General Accreditation Criteria

Metrological Traceability

January 2018

Terms and definitions

The following definitions apply throughout this document:

Metrological traceability (VIM 3 clause 2.41)

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.

In ISO/IEC 17025:2005 and ISO 15189:2012 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this document.

Note: ISO/IEC 17025 requires all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having significant effect on the accuracy or validity of the result to be calibrated before being put into service. In order for a measurement to be valid, there must be documented evidence to support this unbroken traceability chain of calibrations and associated measurement uncertainties. (Clause 5.6.1 of ISO /IEC 17025).

Reference Material: 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. (Clause 2.1.1 of ISO Guide 30:2015)

Certified Reference Material: reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. (Clause 2.1.2 of ISO Guide 30:2015).

Example: Glyphosate in water with assigned property value in terms of μg/L used as a calibrant or measurement trueness control material. This CRM will have been produced in a way where metrological traceability to volume and mass has been evaluated along with associated parameters such as temperature to support the entire traceability chain.

Note: ISO Guide 31 outlines the minimum content of a CRM certificate to ensure reporting of the property value, uncertainty of measurement for the reported property value and to include a statement on how metrological traceability has been supported. CRMs supplied by a producer accredited to ISO Guide 34:2009 will issue a certificate according to ISO Guide 31. A product information sheet supplied with a Reference Material will not necessarily include this additional information, in which case the laboratory intending to use such material as a calibrant will have assessed the material as a critical consumable.

BIPM (International Bureau of Weights and Measures)

The BIPM is an intergovernmental organisation established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards.

The key task of the Bureau is to ensure worldwide uniformity of measurements and their traceability to the International System of Units (SI).

CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement)

Signatories to the MRA include BIPM Member States, Associates of the BIPM General Conference on Weights and Measures, and other international organisations. The MRA provides a means of comparability of national metrology services including national measurement standards and calibration / measurement certificates issued by NMIs.

ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement)

NATA is a member of the ILAC MRA for Testing and Calibration to ISO/IEC 17025 and Inspection to ISO/IEC 17020.

Note: For details of NATA's current MRA partners, refer to NATA's website: www.nata.com.au

JCTLM (Joint Committee for Traceability in Laboratory Medicine)

The joint committee includes the CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC.

KCDB (BIPM Key Comparison Database)

The KCDB is a public website containing all information relating to the CIPM MRA, an arrangement establishing the equivalence of measurements made by, and certificates issued by, all the participating signatories.

The KCDB comprises two main sections, one containing information about the internationally recognised Calibration and Measurement Capabilities (CMCs) of the participating signatories and the other containing information about the comparisons supporting these CMCs.

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 by the same NMI acronym.

Note: Appendix A includes a set of terms used within the appendix only.

Metrological Traceability

1. Purpose

This document covers NATA's requirements on metrological traceability concerning testing and/or calibration activities.

This policy applies to:

- all NATA applicant and accredited facilities;
- all measurements, whether physical, chemical or biological determinations;

  Note: It is acknowledged that the concept of metrological traceability of measurement results in activity types such as the chemical, medical, and biological sciences is still under development.

- calibrations performed by a facility for its own activities and which are not part of its Scope of Accreditation (so called "in-house calibrations" - refer to NATA's *Equipment Assurance, in-house calibration and equipment verification*).

To assist facilities to apply these requirements, several practical examples of test and measurement processes have been included in this document as Appendix A.

2. Policy for traceability when performing calibrations

For equipment and reference standards that must be calibrated, the policy is that this shall be achieved by one of the following:

2.1 Services which are subject to peer review

a) An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of 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 their calibration certificates, 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 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.

b) An accredited calibration laboratory whose service is suitable for the intended need (i.e. the Scope of Accreditation specifically identifies the appropriate calibration) and the accrediting body is covered by the ILAC MRA for calibration.

Note: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognised regional MRA e.g. Asia Pacific Laboratory Accreditation Cooperation (APLAC), may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

2.2 Services which are not subject to peer review

The following two options should only be applicable when options a) and b) above are not possible for a particular calibration.

c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.

d) A non-accredited calibration laboratory whose service is suitable for the intended need.

It is unlikely that a decision to choose option c) and d) will be made purely on economic grounds and is more likely to be a last resort. It should be noted that choosing one of these options will require significant effort

by the facility i.e. it shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected. This evidence will be reviewed by NATA at assessments of the facility (which will add to the duration of assessments with associated additional fees reflective of the effort required).

