GUIDELINES FOR IMPLEMENTATION OF THE INSPECTION, MEASURING AND TEST EQUIPMENT REQUIREMENTS IN REFERENCE TO THE ISO 9000:2000 SERIES STANDARDS

1. INTRODUCTION

This document aims to give auditors and organisations a practical understanding of how to establish and maintain an effective system for managing inspection, measuring, and test equipment.

AS/NZS ISO 9001:2000 requires organisations to 'carry out measurements in a manner that provides evidence of the conformity of product and that, where necessary, measuring equipment shall be calibrated periodically against standards traceable to national standards and that the results of calibration be maintained.'

When assessing an organisation to ISO 9001, auditors expect to find that measuring equipment is within its calibration interval and that the performance (e.g. accuracy) of the equipment is suitable for its application. Auditors also expect to see records of calibration, and a process to assess previous measurement results when equipment is found not to conform to requirements.

2. EQUIPMENT CATEGORIES

2.1 General

One of the major considerations associated with the implementation of a system to control Inspection Measuring and Test Equipment (IMTE) under an ISO 9001 system is the extent to which formal calibration needs to be applied. For those organisations undertaking work that requires highly accurate measurements on which product quality is dependent, formal and fully traceable calibration arrangements need to be applied.

There are however many applications where verification of product conformance, or process control requirements, do not require such high accuracy, or directly traceable, measurements. Lastly, some equipment simply requires a visual or self test.

2.2 Categories of Equipment

To assist in the implementation of the ISO 9001 IMTE requirements, three broad categories of equipment have been identified and are described in Annex A. These categories are based on equipment usage, not on the type of equipment (e.g. a micrometer may appear in Category A or Category B depending on the criticality and accuracy of the measurement being made).

It is stressed that these categories are for guidance only and a risk assessment and/or common sense must still be applied when determining which equipment category is applicable.

In evaluating the category into which equipment fits, the following approach is suggested:

a) Identify which measurements are critical to ensuring product conformance and performance. These measurements include physical measurements of the product

(e.g. size, weight, volts, etc), values of specified performance parameters (e.g. capacity, strength, gain, etc), and overall process control parameters that are critical to ensuring final product quality.

b) Identify the tolerance & accuracy required for these measurements.

c) Then determine the extent/frequency of calibration required.

Annex A comprised two sections designed to be used as follows:

Part 1: Provides guidelines for selecting relevant equipment categories.

Part 2: Provides guidance regarding the "calibration and checking" requirements for each equipment category.

3. TRACEABILITY

3.1 General

a) The concept of traceability has two components.

a) Traceability of the measurement equipment chain, and
b) Traceability of competence (accredited skill of calibration personnel)

(a) means that a working instrument must be calibrated against a reference instrument that has in turn been calibrated against a more accurate reference instrument and so on until the calibration chain reaches the primary national and international standards. In Australia the primary standards are held by the CSIRO National Measurement Institute (http://www.measurement.gov.au).

(b) means that the facilities and personnel working in the organisation performing the test or calibration have been assessed by NATA as competent to undertake the work (or is an approved verifying authority), and can issue a NATA Endorsed (or full) calibration report under the designated signatory.

Note. The Australian Measurement Hierarchy is shown on **Annex B.**

b) An integral part of traceability is confidence in the total accuracy of the calibration.

Calibrations conducted internally (e.g. Cat B instruments calibrated against an externally calibrated Cat A instrument) naturally have a diminished accuracy, often declared at 5-10 times less than the Cat A reference, but still perfectly acceptable. Confidence in externally sourced calibrations can be gained, and demonstrated to customers and auditors by having the calibration performed by one of the following:

i) Calibration performed by CSIRO National Measurement Institute (NMI).

ii) Calibration performed by a NATA accredited calibration facility and reported on a NATA endorsed calibration report.

iii) Calibrations performed by a national measurement laboratory that holds Statements of Equivalent with the CSIRO NMI (e.g. NIST (USA), NPL (UK), NRC (Canada), JRL (NC) or is recognised by CSIRO NMI as demonstrating competence.

iv) Calibration performed by a calibration facility that is accredited by another laboratory accreditation organisation recognised under a Mutual Recognition Agreement with NATA (e.g. TELARC, HOKLAS, NAMAS, NVLAP, A2LA, STERLAB and SWEDAC).

v) Calibration performed by a laboratory or facility recognised by the CSIRO NMI as a verifying authority (i.e. trade measurement) for the particular calibration.

