General Accreditation Criteria

Metrological Traceability Policy

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Purpose

This document is applicable to all accredited and applicant facilities and covers NATA's criteria for metrological traceability for testing and/or calibration activities, including calibrations performed by a facility for its own purposes (i.e. "in-house' calibration).

Note: For "in-house" calibration, refer to NATA's *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification*.

Several practical examples of measurement processes have been included in this document as guidance in Appendix A to assist facilities to apply these criteria,

Terms and definitions

BIPM (Bureau International des Poids et Mesures / International Bureau of Weights and Measures)

The BIPM is an intergovernmental organisation through which Member States act together on matters related to measurement science and measurement standards.

CIPM MRA (BIPM's International Committee Mutual Recognition Arrangement)

The Mutual Recognition Arrangement (MRA) of the International Committee for Weight and Measurement (CIPM) is an arrangement between National Metrology Institutes. This arrangement provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issue by National Metrology Institutes (refer below to KCDB)..

CRM (Certified Reference material)

Reference material characterised by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability (ISO 17034:2016 clause 3.2).

Note: CRMs are a subset of reference materials (RMs). A product information sheet supplied with a RM will not necessarily include the above information unless it is a CRM.

ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement)

The MRA provides the framework for the international recognition of accredited laboratories, inspection bodies, reference material producers and proficiency testing providers by accreditation bodies which are signatories to the MRA.

ILAC signatories have been peer evaluated in accordance with the requirements of ISO/IEC 17011 and applicable ILAC documents.

JCTLM (Joint Committee for Traceability in Laboratory Medicine)

The Committee was formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Cooperation (ILAC). Its aim is to provide guidance on internationally recognised and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards.

KCDB (Key Comparison Database of the CIPM MRA)

The KCDB is a publically available resource (https://www.bipm.org/kcdb) related to the CIPM MRA. The database contains information on the MRA participants, the results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs).

Metrological traceability

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (VIM 3rd edition clause 2.41).

Note 1: For this definition, a 'reference' can be a definition of a measurement unit through its practical realisation, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

Both ISO/IEC 17025:2017 and ISO 15189:2012 refer to the VIM's definition.

Metrological traceability chain

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference (VIM 3rd edition clause 2.42).

Note 1: A metrological traceability chain is defined through a calibration hierarchy.

Note 2: A metrological traceability chain is used to establish metrological traceability of a measurement result.

Note 3: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

Metrological traceability to a measurement unit

Metrological traceability where the reference is the definition of a measurement unit through its practical realisation (VIM 3rd edition clause 2.43).

Note: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'.

NMI (National Metrology Institute)

NMIs and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes.

Australia's national metrology institute is called the National Measurement Institute and is often referred to by the same NMI acronym.

Reference Material (RM)

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034:2016 clause 3.3).

Note: CRMs (refer above) are a subset of RMs.

Policy for metrological traceability

Facilities are required to establish metrological traceability for their measurement results.

Where metrological traceability is required, measuring equipment shall be calibrated by:

- a calibration service which is subject to peer review; or
- a calibration service which has not been subject to peer review, thus requiring the facility to perform extra measures.

Metrological traceability may also be established through the use of certified reference materials or by other means to an appropriate reference.

Calibration services which are subject to peer review

The following two options are possible for the calibration of equipment by providers who are subject to peer review:

1) A NMI whose service is suitable for the intended purpose and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in the BIPM KCDB which includes the range and uncertainty for each listed service.

Notes: Some NMIs may also indicate that their service is covered by the CIPM MRA by including the CIPM MRA logo on the calibration certificates they issue, however, the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

NMIs from Member States participating in the Metre Convention, which is the treaty that created the BIPM, may take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

2) An accredited calibration laboratory whose service is suitable for the intended purpose (i.e. the scope of accreditation specifically covers the appropriate calibration) and the accreditation body is covered by the ILAC MRA or a regional arrangement recognised by ILAC.

Note: Calibration laboratories can indicate that their service is covered by the ILAC MRA by including on the calibration certificates they issue one of the following:

- the Combined ILAC MRA Mark;
- the accreditation mark of the accreditation body.