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 17025:2005):

- Audits of the calibration service provider (4.6.4 and 4.14)
- Documentation for competence of staff (5.2)
- Documentation for accommodation and environmental conditions (5.3)
- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Documentation for traceability of measurements (5.6)
- Documentation for assuring the quality of calibration results (5.9)

In practical terms, the facility would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is signatory to the ILAC MRA.

Note: In-house calibrations that support accredited testing and form part of the assessment of a testing facility are assessed using these criteria and the criteria as stated in NATA's *Equipment assurance, in-house calibration and equipment verification*.

Note: 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 an applicant facility with NATA, NATA may accept their unendorsed calibration certificates on request from the user of these reports.

2.3 When calibration cannot be strictly made to SI units

ISO/IEC 17025, clause 5.6.2.1.2 states:

> *There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:*
>
> - *the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterisation of a material;*
> - *the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.*
>
> *Participation in a suitable programme of inter-laboratory comparisons is required where possible.*

Clause 5.6.2.1.2 can only apply when the facility has demonstrated that options a) to d) cannot reasonably be met. It is the responsibility of the facility to choose a way to satisfy the clause and to provide the appropriate evidence which shall be reviewed by NATA at assessments of the facility.

3. Policy for traceability when performing tests and measurements

For tests and measurements:

e) If the results of calibration of equipment used contributes significantly to the overall uncertainty and validity of the result, the same policy for traceability applies (as detailed above).

f) If the result of a calibration is not a dominant factor in the test or measurement result, the facility shall have evidence to support this claim. This requires demonstrating that the calibration contributes insignificantly to the accuracy or validity of the test or measurement result and associated measurement uncertainty and therefore traceability does not need to be demonstrated.

3.1 When traceability to SI units is not possible

ISO/IEC 17025:2005, clause 5.6.2.2.2 states:

> *Where traceability of measurements to SI units is not possible and/or relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).*

ISO 15189:2012, clause 5.3.1.4 states:

> *Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.*
>
> ***Note:*** *Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.*
>
> *Where this is not possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:*
>
> - *use of certified reference materials*
> - *examination or calibration by another procedure*
> - *mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned*

Accordingly, where traceability to SI units cannot be achieved, the same criteria as covered in 2.3 shall apply.

4. Policy for traceability obtained through a reference material (RM) and certified reference material (CRM)

ISO/IEC 17025:2005, clause 5.6.3.2 states:

> *Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.*

For ISO 15189:2012, clause 5.3.1.4 as noted above applies.

Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

Traceability is considered to have been established where:

g) The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB or, produced by a Reference Material Producer (RMP) who has been accredited for the production of reference materials listed under its accredited Scope of Accreditation to ISO Guide 34:2009.

> **Note:** RMPs accredited by a signatory to a regional body e.g. Asia Pacific Laboratory Cooperation (APLAC), are considered to have established valid traceability.

h) The values assigned to CRMs are covered by entries in the JCTLM database.

i) The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the facility shall demonstrate that each RM or CRM is suitable for its intended use as required by clause 4.6.2 in ISO/IEC 17025:2005 or clause 4.6 in ISO 15189:2012.

5. 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

Appendix A

(informative)

General

The purpose of this appendix is to assist applicant and accredited facilities in applying NATA's policy on metrological traceability. This information is intended for guidance only.

It includes a number of practical examples of test or measurement processes commonly performed in a range of facilities. The examples appear in the following order:

Page number

1. Autoanalyser platform testing enzyme y 10
2. Autoanalyser testing analyte x (excluding enzyme activity) 11
3. Enzyme linked Immunosorbent Assay (ELISA) measuring analyte x 12
4. Erythrocyte sedimentation rate (ESR) 13
5. Isolation and identification of bacteria 14
6. Moisture content by oven drying 15
7. Part A – Solvent extraction of solid sample for organic analyte Y 16
8. Part B – LCMS measuring analyte x 17
9. Concrete compressive strength testing 18
10. Durometer hardness (Shore Type A) 19
11. Rockwell hardness tests 20
12. Movement of retention pin 21

The examples are not intended to be exhaustive.

Terms used

Component – anything used in a measurement process, including, but not limited to, equipment (load cells, verniers, balances, ovens etc.), procedure or technique selected (in-house, standard, consensus etc.), reference materials and standards (calibrators, CRMs, RMs, physical artefacts etc.), consumables and reagents.