3.2 Traceability Requirements for Category "A" Equipment

a) Calibrations are conducted by one of the calibration sources listed in Paragraph 3.1 (i)-(v) (above).

b) Acceptable documentary evidence of traceable calibrations from external sources is:

i) A calibration report issued by the CSIRO NMI or a recognised overseas facility.

ii) A NATA endorsed calibration report issued by a calibration facility accredited by NATA for the particular calibration.

iii) A calibration report issued by a calibration facility accredited by a laboratory accreditation body recognised under a Mutual Recognition Agreement with NATA. (NATA can provide information on request).

iv) A Regulation 13 Certificate issued under the National Measurement Regulations 1999 by a calibration laboratory appointed by the CSIRO NMI as a Verifying Authority.

3.3 Traceability Requirements for Category "B" Equipment

a) Traceability for this category of equipment must still be maintained. However, the requirements are not as stringent as for Category "A" equipment.

b) "In-house" equipment checks must meet the following criteria:

i) Checks are performed using an "in-house" approved (or proven) method.

ii) Checks must be performed by appropriately trained staff.

iii) Reference standards used are traceable to CSIRO NMI through one of the sources detailed in Paragraph 3.1 (above).

iv) Full records of calibration results and environment (where appropriate) are maintained.

c) Equipment checks forming the calibration “chain” may be performed by internal or external sources provided that the above requirements are met as a minimum.

d) Acceptable documentary evidence of traceability for reference sources are given in Paragraph 3.2 (b).

3.4 Traceability Requirements for Category "C" Equipment

a) There are no specific traceability requirements for equipment in this category.

4. PURCHASING IMPLICATIONS

4.1 General

When calibration services are "purchased" from an external source, the full requirements of the purchasing clause of the relevant ISO 9001 standard is applicable. The logic is very simple - if you do not specify what you want, you have no guarantee of getting it.

4.2 Assessment of Suppliers

Before placing an order for calibration services, the capability of the supplier must be ascertained. This can be done by asking the supplier to provide a copy of their NATA scope of accreditation, or an equivalent document that establishes the scope of the supplier's competence and authority under the relevant trade measurement legislation.

If you have determined that a particular instrument (i.e. Cat A) requires a NATA endorsed calibration/test certificate, only a NATA endorsed supplier can issue it. However if your risk is lower (e.g. Cat B equipment), then a non NATA endorsed certificate is valid.

Calibration providers who have been evaluated as above should be incorporated on the list of approved suppliers.

4.3 Purchasing Information

Purchase orders for calibration services are best issued or confirmed in writing. The PO should state the make, model & serial No. of the instrument. Then describe the type of calibration required (e.g. NATA endorsed calibration report, or certificate of conformance, and any special requirements such as specific ranges that will (or will not) require calibration, or perhaps a requirement to “calibrate to manufacture’s specifications”.

5. CALIBRATION REPORTS

Two forms of reporting are usually offered by calibration providers: a **NATA Endorsed** (or full calibration) report, or **Non-NATA Endorsed** (or certificate of conformance).

A calibration report provides (as a minimum) a set of results that show the performance of the instrument being calibrated in comparison to a reference instrument or standard. Measurements are recorded for each function, range and points tested, and the uncertainty of the measurement is stated, usually in the range 95-99%. The report enables users to be aware of the errors of their instrument, and if necessary, apply corrections based on the results given in the report. Depending on the magnitude of errors the calibrator or equipment owner may decide to have the instrument adjusted.