Both of these two dot points may be taken as evidence of traceability.

Calibration services which are not subject to peer review

The following two options are possible for the calibration of equipment by providers who are not subject to peer review:

3) A NMI whose service is suitable for the intended purpose but not covered by the CIPM MRA;

4) A non-accredited calibration laboratory whose service is suitable for the intended purpose.

Option 3) or 4) should only be applicable when option 1) or 2) are not possible for a particular calibration.

It is unlikely that either option 3) or 4) will be chosen purely on economic grounds and is more likely to be a last resort.

It must be appreciated that choosing option 3) or 4) will require significant effort by the facility to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration service(s) selected. This evidence will be reviewed by NATA during the assessment of the facility which will add to its duration.

The evidence the facility must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following (the numbers in brackets refer to the clause numbers of ISO/IEC 17025:2017):

- documentation for competence of personnel (6.2);
- documentation for accommodation and environmental conditions (6.3);
- documentation for equipment (6.4);
- documentation for traceability of measurements results (6.5);
- audits of the calibration service provider (6.6 and 8.8);
- records of calibration method validation (7.2.2);
- documentation for evaluation of measurement uncertainty (7.6);
- documentation for assuring the validity of calibration results (7.7).

In practical terms, the facility would need to perform an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is a signatory to the ILAC MRA or a regional arrangement recognised by ILAC.

Notes: In-house calibrations that support accredited testing and form part of the assessment of a testing facility are assessed using these criteria.

In instances where the National Measurement Institute Australia is not accredited for a specific calibration but is accredited for similar measurements, or where the calibration laboratory is in the process of seeking NATA accreditation and has been assessed, NATA may accept the calibration(s) services offered.

Use of Certified Reference Materials

Metrological traceability can be provided by Reference Material Producers (RMPs) through use of RMs that have certified values, when:

- the CRM is produced by a NMI and included in the BIPM KCDB; or
- the CRM is produced by an accredited Reference Material Producer (RMP) under its scope of accreditation and the accreditation body is a signatory to the ILAC MRA or a regional arrangement recognised by ILAC; or
- the value/s assigned to the CRM is/are covered by entries in the JCTLM database.

Note: Not all CRMs are traceable to the SI (i.e. they may be traceable to another reference). Refer below to when metrological traceability is not possible to SI units.

It is recognised that the availability of CRMs with established metrological traceability is still developing. Where CRMs are used from providers not satisfying one of the three points above, the facility must demonstrate that the CRMs are suitable for their intended use.

When metrological traceability to the SI is not technically possible

Traceability of measurement results to another appropriate reference can be established by either:

- using CRMs produced by a competent Reference Material Producer (RMP);
- comparing results using reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use.

Notes: When metrological traceability to the SI is not appropriate or applicable, a defined measurand should be selected. Traceability of this measurand should include both the proof of its property identity and the comparison of the result to an appropriate stated reference. Comparison is established through validation and/or verification, calibration of the measuring equipment and appropriate control of the measurement conditions.

Proficiency Testing (PT) providers may have available surplus material. The assigned value(s) of the material should only be used as a reference where the PT provider can provide additional information concerning the material's stability. If this cannot be provided, then such material should not be considered as an appropriate reference.

Further information

If you have any queries in relation to this policy please contact your nominated NATA Client Coordinator.

General questions on measurement traceability may be sent to the Sector Manager Calibration, Paul McMullen, paul.mcmullen@nata.com.au.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO 15189	*Medical laboratories - Requirements for quality and competence*
ISO 17034	*General requirements for the competence of reference materials producers*
ISO/IEC 17011	*Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*
ISO/IEC 17025	*General requirements for the competence of testing and calibration laboratories*

NATA Publications

General Accreditation Criteria	*Equipment Assurance, in-house calibration and equipment verification*

Other Publications

International Vocabulary of Metrology - Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:2008 with minor corrections) available from the BIPM (https://www.bipm.org/en/publications/guides/vim.html) or ISO/IEC Guide 99:2007 available from ISO (https://www.iso.org/standard/45324.html).