Measurement process – the method that includes everything, from selection of the procedure or technique through to the report. The method can be in-house, consensus or standard. 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 – if the units of the final result include, for example, volume, then components measuring volume would be captured by this question. Indirect reporting covers results that are calculated or proportions where the inputs to the calculation would be included.

Critical - a component on which the validity of the measurement process relies. 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)

How to use the schema

The schema on page 9 of this document is general in nature and should be used in combination with each written example.

Each facility is encouraged to apply the schema as appropriate to their unique situation and range of tests and measurements performed in an effort to assist in determining if metrological traceability is required.

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)

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

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

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

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

*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

1. Autoanalyser platform testing enzyme y

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 instrument 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, and they are not available for all enzymes (IFCC enzyme activity reference materials are traceable to SI units *mole per second per cubic metre* (mol s^{-1} m^{-3}, or kat m^{-3})). In this case there is no calibrator included in the laboratory 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'); and
- 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 from laboratory to laboratory where each laboratory is using the same standard method), the 'standard method' must be followed – that is, the autoanalyser must demonstrably function correctly.
  The manufacturer has validated the method against published IFCC methods, and where possible, using Certified Reference Material.
- Evidence that the method is performing to specification could include, but is not limited to:
  - For new equipment, Installation and Operational Qualification records (however named);
  - Routine maintenance according to the manufacturer's specifications;
  - Satisfactory QAP results; and
  - QA and 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.
- 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 SI units for enzyme activity through the IFCC standard method, or IFCC CRM (depending on the measurand), via the manufacturer.

2. Autoanalyser platform testing analyte x (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; and
- 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 from laboratory to laboratory where each laboratory is using the same standard method), the 'standard method' must be followed – that is, the autoanalyser must demonstrably function correctly.
- Evidence that the method is performing adequately could include, but is not limited to:
    - For new equipment, Installation and Operational Qualification records (however named);
    - Routine maintenance according to the manufacturer's specifications;
    - Satisfactory QAP results; and
    - QA and 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 laboratory 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 both to the value assigned to the calibrator, and to the standard method.

3. Enzyme Linked Immunosorbent Assay (ELISA) measuring analyte x

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

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

Consider each component in turn:

Plate reader:

- No question applies. Plate readers report the difference between two readings, not an absolute measurement. Plate readers are generally verified with manufacturer supplied plates in use.
- Traceability need not be established for the plate reader. There must be evidence of adequate performance usually achieved through the use of the standard plate, and ensuring that routine maintenance and servicing is performed according to manufacturer's specifications.

Calibrator:

- Questions UQ and RQ apply. Calibrators include the units in the final report and they are a reference material.
- Traceability is therefore required for calibrators. Note that this also captures POVA, balances, Class A glassware etc. that may be used to prepare the calibrator.
- Traceable calibrators may be CRMs. Where a non-CRM Reference Material (RM) is used, the laboratory must be able to demonstrate that it is fit-for-purpose.

Method:

- If the method in use is a Standard or consensus method for this analyte, then PQ applies, and the laboratory must be able to demonstrate that it is following the standard method in order for the result to be comparable to other laboratories using this method.
- In-house methods must be validated, but are not considered 'traceable', and no question applies.

Incubator:

- Question CQ applies. Methods usually specify the optimal temperature required, but the decision as to whether it is 'critical' will be made by the laboratory in consideration of their knowledge and experience with both the method and the target analyte.
- Where the temperature is 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.
    - It was calibrated: the temperature measuring device must continue to be calibrated at suitable intervals.
    - It was checked, not calibrated: the temperature measuring device must continue to be checked against 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.
- Note that POVA, balances, Class A glassware etc. that may be used to aliquot or prepare kit reagents may be critical, and if so, each critical item must have evidence of metrological traceability.
- 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 units of the calibrator. The result may also be traceable to a standard method.

4. 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; and
- Timer.

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 from laboratory to laboratory), performance of the method must be assured.
- 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 the application of this test – the 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 likely to be sufficient traceability for the measurement component of the units.

Timer:

- Question UQ applies. The result is read at 60 minutes.
- When considering how traceability is demonstrated for this test it is important to consider the application of this test – the clinical utility. For the ESR clinical utility is limited, and the result is generally indicatory.
- Comparing the laboratory timer to a GPS timer will provide satisfactory traceability for the time component of the units.

The reported result of this measurement process is traceable the SI Units time and length, and to the standard method.

5. 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; and
- Method.

Consider each component in turn:

Agar plates:

- These are consumables that must be quality controlled, but no questions are answered 'Yes' – metrological traceability is not essential. Controls must still be applied to the use and manufacture 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 laboratory must be able to demonstrate that the control organism is fit-for-purpose. For example: demonstrate that the wild strain gives the same morphological and biochemical reactions as strains from reference collections.

