Measurement Standards Laboratory of New Zealand

Developing and Validating Technical Procedures

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A business of CallaghanInnovation

What's in a name?

Choose 1 or 2

- Technical
- Measurement
- Operating
- Standard
- Controlled

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Choose 1

- Method
- Procedure

JCGM 200:2008 2.6
measurement procedure
detailed description of a **measurement** according to one or more **measurement principles** and to a given **measurement method**, based on a **measurement model** and including any calculation to obtain a **measurement result**
NOTE 3 A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

Outline

- Why have Technical Procedures?
- What needs to be in a Technical Procedure
- ISO 17025 requirements
- Level of detail
- Method design
- Influence effects
- Difference between verification and validation
- Validation
- Suggested Technical Procedure outline

Purpose

To meet ISO 17025 requirements

Define and document process

Make process repeatable

Train Staff

Allow process to be reviewed

Store knowledge

Content

Scope – what is and isn't covered	Version control Change History	Equipment and software to use
Who can do it	IANZ – best measurement capability	Setup
How to calculate result	Uncertainty calculation	Process
Health and Safety	What can go wrong	Indicators of failure

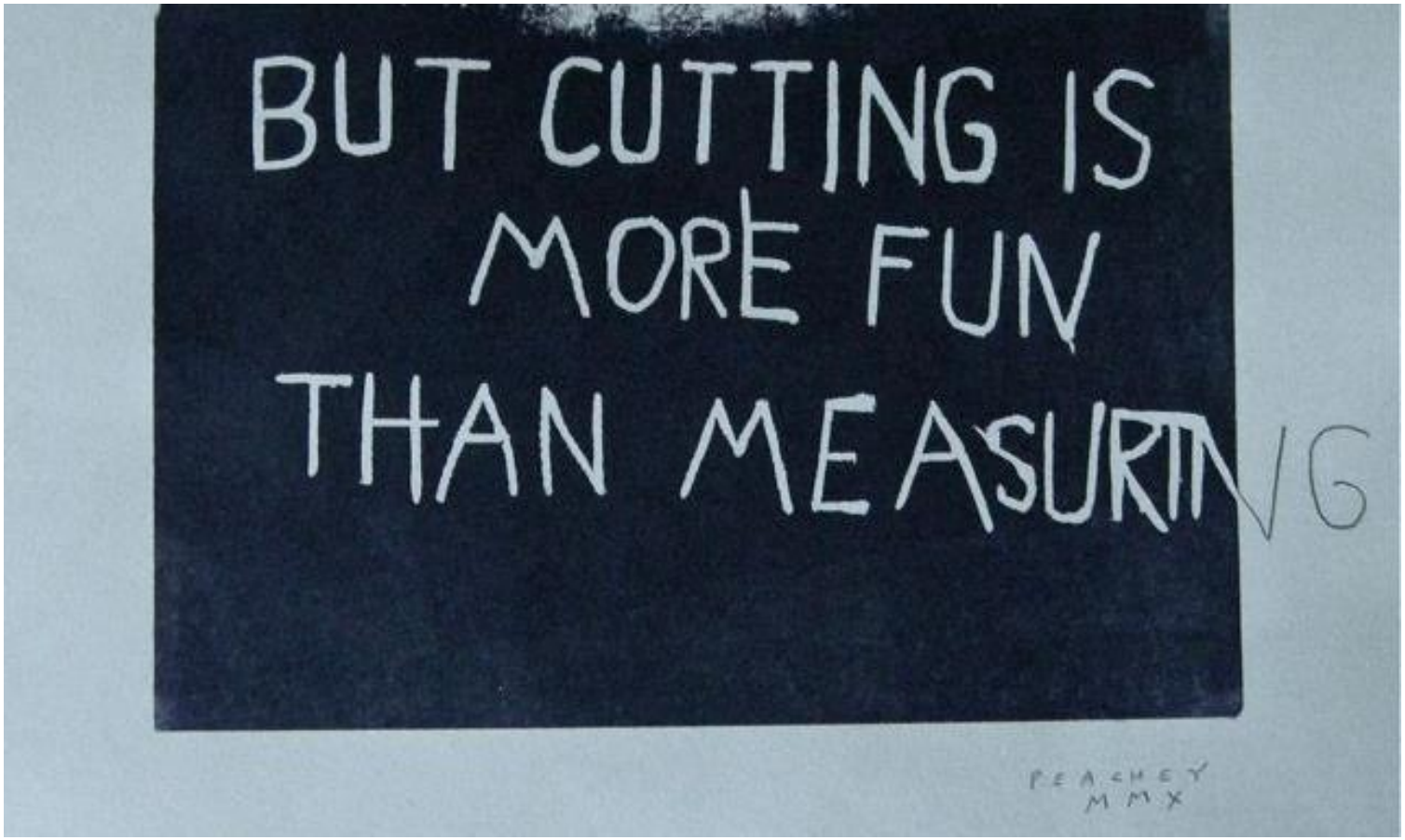
ISO 17025 Requirements

- Select “appropriate” method
  A. Customer specified
  B. Published
  C. Laboratory developed
- “shall be kept up to date” (2.1.2) – requires regular review
- Method development shall be reviewed to confirm customer needs are being met
- Deviation from method, documented, technically justified, authorized, and accepted by customer

Level of Detail

- as concise as possible while still fit for purpose
- Additional technical detail can be in supporting documents or appendix

Also measuring is more fun than writing procedures



Method Design

- Gather information from other sources
  - Manufacturer's specs
  - Documentary Standards
  - Experienced colleagues
  - Training courses
  - web
- Make a list of everything that can go wrong with measurement – influence effects

Influence Effects – What's the cause?

- Device Under Test
  - Resolution
  - Range
  - Time Constant
  - Form
- Environment
  - Temperature
  - Pressure
  - Vibration
  - Gravity
- Reference Equipment
  - Uncertainty
  - Corrections
- Operator
  - Parallax
  - Experience
  - Interpolation
  - Visual Acuity

S	Standard
W	Workpiece
I	Instrument
P	People
E	Environment

People
Methods
Machines
Materials
Measurements