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
Whole document	This policy has been aligned with the latest ILAC P10: *ILAC Policy on Metrological Traceability of Measurement Results* (https://ilac.org/publications-and-resources/ilac-policy-series/) published in July 2020. Other than the addition noted below, this policy document does not include new criteria for accreditation.
Services which are not subject to peer review	Addition of one new point: • documentation for equipment (6.4)

Appendix A
Practical examples of metrological traceability for measurement processes

(Informative)

General

The purpose of this appendix is to assist and provide guidance to applicant and accredited facilities in applying NATA's policy on metrological traceability.

It includes a number of practical examples of test or measurement processes commonly performed in a range of facilities. The examples are not intended to be exhaustive and appear in the following order:

- Autoanalyser platform measuring enzyme activity
- Autoanalyser measuring an analyte (excluding enzyme activity)
- Enzyme Linked Immunosorbent Assay (ELISA) measuring an analyte
- Erythrocyte Sedimentation Rate (ESR)
- Isolation and identification of bacteria
- Moisture content by oven drying
- Part A – Solvent extraction of solid sample for an organic analyte
- Part B – LCMS measuring an analyte
- Concrete compressive strength testing
- Durometer hardness (Shore Type A)
- Rockwell hardness tests
- Movement of retention pin

Terms used

Component

Anything used in a measurement process, including, but not limited to:

- equipment (e.g. load cells, verniers, balances, ovens etc);
- the procedure or technique selected (e.g. in-house, standard, consensus etc);
- reference materials and standards (e.g. calibrators, CRMs, RMs, physical artefacts etc);
- consumables and reagents.

Critical

A component on which the validity of the measurement process relies upon. If uncontrolled, the repeatability, reproducibility or bias of the test will be compromised.

VQ, CQ, UQ, RQ, PQ refer to the questions in the schema (see below).

Measurement process

The method which includes everything, from selection of the procedure or technique, through to the reporting of the results.

Note that 'black box' equipment such as autoanalyser platforms are considered a 'standard method'.

Reference measurement procedure / Accepted consensus method / Standard method / Specified method

Terms describing published or widely accepted measurement procedures that are clearly described and accepted by appropriate authoritative bodies.

Units directly or indirectly reported in the final result

Direct reporting applies when traceability of the final result is determined by a single parameter (e.g. volume). In such cases, all components measuring the parameter are to be considered.

Indirect reporting applies when traceability of the final result is dependent on various inputs leading to a calculation. In such cases, the inputs to the calculation are to be considered.

How to use the schema

The schema in this Appendix is general in nature and should be used in combination with each example.

Each facility is encouraged to apply the schema to their unique situation and range of measurements to facilitate how metrological traceability of their results is determined.

Consider all of the components of the **measurement process (the "method")**, and the application[1] of the result

For each component of the measurement process, consider:

- Equipment
- Reference Materials & Measurement Standards
- Consumables / Reagents
- Procedure

Was the component controlled through calibration during validation or verification?
(VQ)

Does this component have values specified in the measurement process that are critical to the result?
(CQ)

Does the component contribute (directly or indirectly) to the units of the reported result?
(UQ)

Is the procedure a reference measurement procedure or an accepted consensus standard, standard method or specified method?
(PQ)

Is this component a Reference Material or Measurement Standard used in calibration or measurement control?
(RQ)

*If the answer to **any** question is 'YES'*, then the facility must establish evidence of traceability for the component to a stated reference[2], appropriate to the component and measurement task.

*If the answer to **all** questions is 'NO'*, then traceability is not essential for the component.
Controls applied during validation or verification must continue to be applied for the results to remain valid.
Implement additional controls if these improve measurement performance.

