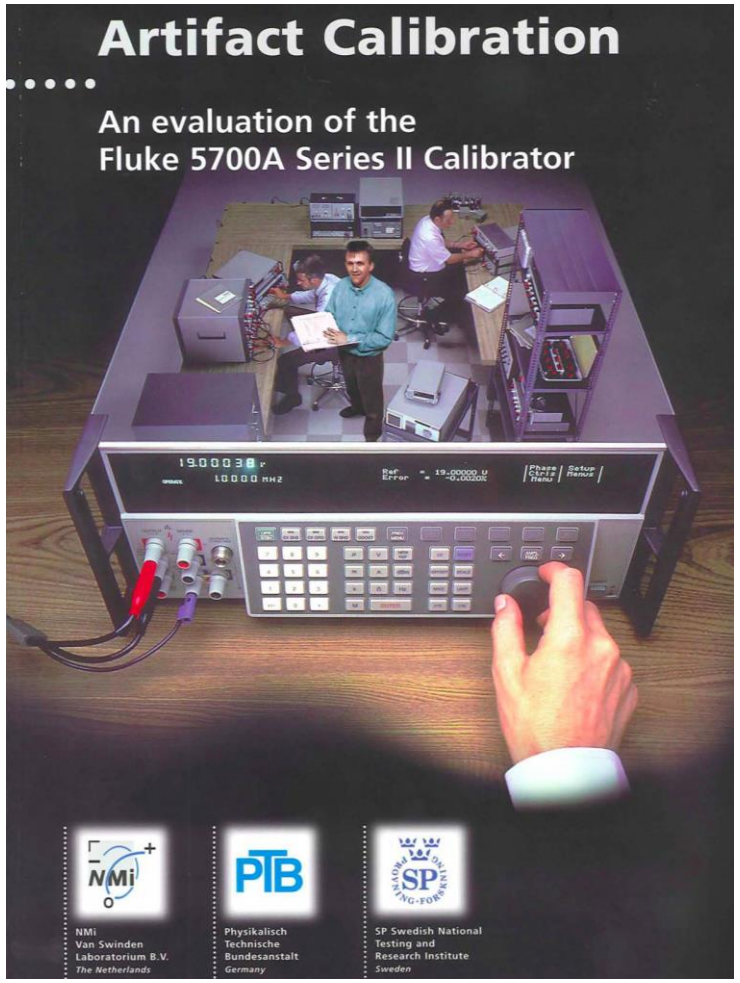
- Quality manual fully audited prior to technical reassessment
  - Otherwise, any changes to quality manual, handled correctly?
- Management review
  - Reasonably regularly
  - Appropriate staff attendance
  - Communication of minutes/outcomes/actions
  - Content and agenda items relevant to activities of accredited laboratory
- Internal audit
  - Reasonably regularly
  - Audit of quality manual AND activities for compliance with criteria
  - Findings managed appropriately

Technical procedures

- How detailed should they be?
  - More automation means less written information required.
  - Enough information to ensure that all operators can reliably get the same results.
    - Inter-operator tests can be useful for determining whether there needs to be more information or better staff training.
- Is version control of software and technical procedures adequate?
  - Are all staff using the same current version of the procedure?
  - Paper printouts vs. electronic.

Traceability and modern instrumentation

- Automation of calibration procedures is desirable in terms of efficiency.
  - Validation of the software used is required (clause 7.11.2 (b) of ISO 17025:2017).
- What about the thousands of lines of code used inside your instruments?
  - How can you validate something that you cannot inspect? Choose your instrument supplier carefully.
  - Clause 6.4.13 requires the laboratory keeps records of software and firmware versions.
- This is a work-in-progress issue for laboratories and NMIs around the world.



Proficiency testing and other quality assurance

- Knowledge of and reference to IANZ Technical policy 2
- Plan or schedule for types of quality assurance including PT and inter-operator where available
- Other types of QA considered and documented (see 7.7 examples)
- Records of activities undertaken according to schedule
- Results and ANALYSIS
- Discussion with relevant staff and in management review
- Follow-up if necessary (repeats, changes to processes, improvements, CMCs?)

Demonstrations of staff competence

- In most labs there will be the person who carries out the technical procedure routinely and those who are the back-up.
- The training record should reflect reality.
  - Can the back-up operator carry out the technical procedure without supervision?
- It is okay to read the procedure if you are the back-up (or even if you're not!)
  - In fact it is better that you do rather than do the wrong thing!
- Regular inter-operator/group training can help maintain competence and confidence.

Review of endorsed reports

Accreditation Symbols

Endorsement Statements

- Correct use of endorsement statement and symbol (inc. exclusions)
- Inclusion of all relevant requirements from ISO 17025
- Technical details match technical records (serial number, data, dates etc.)
- Correct references to methods
- Clarity of information, page numbering
- Uncertainty not < CMC
- Compliance/conformity statement and uncertainty (decision rule)
- General presentation (spelling, formatting etc.)