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 laboratory in consideration of their 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.
- It was calibrated: the temperature measuring device must continue to be calibrated at suitable intervals.
- It was checked, not calibrated: the temperature measuring device must continue be checked against 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, and the laboratory must be able to demonstrate that it is following that method in order for the result to be comparable to other laboratories using this method.
- In-house methods must be validated, but are not considered 'traceable', and no question applies.

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

6. 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; and
- 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.
- Traceability is therefore expected for the balance.

Method AS 1289.2.1.1:

- Question PQ applies. The laboratory 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.

Reported results depend upon traceable measurement of mass and the correct implementation of the method AS 1289.2.1.1.

7. Part A – Solvent extraction of solid sample for organic analyte Y

Preparation of sample for analysis with multiple measuring and extraction steps. The prepared extract is analysed in a subsequent procedure (see Example 8: 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;
- POVA;
- Balance;
- Reagents; and
- 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 QA, 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.
- 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.

POVA:

- No question applies. The POVA used to introduce a surrogate to monitor recovery is not critical as repeatability is more important than the precise 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 method. 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 8: Part B

8. Part B – LCMS measuring analyte x

(extracted as described in Example 7 above – Part A)

The LCMS is measuring the analyte extracted from a sample as described in Example7: 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; and
- Sample preparation – Refer Example 8: Part A – Solvent Extraction of solid sample for organic analyte Y.

Consider each component in turn:

LCMS:

- No question applies. The facility must still have evidence that the equipment is performing adequately including:
  - Installation and Operational Qualification records (however named)
  - Routine maintenance according to the manufacturer's specifications
  - Satisfactory PT results (reflecting the whole method)
  - QA and 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 report and they are reference materials.
- Traceability is therefore 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.
- Where non-certified RMs are used, the laboratory must be able to demonstrate that they are fit-for-purpose.

Sample Preparation:

Refer Example 7: Part A – Solvent Extraction of solid sample for organic analyte Y

- 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 sample preparation method. Traceability of the volume is required.

The reported result of this measurement process is traceable to the units of the reference material and SI units for mass and volume.

9. Concrete compressive strength testing

This measurement process determines 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; and
- Method – AS 1012.9.

Consider each component in turn:

Dimensional measuring device:

- Question UQ applies. The measuring device(s) returns a length measurement used to calculate area, which is part of the reported result.
- Traceability is therefore expected for the measuring device.

Compression machine

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

Method:

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

Reported results depend upon traceable measurement of length, force as well as the correct implementation of the method AS 1012.9.

10. 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; and
- 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.
- Traceability is expected for the equipment used to monitor environmental conditions.

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) is 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 laboratory will need to demonstrate that it is following that method in order for the result to be comparable to other laboratories using this method.

Reported results depend upon the calibration of the durometer, compliance with the standard method AS1683.15.2 and traceable measurement of temperature (and humidity where applicable) and the hardness of standard rubbers (where used to validate durometer performance).

11. 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; and
- 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.).
- Traceability is expected for the measurement of the applied force, depth measurement and initial characterisation of the indenter.

Method:

- Question PQ applies. The laboratory will need to demonstrate that it is following that method in order for the result to be comparable to other laboratories using this 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
- Traceability is therefore not essential for test blocks.

Reported results depend upon compliance with the standard method AS 1815.1 and traceable control over the testing machine parameters, i.e. depth measurement, applied force and indenter characterisation.

12. Movement of retention pin

This measurement process determines the axial movement of a retaining pin in a freight container. Inspection considers the fitness for use of the container, including labelling, seals, rigging, container history, as well as container structural integrity and coating integrity. The specification indicates "excessive" movement in a retaining pin is cause for holding the item for repair. To facilitate consistency between inspectors the inspection body has determined to measure and report axial movement, and has provided a magnetically mounted dial gauge to measure this movement.

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 fitness for purpose of the container 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 criteria.
- Traceability is therefore not expected for the measuring device.

Method:

- Question PQ does not apply. The procedure is a nominal method, and while it may reflect a good practice it carries no weight as a reference, accepted of specified method outside this facility.
- 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.

Reported measurement results are indicative and may be 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.

AMENDMENTS

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

Section	Amendment
Entire document	This document replaces the former Policy Circular 11. The document has been reviewed and updated to reflect the new accreditation documentation structure and replace field with activity type.