1 Applications of the results could include:

- Regulatory or specified limits
- Approximate/presumptive/screening test versus definitive/precise/confirmatory testing
- The clinical utility of a test
- Use for evidentiary purposes

2 A stated reference can be, but is not limited to:

- SI Units
- Certified reference material (CRM)
- Reference measurement procedures
- Accepted specified method
- Accepted consensus standards

AUTOANALYSER PLATFORM MEASURING ENZYME ACTIVITY

For this example, the measurand under consideration is enzyme activity (or, more specifically, catalytic activity concentration of the enzyme as measured by the conversion rate of NADH in the IFCC Reference procedure), calculated by the analyser using Beer's Law.

While reference materials for some enzymes are available from the IFCC, these are mostly used by equipment manufacturers to validate their methods and equipment.

IFCC enzyme activity reference materials are traceable to SI units i.e. *mole per second per cubic metre* (mol s^{-1} m^{-3}, or kat m^{-3}).

For this example, there is no calibrator included in the measurement process. The autoanalyser is a black box 'standard method'. The result is reported in units per volume.

Components of the measurement process include:

- Autoanalyser (the 'standard method');
- Reagents.

Consider each component in turn:

Autoanalyser

- Question PQ applies. In this case, for results to be traceable to the 'standard method' (i.e. comparable between laboratories), the 'standard method' must be followed in full and the autoanalyser must function correctly.

  The manufacturer has validated the method against published IFCC methods, and where possible, using Certified Reference Material.

- Evidence that the analyser is performing to specification could include, but is not limited to:
  - installation and commissioning records for new equipment;
  - routine maintenance according to the manufacturer's specifications;
  - satisfactory proficiency testing / quality assurance program results;
  - QC showing that the method is in good statistical control.

Reagents

- No question applies. Reagents in use are important to the measurement process, but are not the source of traceability for the reported results.
- Variation of reagents between lots may affect the final result and so quality of the reagents must be monitored. Routine QC may be an indicator of performance.

The reported result of this measurement process is traceable to SI units for enzyme activity through the IFCC standard method, or IFCC CRM (depending on the measurand) via the manufacturer.

AUTOANALYSER PLATFORM MEASURING AN ANALYTE (EXCLUDING ENZYME ACTIVITY)

The autoanalyser is a black box 'standard method'. The result is reported in units per volume.

Components of the measurement process include:

- Autoanalyser (the 'standard method');
- Reagents;
- Calibrator.

Consider each component in turn:

Autoanalyser

- Question PQ applies. In this case, for results to be traceable to the 'standard method' (i.e. comparable between laboratories), the 'standard method' must be followed in full and the autoanalyser must function correctly.
- Evidence that the method is performing adequately could include, but is not limited to:
  - installation and commissioning records for new equipment;
  - routine maintenance according to the manufacturer's specifications;
  - satisfactory proficiency testing / quality assurance program results;
  - QC showing that the method is in good statistical control.

Calibrator

- Questions UQ and RQ apply. Calibrators contribute to the units in the final report and they are generally a reference material of some kind. Traceability is therefore required for calibrators. Note that this also captures POVA, balances, Class A glassware etc that may be used to make up the calibrator.
- Traceable calibrators may be CRMs. Where non-certified RMs are used, the facility must be able to demonstrate that they are fit-for-purpose.

Reagents

- No question applies. Reagents in use are important to the measurement process, but are not the source of traceability for the reported results.
- It is noted that lot-to-lot variation of reagents may affect the final result, and so quality of the reagents must be monitored. Routine QC may be an indicator of performance.

The reported result of this measurement process is traceable to the standard method and the units assigned to the calibrator.

ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) MEASURING AN ANALYTE

The result is reported in units per volume. Components of the measurement process include:

- Plate reader;
- Calibrator;
- Method;
- Incubator;
- Reagent kit.

Consider each component in turn:

Plate reader

- No question applies. Plate readers report the difference between two readings, not an absolute measurement.
- There must be evidence of adequate performance of the plate reader usually achieved through use of a standard plate. Routine maintenance / servicing is also to be performed according to the manufacturer's specifications.

Calibrator

- Questions UQ and RQ apply. Calibrators include the units of measurement and hence serve as reference materials.
- Traceability of the calibrators is required. Thus any equipment used to prepare the calibrators will also need to be calibrated including POVAs, balances, Class A glassware etc.
- Traceable calibrators may be CRMs. Where a non-CRM Reference Material (RM) is used, the facility must be able to demonstrate that it is fit-for-purpose.