Uncertainty calculations supporting CMCs

IANZ

Laboratory Accreditation Programmes

Schedule to
CERTIFICATE OF ACCREDITATION

Laboratory	Callaghan Innovation Measurement Standards Laboratory of New Zealand
Address	PO Box 31310, Lower Hutt, 5040 69 Gracefield Road, Gracefield, Lower Hutt, 5010
Telephone	04 931-3000
Fax	04 931-3117
URL	http://www.measurement.govt.nz/
Authorised Representative	Dr Blair Hall Quality Manager
Client No.	8
Programme	Metrology & Calibration Laboratory
Accreditation Number	1
Initial Accreditation Date	30 July 2004
Conformance Standard	NZS ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
Testing Services Summary	5.01 Engineers' Limit Gauges 5.02 Jigs, Fixtures, Cutting Tools and Components 5.04 Machine Tools 5.05 Geometric Form 5.11 Working Standards of Length and Angle 5.12 Precision Measuring Instruments 5.14 Laser Frequency 5.21 Masses 5.31 Volumetric Equipment 5.32 Density 5.33 Hydrometers 5.35 Hygrometry 5.41 Barometers 5.42 Differential Pressure Measuring Devices (including Manometers) 5.43 Pressure Gauge Testers and Pressure Balances 5.44 Pressure and Vacuum Measurement 5.61 Temperature Measuring Equipment 5.65 Photometers and Radiometers 5.66 Lamps, LEDs, Lasers and Other Light Sources 5.67 Colour of Light Sources and Colorimeters 5.68 Optical Properties of Materials: Spectral 5.69 Optical Properties of Materials: Spectrally integrated 5.70 Optical Instruments

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Telephone 09-525 6655 - Facsimile 09-525 2266
www.ianz.govt.nz

5.82 Resistors, Resistance Boxes and Potential Dividers

(a) Precision resistors, resistance boxes and conductance boxes

0.1 Ω to 1 Ω (Current ≤ 100 mA)	0.2 μΩ/Ω
1 Ω to 10 kΩ (Power dissipation ≤ 10 mW)	0.12 μΩ/Ω
10 mΩ to 1000 mΩ (Current ≤ 1A)	25 μΩ/Ω
0.1 mΩ to 1000 mΩ (Current = 1 A to 875 A)	63 $R^{-0.35}$ μΩ/Ω, R in mΩ values range from 141 μΩ/Ω to 6 μΩ/Ω
0.01 MΩ to 1 MΩ (Applied voltages = 5 V to 100 V)	0.7 μΩ/Ω
0.001 GΩ to 1 GΩ (Applied voltages = 5 V to 100 V)	(0.7 + 27 R – 20 R^3) μΩ/Ω, R in GΩ, values range from 0.7

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Uncertainty calculations

MSL Uncertainty Calculator

Cause of uncertainty	standard uncertainty u	degrees of freedom (n-1)	coverage factor k	accuracy of u estimate (%)	calculated degrees of freedom	Comment
		one entry only				
One ohm restraint value	0.041		2.57		5	Source G:\estds\QUAL\TECHPROC\E009-DCR 0.0001 to 14k\Current Restraint\2009 Restraint.xls, Restraint worksheet.
Temperature	0.004		2.0		60	Assume 0.01 C at 95%, including gradients
Hysteresis	0.000			30	6	Based on a weeks observation
Noise/scatter around temp fits	0.000	9			9	Scatter observed from measurements taken.
MI Gain error	0.021		2.0		60	MI gain error up to 0.04 ppm at 1:1 and .057ppm for 10:1
MI Linearity	0.004		2.0		60	MI Linearity error up to 0.015ppm
Leakage	0.001		2.0		60	
					0	
Heating correction	0.003			20	13	Assume heating between 0 to 0.006 ppm, rect distbn: probably less
Reference (other than 1 ohm)	0.000		2.2		11	From fitted curve.
Transfer at 1 Ohm	0.023	18			18	The transfer at the 1 Ohm level to the Hamon is noisy
Transfer at 10 Ohm	0.004	18			18	The transfer at the 100 Ohm level.
Transfer at 10k Ohm	0.000	8				The transfer at the 10l Ohm level is noisy.
combined standard uncertainty	*5.18E-02*					
expanded uncertainty	***1.1E-01***	ppm				
effective degrees of freedom	*13*					
coverage factor	***2.16***					

=0.01/2*1.6/2

- MSL uncertainty calculator (or other ways of recording your uncertainty calculations).
  - You will not regret spending a minute or two explaining/commenting on each of the uncertainty components and where it came from!
  - …especially when it comes to explaining the budget to the assessment team!
  - Can save significant time and money if clearly and concisely written.

The (nervous) anticipation far exceeded the actual event

- Hopefully you will feel like this when the assessment is over (more likely if you prepared well and had realistic expectations!).
- There will likely be follow-up and there is value in involving all staff in this.
- The assessment is an important way that all staff become aware of the what and why of the quality system and the specific laboratory procedures.

Thanks for your attention

- Questions, comments?