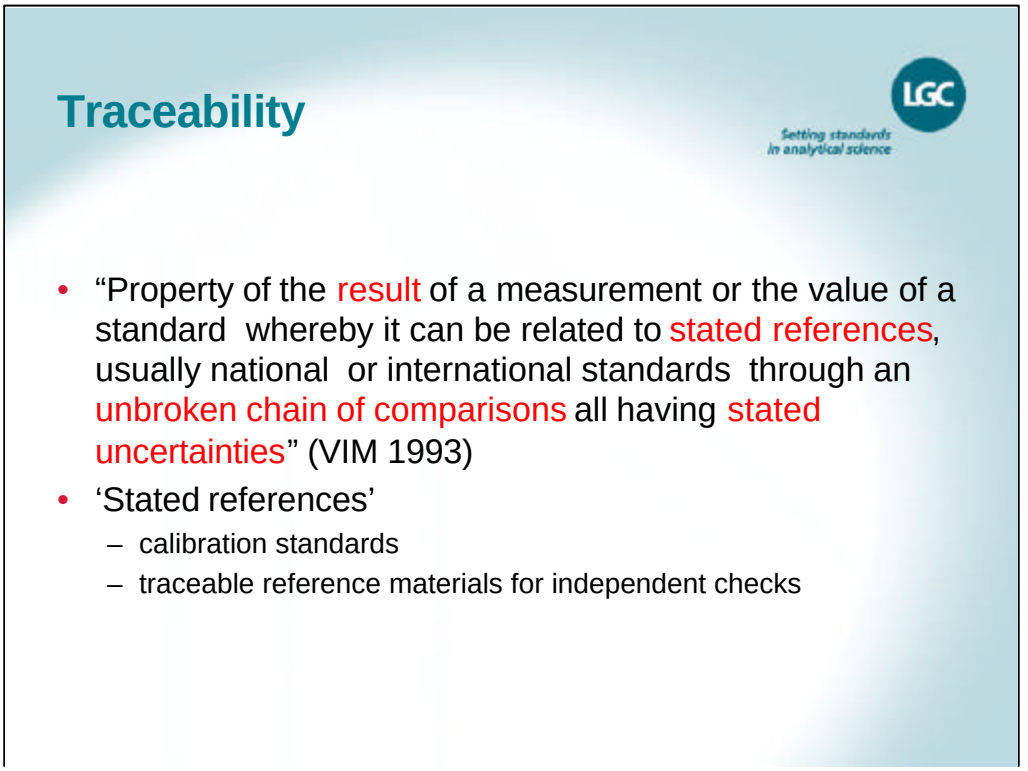
# Traceability

Technical Requirements

# Introduction

Setting standards in analytical science

- Traceability in practice
  - an exercise
- Requirements of ISO/IEC 17025
- Practical implementation
  - standards
  - reference materials