Method

- If the measurement process is a standard or consensus method for the analyte, then PQ applies. The facility must follow the method in full in order for the result to be comparable to other laboratories using the same method.
- If the measurement process is developed in-house, then it must be validated, including the use of appropriate reference materials in order to demonstrate the comparability of results between laboratories using the same process.

Incubator

- Question CQ applies. Methods usually specify the optimal temperature required. The decision as to whether it is 'critical' will be made by the facility taking into account its knowledge and experience with both the method used and the target analyte.
- If the temperature is determined to be critical, the incubator temperature monitoring device must be calibrated.
- Where the temperature is important, but not critical, question VQ asks how the temperature measuring device was controlled during method validation/verification:
  - if it was calibrated, then it must continue to be so at suitable intervals;
  - if it was checked and not calibrated, then it must continue to be so using a suitably calibrated reference thermometer at scheduled intervals.

Reagent kit

- No question applies. Reagent kits are important, but are not the source of traceability for the reported results.
- If POVAs, balances, Class A glassware etc are used to aliquot or prepare kit reagents, these may be critical, and if so, each critical item is to be calibrated.
- Variation between reagent lots may affect the final result, thus the quality of reagents must be monitored. Routine QC may be an indicator of performance.

The reported result of this measurement process is traceable to the units of the calibrator. The result may also be traceable to a standard method.

ERYTHROCYTE SEDIMENTATION RATE (ESR)

The rate of sedimentation of red cells in a column of standard size is measured over a set time. The result is reported in millimetres per hour.

Components of the measurement process include:

- Method;
- Standard column;
- Timer, thermometer and levelling measuring device.

Consider each component in turn:

Method

- Question PQ applies. This is a longstanding, well-characterised method, and is considered a standard method. For results to be traceable to the standard method (i.e. comparable between laboratories), the facility must follow the method in full. This includes controlling laboratory factors such a temperature, vibration and vertical set up of the ESR columns.
- Evidence that the method is performing adequately could include satisfactory QAP results.

Standard column

- Question UQ applies. Columns are marked in millimetre gradations to facilitate reading the result.
- When considering how traceability is demonstrated for this test it is important to consider its application (i.e. clinical utility). For the ESR, clinical utility is limited and the result is generally indicatory.
- Purchasing columns that are specifically made for the ESR is considered sufficient.

Timer, thermometer, levelling measuring device

- Question UQ applies. The result is read at 60 minutes, at room temperature, on a level bench and with columns set-up vertically.
- Comparing the laboratory timer to a GPS timer and checking the temperature and levelling measuring devices should be adequate in view of the clinical utility of the test (as noted above).

The reported result of this measurement process is traceable to the standard method.

ISOLATION AND IDENTIFICATION OF BACTERIA

A sample is applied to an agar plate, which is then incubated. Colonies are identified by morphology. The result is reported as presence/absence of bacteria.

Components of the measurement process include:

- Agar Plates;
- Incubator;
- Control organism;
- Method.

Consider each component in turn:

Agar plates

- These are consumables that must be quality controlled, but no questions are answered 'Yes'. Controls must still be applied for the manufacture and use of the plates.

Control organism

- Question RQ applies as this is a reference material. Traceability is therefore required for control organisms. Note that this may also capture storage conditions for sensitive organisms.
- Where traceability is claimed to wild strains, the facility must be able to demonstrate that these are fit-for-purpose (e.g. demonstrate that a wild strain gives the same morphological and biochemical reactions as a strain from a reference collection).

Incubator

- Question CQ applies. Methods usually specify the optimal temperature range for growth, but the decision as to whether this is a 'critical' temperature will be made by the facility in consideration of its knowledge and experience with both the method and the target organism.
- If the temperature is determined to be critical, the incubator temperature monitoring device must be calibrated.
- Where temperature is important, but not critical, question VQ asks how the temperature measuring device was controlled during method validation/verification:
  - if it was calibrated, then it must continue to be so at suitable intervals;
  - if it was checked and not calibrated, then it must continue to be so using a suitably calibrated reference thermometer at scheduled intervals.