When a non-endorsed calibration certificate is requested, it usually states the compliance of an instrument against the manufacturer's specification (unless some other specific report is requested). Measurements made by the instrument being calibrated are compared to the manufacturer's specification. If the instrument is within specification, a statement that the instrument meets the manufacturer's specification at the points tested is made in the conformance certificate. Any points that are outside specification, or not able to be determined,

are reported as exceptions. Assessment of meeting the manufacturer's specification takes into account the measurement uncertainty. A statement of conformance to the manufacturer's specification may also be given in calibration reports.

It is essential that calibration reports are examined to determine if any corrections or repairs were carried out that may trigger the need to re-check stock, or at worse, a product recall.

6. CALIBRATION INTERVALS

A question that is often asked is 'How often do I need my instrument calibrated?' The answer is not straightforward and depends on factors such as: the impact of the instrument on quality, the environment and the way in which the instrument is used, periodic checking against other instruments, and recorded history of the instrument. Ultimately it comes down to the risk period that, should the equipment become faulty, the company is prepared to continue delivering product. This in turn is a factor of cost and business impact in the event of a recall.

The supplementary requirements for accreditation by NATA to ISO 17025 are a useful guide in determining calibration intervals. The NATA document sets out the requirements for the frequency of recalibration of test equipment used by testing and calibration laboratories. For digital instruments the required recalibration interval is a maximum of 12 months and this interval is frequently used for instrument calibration generally. However if the instrument is subject to wear or physical impact, 6 months might be more prudent. If the equipment is used to verify critical parameters that are costly to correct after delivery, 3 months is common.

Manufacturers often recommend calibration intervals for their instruments. These recommendations are based on their knowledge of the design of the instrument and the performance history of a significant number of the same instruments over a period of time. Generally manufacturers recommend an extended calibration interval once they have gained confidence in the instrument's performance.
Calibration intervals can always be supplemented by more frequent equipment checks.

7. DEFINITIONS

The following definitions are taken from the International Vocabulary of Basic and General Terms in Metrology published by ISO/IEC (2nd Ed., 1993).

7.1 **True value (of a quantity)** - value consistent with the definition of a given particular quantity.

Notes: 1. This is a value that would be obtained by a perfect measurement.
2. True values are by nature indeterminate.

7.2 **Measurement** - set of operations having the object of determining a value of a quantity.

Note: The operation may be performed automatically.

7.3 **Measurand** - particular quantity subject to measurement.

Example: Vapour pressure of a given sample of water at 20^{o}C.
Note: The specification of a measurand may require statements about quantities such as time, temperature and pressure.

7.4 **Measuring instrument** - device intended to be used to make measurements, alone or in conjunction with supplementary devices.

7.5 **Accuracy of measurement** - closeness of the agreement between the result of a measurement and a true value of a measurand.

Notes: 1. Accuracy is a qualitative concept.
2. The term "precision" should not be used for "accuracy".

7.6 **Calibration** - set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.

Notes: 1. The result of a calibration permits the assignment of values of measurands to the indications or the determination of corrections with respect to indications.
2. A calibration may also determine other meteorological properties such as the effect of influence quantities.
3. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or calibration report.

7.7 **Material measure** - device intended to reproduce or supply, in a permanent manner during its use, one or more known values of given quantity.

Examples: a) a weight;
b) a measure of volume (of one or several values, with or without a scale);
c) a standard electrical resistor;
d) a gauge block;
e) a standard signal generator;
f) a reference material.

7.8 **Repeatability (of a measuring instrument)** - ability of a measuring instrument to provide closely similar indications for repeated applications of the same measurand under the same conditions of measurement.

Notes: 1. these conditions include:
- reduction to a minimum of variations due to the observer;
- the same measurement procedure;
- the same observer;
- the same measuring equipment, used under the same conditions;
- the same location;
- repetition over a short period of time.

2. Repeatability may be expressed quantitatively in terms of the dispersion characteristic of the indications.

7.9 **Repeatability (of results of measurements**) - closeness of agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.

Notes: 1. These conditions are called repeatability conditions.
2. Repeatability conditions include;
- the same measurement procedure;
- the same observer;
- the same measuring equipment, used under the same conditions;

- the same location;
- repetition over a short period of time.

3. Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

7.10 **Uncertainty of measurement** - parameter associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand.

Notes: 1. The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

2. Uncertainty of measurement comprise, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterised by experimental standard deviations. The other components, which can also be characterised by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

3. It is understood that the result of the measurement if the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

7.11 **Measurement standard** - material measure, measuring instrument, reference material or measuring system intended to define, realise, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

Examples: a) 1 kg mass standard;
b) 100 standard resistor;
c) standard ammeter;
d) caesium frequency standard;
e) standard hydrogen electrode;
f) reference solution of cortisol in human serum having a certified reference concentration.

7.12 **Traceability** - property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Notes: 1. The concept is often expressed by the adjective "traceable".

2. The unbroken chain of comparisons is called a traceability chain.

7.13 **Tolerance** - The permissible range of variation of some characteristic from its nominal value

ANNEX A PART 1 – GUIDELINES FOR SELECTING RELEVANT EQUIPMENT CATEGORIES

This table is intended to help you to determine the appropriate measure confirmation requirements for measuring equipment based on the purpose for which the measuring equipment is being used.

CATEGORY A FORMAL CALIBRATION	CATEGORY B PERFORMANCE CHECK	CATEGORY C VISUAL INSPECTION
Formal calibration is required when the measuring equipment is being used to: * verify conformance of product to specified tolerances that are critical to product performance and conformance to manufacturers' or customers' specified requirements * monitor processes where process limits critical to final product performance and conformance have been specified * meet regulatory requirements that specify calibration as a mandatory requirement	Performance checks are appropriate when measuring equipment is used to: * measure parameters that are less critical to product performance and conformance to manufacturers' or customers' specified requirements *monitor processes where control of process parameters and variation is not critical for ensuring product performance and conformance to specified requirements, but where manufacturing efficiencies may be affected *monitor product or service parameters where there is a subsequent verification in the production process that fulfils final requirements for conformance testing.	Visual inspection may be adequate when measuring equipment is used to: * transfer or comparison measurements (e.g. using callipers to transfer a dimension from one workpiece to another) * for indication but not measurement purposes (e.g. to indicate an on/off situation) * for broad tolerance measurements where continued useability of the equipment can be confirmed by visual check for damage or deterioration (e.g. steel tape measurements for some application) Note. Some Cat C equipment is self checking

ANNEX A GUIDANCE FOR CALIBRATION AND CHECKING REQUIREMENTS FOR EACH EQUIPMENT CATEGORY

MEASUREMENT CONFIRMATION Which of the following actions would be required in each of the categories of measurement verification?	**CATEGORY "A" FORMAL CALIBRATION**	**CATEGORY "B" PERFORMANCE CHECK**	**CATEGORY "C" VISUAL INSPECTION**
1 Traceability of reference equipment to national standards- Direct Indirect	YES	 YES	
2 A documented method with the following characteristics - technical validation based on a recognised documented standard where available - an in-house work instruction - a visual check instruction	 YES YES YES	 YES YES	 YES
3 Control/monitoring of calibration/checking environment. Knowledge of the influence of environment on use of the instrument.	YES YES	MAYBE YES	
4 Competent staff - trained in the technique - evaluated externally - provided with internal references or sources	 YES YES	YES YES	YES
5 Data & Records - required accuracy & tolerances - applied, measured, and corrected values stated - details of reference equipment or sources used - NATA endorsed test report (or equivalent)	 YES YES YES YES	 YES YES	

ANNEX A CHOICES FOR CONFIRMING THE PERFORMANCE OF MEASURING EQUIPMENT

MEASUREMENT CONFIRMATION	CATEGORY "A" FORMAL CALIBRATION	CATEGORY "B" PERFORMANCE CHECK	CATEGORY "C" VISUAL INSPECTION
Specified frequency of calibration/check	YES	YES	YES
Safeguard against adjustment	YES	MAYBE	
Identification of equipment	YES	YES	YES

ANNEX B THE AUSTRALIAN NATIONAL MEASUREMENT HIERACHY