



# Ensuring Traceability in a Food Microbiology Laboratory Environment

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# Traceability

- Implies an unbroken path to a higher level of accuracy or authority.



# Traceability

- Characterized by a number of essential elements:
  - Unbroken chain of comparisons
  - Measurement uncertainty
  - Documentation of each step
  - Technical competence
  - Reference to SI units (where possible)
  - Recalibrations at appropriate intervals



# Establishing Traceability

- Equipment
- Certified Reference Materials / Reference Materials
- To Method



# Traceability

- ILAC P10:2002

“Critical” equipment used by testing and calibration laboratories is considered by ILAC to be those items of equipment necessary to perform a test or calibration from the scope of accreditation and which have a significant effect on the uncertainty of measurement of test or calibration results.



# Equipment

- Laboratory program
  - calibration
  - Verification
- To the SI where possible



# Factors affecting frequencies of calibration/ verification

- Uncertainty of measurement
- Risk of instrument exceeding the limits of the maximum permissible error
- Cost of necessary correction measures when instrument was not appropriate over a long period of time



# Factors affecting frequencies of calibration/ verification

- Type of instrument
- Tendency to wear and drift
- Manufacturer's recommendation
- Extent and severity of use





# Factors affecting frequencies of calibration/ verification

- Environmental conditions (climatic conditions, vibration, ionizing radiation, etc.)
- Trend data obtained from previous calibration records
- Recorded history of maintenance and servicing



# Factors affecting frequencies of calibration/ verification

- Frequency of cross-checking
  - other reference standards
  - measuring devices
- Frequency and quality of intermediate checks in the meantime
- Transportation arrangements and risk, and
- Degree to which the servicing personnel are trained



# Temperature measurement devices

- Where T has a direct effect on the result of an analysis or is critical for the correct performance of equipment
- Temperature measuring devices shall be of an appropriate quality
  - Traceable to national or international standards for temperature, or...



# Temperature measurement devices

- Where the accuracy permits, devices that can be demonstrated to conform to an appropriate and nationally or internationally accepted manufacturing specification may be used
  - Such devices may, for example, be used for monitoring storage fridges and freezers and also incubators and water baths where acceptable tolerance around the target temperature permits.
  - Verification of the performance of such devices is necessary.



# Incubators, water baths, ovens

- Established initially and documented
  - Stability of T
  - Uniformity of thermal distribution
  - Time required to achieve equilibrium conditions
- With respect to typical uses
  - Position
  - Space between
  - Height



# Autoclaves

- Autoclaves capable of meeting specified time and temperature tolerances.
  - Sensors used for controlling or monitoring operating cycles require calibration and the timers verified.
  - Pressure cookers fitted only with a pressure gauge are not acceptable.



# Autoclaves

- Initial validation to include spatial temperature distribution surveys for each operating cycle and each load configuration used in practice.



# Weights and balances

- Weights and balances shall be calibrated traceably at regular intervals (according to their intended use).





# Other Equipment

- Conductivity meters, oxygen meters, pH meters verified regularly or before each use.
  - The buffers used for verifications purposes should be stored in appropriate conditions and should be marked with an expiry date.
- Where humidity is important to the outcome of the test, hygrometers should be calibrated, the calibration being traceable to national or international standards.



# Other Equipment

- Timers, including the autoclave timer, should be verified using a calibrated timer or national time signal.
- Where centrifuges are used in test procedures, an assessment should be made of the criticality of the centrifugal force.
  - Note: where it is critical, the centrifuge will require calibration.



# Certified Reference Materials

## Reference Materials

- Provide essential traceability in measurements and are used, for example;
  - to demonstrate the accuracy of results,
  - to calibrate equipment,
  - to monitor laboratory performance,
  - to validate methods, and
  - to enable comparison of methods.



# Reference cultures

- To demonstrate traceability, laboratories use reference strains of microorganisms obtained directly from a recognized national or international culture collection, where these exist.
- Alternatively, commercial derivatives for which all relevant properties have been shown by the laboratory to be equivalent at the point of use may be used



# Reference cultures

- Are used to demonstrate the color reactions which are considered typical. These are then visually compared with the color reactions shown by the test microorganisms. If they correspond this will confirm the test results generated using the microbiological media.
- Are used to assess the quality of microbiological media prior to use.
  - For this purpose, certain cultures that grow well in the media (positive) and those do not (negative) are used.
  - This provides a mechanism to assess the selectivity of a given microbiological medium in isolation and identification of the microorganism separated from the matrices under test



# Issues with Traceability

- The traceability to the SI for chemical and biological measurements is often not achievable.
  - For chemical measurements the ideal is the traceability to the mole
  - For biological measurements no SI has been defined



# Issues with Traceability

- For microbiological measuring systems, the use of reference cultures (materials) from an accredited or recognized microbiological reference material producer is the best practice for traceability of the measuring system.



# Issues with Traceability

- For chemical measuring systems, the use of reference material from accredited reference material producers or NMIs, when possible, is the best practice for traceability of the measuring system.





# Issues with Traceability

- With over 10,000 possible chemical and microbiological measurands, reference standards from accredited producers are not always available.



# Traceability by method

- Most food testing methods are empirical
  - the result depends on the defined method
  - therefore traceability can be to the consensus result for that method and matrix.



# Methods

- It is advisable to select well-validated test methods, written by organizations engaged in writing test methods.
  - Official Methods, Association of Official Analytical Chemists (AOAC)
  - Microbiology Manual of the Food and Agriculture Organization (FAO)
  - Bacteriological Analytical Manual (FDA)
  - American Public Health Association (APHA)
  - International Organization for Standardization (ISO)



# Traceability

- Modifications
  - even minor deviations
- Validation
  - for all matrices
  - to confirm that the results are the same as those obtained from defined standard methods