Method

- If the method in use is a standard or consensus method for growth and identification of this organism, then question PQ applies. In this case, the facility must be able to demonstrate that it is following the method in full in order for the result to be comparable to other laboratories using this method.
- If the method is developed in-house, then it must be validated, including the use of reference organisms in order to demonstrate the comparability of results using the method.

The reported result of this measurement process is traceable to the reference organism and may also be traceable to a standard method.

MOISTURE CONTENT BY OVEN DRYING

The method dries material in sequential steps until repeated weighing shows no change. The result is reported as % moisture, which is calculated by a mass comparison.

Components of the measurement process include:

- Drying oven and temperature indicating device;
- Balance;
- Method – AS 1289.2.1.1.

Consider each component in turn:

Drying oven and temperature indicating device

- In relation to question CQ, the method specifies that the oven is to operate within the range 105-110 degrees, with adequate temperature recovery characteristics when loaded with samples. Experience and knowledge of this method show that modest deviations from the specified temperature range are unlikely to compromise the test outcome for commonly tested materials. The oven performance (stability, recovery, spatial uniformity) will be initially established and controlled during testing, however, the accuracy, in absolute terms, of the temperature indicating device is not necessarily critical to the result.
- To demonstrate suitability for the test, characterisation of an oven's performance will reflect the circumstances in which it is used. If the oven continually operates at a fixed setting and the temperature stability has been verified at this fixed setting then the temperature indicator is not relevant to the test (except as potentially indicative of an equipment fault). If the temperature indicator is relied upon as evidence of oven performance during testing then the indicator itself will have been subject to a validation process appropriate to the nature of the testing, in addition to other aspects of oven performance.
- It is noted that oven performance may change over time and so affect the final result. A program for monitoring the performance of equipment is necessary and may include protocols for effective use of the oven, such as avoidance of prolonged temperature suppression due to sample overloading.

Balance

- Question UQ applies. Mass is an indirectly reported unit. Calibration of the balance is therefore required.

Method AS 1289.2.1.1

- Question PQ applies. The facility will need to demonstrate that it is following the method in order for the result to be comparable to other laboratories using the same method.

The reported result of this measurement process is traceable to the standard method (AS 1289.2.1.1) and is depend on the measurement of mass.

PART A – SOLVENT EXTRACTION OF A SOLID SAMPLE FOR AN ORGANIC ANALYTE

Process involves the preparation of a sample extract with multiple measuring and extraction steps. The prepared extract is analysed in a subsequent procedure (see example: Part B), from which a reported result is in the units of mass of analyte per mass of sample.

Components of the measurement process include:

- Method – validated internally, not standard;
- Reagents;
- POVA;
- Balance;
- Volumetric glassware.

Consider each component in turn:

Method

- No question applies. The facility must still have evidence that the method has been validated and that recovery rates were established appropriately.
- Continued performance assurance may be demonstrated through QC and PT.

Reagents

- No questions apply. Solvents used for extraction were selected during method development and demonstrated as fit-for-purpose during validation.
- Solvents and diluents in use are important to the measurement process, but are not the source of traceability for the reported results.
- Variation between reagent lots may affect the final result and so quality of the reagents must be monitored. Routine QC may be an indicator of performance.

POVA

- No question applies. The POVA used to introduce a surrogate to monitor recovery is not critical as repeatability is more important than the exact quantity, in the laboratory's estimation.
- The means of controlling POVA during validation or verification of the method must continue to be applied for results to remain valid. For example, periodic gravimetric checks to assure confidence in the volume dispensed.
- Additional controls should be implemented if necessary to improve measurement performance.

Balance

- Question UQ applies. The final reported result includes a stated amount of analyte per mass of original sample.

Volumetric glassware

- Question CQ applies. The volumetric glassware used to dilute the concentrated extract to a known volume is a critical step in the process. Traceability of the volume is required.