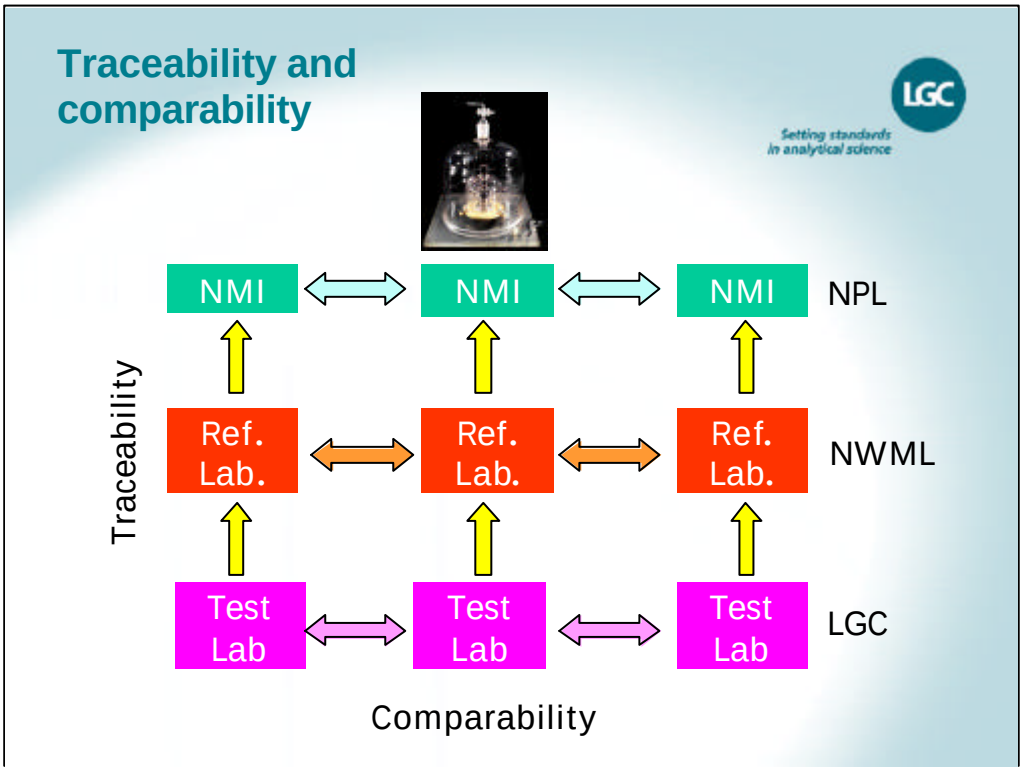



Traceability is all about relating measurements to a common reference point.

Measurements need to be made on a common scale and related to common measurement standards. Meaningful comparisons between measurement results are only possible if the results are expressed in the same units. Results are then given in multiples of the given unit. For example, there is a kilogram standard held by BIPM (International Bureau of Weights and Measures) and all masses are compared with that one unit through a chain of comparisons.

Traceability helps ensure that measurements made in different laboratories or at different times are in agreement, within the limits of the uncertainty of the results.

Reference: International Vocabulary of Basic and General Terms in Metrology (VIM), ISO 1993.




Agreement in physical measurements made at different locations has existed for many years. This has been achieved for time, mass, length etc. by agreeing a standard. Everyone accepts the standards and how they are maintained. The slide illustrates how agreement is achieved.

The kilogram is defined as the mass of the international prototype kilogram, which is held by BIPM in France. This kilogram is used to calibrate all the weights in the world. Many countries hold a copy of the prototype kilogram. In the UK the national kilogram (copy no. 18) is maintained by the National Physical Laboratory (NPL). Periodically, the national kilogram is compared with the international standard. A laboratory such as LGC will have its analytical balances calibrated regularly. The calibration is done using a set of calibrated weights. These weights will have been calibrated by comparison with a set of weights held by a reference laboratory such as the National Weights and Measurements Laboratory (NWML). The NWML weights are calibrated by comparison with the national standard kilogram. Therefore, measurements of mass made using a properly calibrated and maintained analytical balance are traceable to the international standard kilogram through a chain of comparisons.

National measurement institutes (NMIs) for chemical measurements are being established all around the world, to do for chemistry what, in the UK, NPL has done for physical measurements. LGC is the UK's NMI for chemical and biochemical measurements.

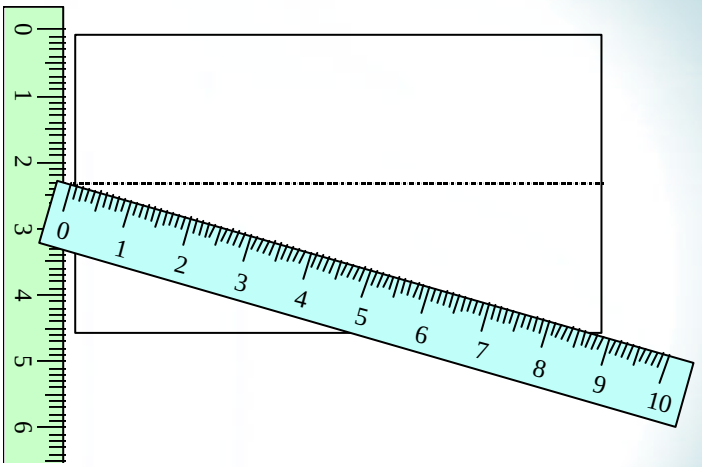
## Traceability in practice

Setting standards in analytical science

- A measurement exercise
- Will consist of:
  - a round of product ‘analysis’
  - an intercomparison
  - a calibration exercise
  - a final round of ‘analysis’
  - a thought experiment

For information on how to run this exercise, see the document ‘Traceability exercise’.