Environment

Influence effects – What can we do?

- It's not good enough: Evidence of unreliability → add instructions on testing the device is fit for calibration to method
  - Corrosion, electrical short, bent gauge block, broken leads
- Things we can control or correct : Eliminated or reduced by good practice → add instructions on good practice to method → add environment conditions to report
  - Lab temperature, time constants, lead resistance, parallax, thermal expansion
- Things we can't fix: Unavoidable effects → determine size of effect and include in uncertainty analysis
  - Hysteresis, uncertainty in reference, uncontrollable temperature effects, resolution of instruments,

Measurement Error or Method Failure?

Verification and Validation

- Verification – required for all methods (lab-developed and external)
  - Determine method is fit for purpose – meets customer needs
  - Prove that lab can properly perform method and achieve required performance.
- Validation – required for lab-developed methods
  - More rigorous than verification
  - Prove the method is capable of achieving required results
  - Applies to the whole process, not just the instrument and operator.
- For both verification and validation we must keep records and repeat process if method changes

Validation

- Use reference standards to evaluate bias and precision
- Assess all factors influencing the result
- Test the robustness of the method by varying controlled parameters, also do inter-operator comparisons
- Compare the results with other validated methods
- Participate in interlaboratory comparisons
- Evaluate the measurement uncertainty based on theoretical principles and practical experience.

Suggested Outline for Procedure

- Scope, CMC
- Things to determine during contract negotiation
- Staff, site, equipment restrictions
- Initial visual inspection
- Conditioning, cleaning and adjustment
- Check item is fit for calibration
- Comparison/ calibration
- Analysis , reality checks and report writing
- List of influence variables
- Uncertainty evaluation, including CMC calculation
- Description and results of validation process

Unit definition or lack of reality check?

" I thought I knew what a cubit was. "

Summary

- Decide whether procedure will also be a training document, knowledge store etc.
- Develop a technical method by considering all the things that could go wrong with your measurement
- Systematically assess these influence effects and determine the magnitude of those you can’t eliminate
- Wrap it up into a procedure that includes scope, checks, method, analysis, uncertainty etc.
- Validate and verify method
- Document everything!