The concentration of the extract (going forward for analysis) is traceable to units for mass and volume. Consideration of the analysis of the extracted sample continues in example Part B.

PART B – LCMS MEASURING AN ANALYTE (EXTRACTED AS DESCRIBED IN PREVIOUS EXAMPLE– PART A)

The LCMS is measuring the analyte extracted from a sample as described in the previous example (Part A).

Reference materials are run in parallel with the sample to be tested.

The reported result is in the units of mass of analyte per mass of sample.

Components of the measurement process include:

- LCMS;
- Standard – CRM;
- Sample preparation – refer to Part A – Solvent Extraction of a Solid Sample for an Organic Analyte.

Consider each component in turn:

LCMS

- No question applies. The facility must still have evidence that the equipment is performing adequately including:
  - installation and commissioning records for new equipment;
  - routine maintenance according to the manufacturer's specifications;
  - satisfactory proficiency testing results (reflecting the whole method);
  - QC showing that the method is in statistical control;
  - CRM in compliance with acceptance criteria.

Standard - CRM

- Questions UQ and RQ apply. CRMs include the units in the final;
- Traceability is required for reference materials and standards. Note that this also captures POVA, balances, Class A glassware etc that may be used to make up the reference materials and standards, hence these are critical and need to be calibrated;
- Where non-certified RMs are used, the facility must be able to demonstrate that they are fit-for-purpose.

Sample Preparation

Refer to example: Part A – Solvent Extraction of a Solid Sample for an Organic Analyte

- Question UQ applies. The final reported result includes a stated amount of analyte per mass of original sample. The balance used to measure the amount of sample used must be traceable.
- Question CQ also applies to volumetric glassware used for critical dilutions and sample preparation. Traceability of the volume is required.

The reported result of this measurement process is traceable through the CRM.

CONCRETE COMPRESSIVE STRENGTH TESTING

This measurement process determines the compressive strength of concrete. The result is reported in force per area.

Components of the measurement process include:

- Dimensional measuring device (may be a vernier and/or measuring jig);
- Compression machine;
- Method – AS 1012.9.

Consider each component in turn:

Dimensional measuring device

- Question UQ applies. The measuring device(s) is used to determine a length measurement to calculate area, which is part of the reported result.
- Calibration of the measuring device is therefore required.

Compression machine

- Question UQ applies. The compression machine returns a force measurement which is part of the reported result.
- Calibration of the compression machine is therefore required.

Method

- Question PQ applies. The facility will need to demonstrate that it is following the method in full in order for the result to be comparable to other laboratories using this method.

The reported result of this measurement process is traceable to the standard method (AS 1012.9) and is dependent on the measurements of length and force.

DUROMETER HARDNESS (SHORE TYPE A)

Hardness of elastomeric material is determined by the penetration of specified indenters into the material under prescribed conditions. Durometer Rubber Degrees, Type A, is used for measuring softer materials (in the range of 30-90 IRHD). The result is reported as Hardness, expressed as Type A degrees.

Components of the measurement process include:

- Type A Durometer;
- Standard rubbers;
- Conditioning;
- Method – AS1683.15.2.

Consider each component in turn:

Durometer

- Questions CQ, UQ and VQ apply: AS1683.15.2 describes how conformance with the stipulated calibration equation is established for the spring. This involves balancing the forces applied to the spring and indicating mechanism against known masses at various scale readings. Since the durometer hardness reading is directly related to the force applied, traceability is expected to extend to all of the known masses used. To ensure the indenting force is applied in a controlled manner during testing, a number of equipment dimensions have also been defined in AS 1683.15.2, including the critical distance by which the indenter protrudes beyond the pressor plate in the relaxed state.
- The readings depend upon parameters normally controlled through calibration of the durometer.

Conditioning

- Question CQ applies: A range is specified for temperature (and for humidity for elastomers whose hardness is affected by relative humidity) and this is considered critical to the reported outcome. Therefore, calibration of the equipment used to monitor environmental conditions is required.