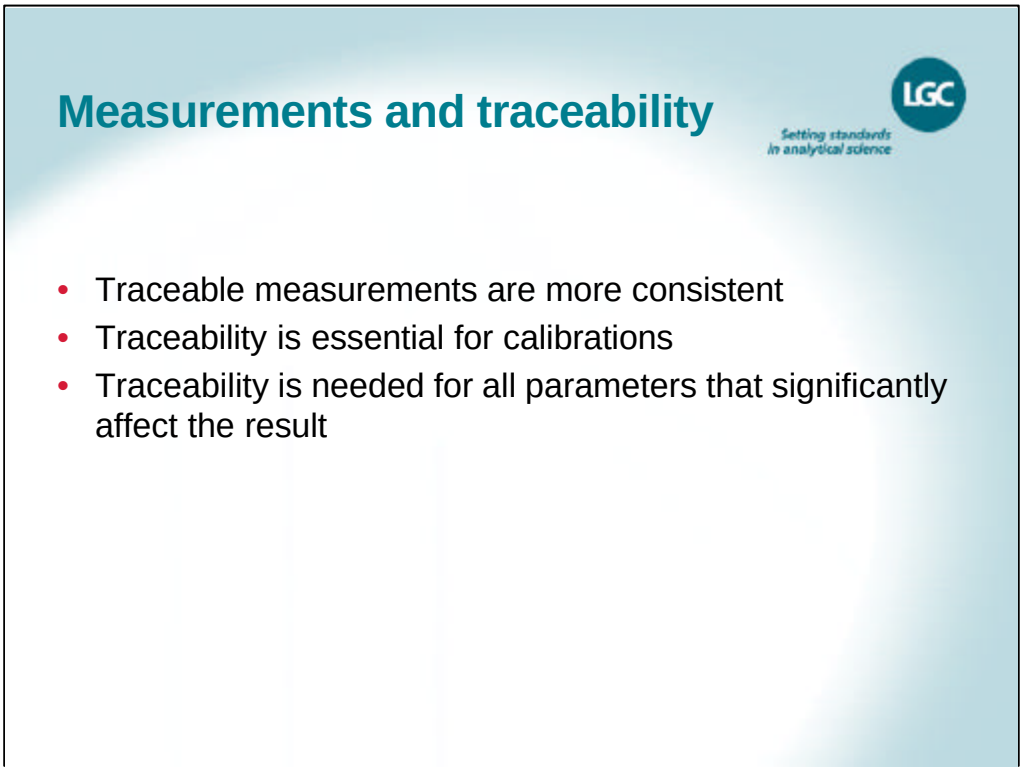
# Standard method



# Traceability: A thought experiment

Setting standards in analytical science

- New method
  - measure a 4x4 square of card using the ruler
  - cut it out
  - weigh the square on a traceable balance
- Does the ruler still need calibrating? Why?




As the exercise showed, using a common standard reduced the variability in the results reported by different people.

Traceable measurements are more consistent. This should lead to better agreement between measurement results produced at different times and/or in different locations.

When calibrating a piece of equipment, it is essential that the standards used are traceable.

When considering the traceability of results produced by an analytical method, the traceability needs to be established for every aspect of the method that has a significant effect on the result.

## ISO/IEC 17025 requirements

- 5.6.1 All equipment.. calibrated; programme for calibration established
  - traceable to SI for calibrations
  - traceable to SI if possible for testing
- 5.6.3.1 Reference standards
  - procedure for calibration...
  - reference materials traceable to SI (where possible)

All the equipment used for tests and/or calibrations that have a significant effect on the fitness for purpose of the result need to be calibrated. This also includes the equipment used to measure the environmental conditions or used for sampling.

The laboratory has to have established procedures for carrying out these calibrations.

## Practical implementation - transfer standards


- Reference materials
  - e.g. pure substance CRMs, standard solutions, matrix CRMs
- Physical standards
  - e.g. mass, temperature
- Reference values
  - e.g. atomic mass values
- Results from primary / reference methods
- Used for both validation and calibration

When traceability cannot be made directly to SI units, it can be achieved through transfer standards such as certified reference materials produced by competent (accredited) suppliers. Transfer standards carry measurement values and can be used to calibrate measurement systems and validate methods.

Traceability can also be achieved through the use of specified methods or consensus standards.

# Reference standards and equipment

- Mass standards
- Spectroscopic solutions, reagents etc.
- Equipment
  - including significant environmental controls

**..... Must be calibrated**

# Summary

Setting standards in analytical science

Traceability guarantees that:

- Results do not vary because of changes in standards
  - within limits!
- Results are comparable with other laboratories
  - comparison guarantee is no better than the uncertainties on reference standards

# Acknowledgement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- For further information on the VAM programme visit www.vam.org.uk