Standard rubbers

- Questions PQ and VQ apply: AS 1683.15.2 describes a ‘verification’ process by which a set of standard rubbers (at least 6) are used to establish the ongoing performance of a Type A durometer. However, since these rubbers are subject to physical change over time, the standard also details a periodic ‘calibration’ process for the standard rubbers themselves, which involves use of a ‘certified’ dead-load IRHD hardness testing device. Given this particular process described within AS1683.15.2, the standard rubber hardness can be inferred to have been controlled by traceable means during the validation of the standard method.
- On this basis, traceability would be expected for the hardness of standard rubbers (or the dead-load IRHD hardness device used for ‘calibrating’ the rubbers, as described in the standard) where these are used for verifying durometer performance.

Method

- Question PQ applies. The facility will need to demonstrate that it is following the method in full in order for the result to be comparable to other laboratories using the method.

The reported result of this measurement process is traceable to the standard method (AS1683.15.2) and dependent on the calibration of the durometer and where applicable, calibration of the humidity measuring device and the hardness of the standard rubbers (where used to validate durometer performance).

ROCKWELL HARDNESS TESTS

An indenter of specified size, shape and material is forced into the flat surface of a test piece in two steps under specified conditions. The permanent depth "h" of indentation is measured under preliminary test force after removal of additional test force. From the values "h" and that of the two constants N (number specific to the scale) and S (Scale unit specific to the scale), the Rockwell hardness is calculated according to the formula:

Rockwell hardness = N – h/S and expressed as HR(S) where "S" is the scale (A, B, C, D, E, F, G, H, K, N, T)

Components of the measurement process include:

- Testing machine;
- Method – AS 1815.1;
- Test block.

Consider each component in turn:

Testing machine

- Question UQ applies. Following the application of a test force using an indenter whose characteristics have been established, the depth measuring system returns a value (h) which is used in the calculation of the reported hardness test result. Due to the risk of wear during use, the condition of indenters is also expected to be checked at defined intervals using appropriate optical devices (microscope, magnifying glass, etc). Calibration of the machine is therefore required to confirm the accuracy of force and depth measurements and initial characterisation of the indenter.

Method

- Question PQ applies. The facility will need to demonstrate that it is following the method in full in order for the result to be comparable to other laboratories using the method.

Test block

- No question applies: While ongoing checks against the blocks are used to monitor machine drift over time as described in AS1815.2 Clause 5.1 (i.e. not as a reference material contributing to the result), the blocks can be adequately characterised for this purpose by measuring their hardness at the same time as the machine calibration. The hardness will not alter over time and so periodic visual inspection for deterioration can be adequate for ongoing verification.

The reported result of this measurement process is traceable to the standard method (AS 1815.1) and dependent on the control of the testing machine parameters (i.e. depth measurement, applied force and indenter characterisation).

MOVEMENT OF RETENTION PIN

Inspection of a freight container considers its fitness for use, including integrity and axial movement of the retention pins using a dial gauge. The axial movement is reported as part of the overall inspection. "Excessive" movement in a retaining pin requires for it to be repaired.

Components of the measurement process include:

- Dimensional measuring device (dial gauge);
- Method developed in-house.

Considering each component in turn:

Dimensional measuring device

- Question UQ does not apply. While the measuring device(s) returns a length measurement which is reported, the report addresses the container's fitness for use rather than a measurement.
- Question CQ does not apply. No acceptance criteria are identified and the measurement provides a framework for discussion rather than a pass/fail result (i.e. the result is indicative).
- Calibration of the measuring device is therefore not required.

Method

- Question PQ does not apply. The procedure is a nominal method specified for a given inspection.
- Question VQ does not apply. The method has not been subjected to validation or verification as to how much movement is considered "excessive".
- Question RQ does not apply. The determination is not used as a calibrator or standard.
- Traceability is therefore not expected through the measuring method.

The reported result for this measurement process is only indicative and used to inform discussions with the client / asset owner. Traceability is not required to support this component of the inspection. However, additional controls such as a spot check of equipment performance using a gauge block of relevant thickness, and checks to establish co-axial alignment between pin and dial gauge could be added to improve measurement performance.