Recommended Practices for Calibration Laboratories

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1.0 General

This document recommends environmental practices and documentary and operational protocols for calibration laboratories that provide Type I, Type II, and Type III calibration services. The recommendations are not necessarily requirements for accreditation into the Canadian Calibration Network. Such requirements are given in ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories* and in supporting CLAS Requirements Documents and in the PALCAN Handbook published by the Standards Council of Canada.

2.0 Purpose

To provide Canadian calibration laboratories with some operating procedures and good laboratory practices that, if followed, will help the laboratories to produce appropriate measurement results and to provide suitable calibration certificates.

3.0 Definitions

The following definitions apply in this document:

Test Uncertainty Ratio (TUR) - The ratio of the tolerance limit(s) of the object being measured to the uncertainty of the measurement system. See CLAS Requirements Document 3 *Minimum Requirements for Measurement Standards for Laboratory Certification*.

Calibration - The set of operations that establishes, 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 realized by standards. The result of a calibration permits either the assignment of values of measurands to the indications or the determination of corrections with respect to indications. A calibration may also determine other metrological properties such as the effect of other influence quantities. The result of a calibration may be recorded in a document, sometimes called a **calibration certificate** or a **calibration report**. See CLAS Requirements Document 6 *Requirements for Calibration Certificates issued by CLAS Laboratories*.

Calibration Laboratory - Laboratory that performs calibration . A calibration laboratory may offer one or more of the following types of service. See CLAS Requirements Document 3 *Minimum Requirements for Measurement Standards for Laboratory Certifications* for details on these types of service.

Type I: A service that is intended primarily for the calibration of measurement standards.

Type II: A service that is intended primarily for the calibration and adjustment of test, measurement, and diagnostic equipment for use in such areas as product testing, manufacturing, and servicing.

Type III: The service is the same as Type II service except that the laboratory does not have the means to verify directly its measurement standards using redundant equipment. The laboratory instead assures the quality of the measurement results through such other quality control techniques as interlaboratory comparison, replication, retesting, and correlation with other measurement characteristics. Measurement standards used for Type III services are robust and are generally not subject to large drift or change within the laboratory's scope of measurement.

NOTES:

(1) A mobile laboratory can offer any type of service as long as it meets the appropriate criteria.

(2) Some laboratories may offer more than one type of service.

<u>Designated Measurement Standards</u> - These include:

(a) National standards held or accepted by the National Research Council of Canada.

(b) National standards of other countries whose measurement results are correlated with international standards through the BIPM (Bureau international des poids et mesures) or with Canadian national standards.

(c) Accepted values of natural physical constants.

(d) Ratio type of self-calibration techniques.

(e) Consensus measurement standards.

(f) Certified (standard) reference materials.

NOTES:

(1) When calibrations are traced to foreign standards, differences between the nationally-adopted measurement unit values and the Canadian values must be taken into consideration, when warranted.

(2) A consensus measurement standard is an artifact or process that is used as a *de facto* standard by agreement between contracting parties when no national measurement standard is available.

(3) A reference material is a material or substance, one or more of whose properties are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. A certified reference material (sometimes referred to as a standard reference material) is a reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

<u>Measurement Standard</u> - A material measure, measuring instrument, reference material, or measuring system intended to define, realize, conserve, or reproduce a unit or one or more values of a quantity to serve as a reference.

National Metrology Institute (NMI) - A facility that realizes, maintains, and disseminates the primary measurement standards in a country (also referred to as National Measurement Standards).

Primary Measurement Standard - A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Traceability - the 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. CLAS requires that all laboratories in the traceability chain be verified (e.g., accredited) to be competent to carry out the particular measurements. See CLAS Requirements Document 9 *Requirements for Measurement Traceability*.

Transfer Standard - A standard used as an intermediary to compare standards. The term *transfer device* should be used when the intermediary is not a standard; e.g., adjustable callipers used to intercompare end standards.

Travelling Measurement Standard - A standard, sometimes of special construction, intended for transport between different locations ; e.g., a portable battery-operated caesium frequency standard.

Uncertainty of measurement - A parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. In the case of compliance testing, the uncertainty of measurement can be inferred from the test uncertainty ratio (TUR). See CLAS Requirements Document 3 *Minimum Requirements for Measurement Standards for Laboratory Certification* for details on compliance testing.

Uncertainty List - An itemized list of the sources and magnitudes of the uncertainties that contribute to the total uncertainty attributed to any measurement result. The list includes the uncertainties associated with:

(a) The traceability to designated standards.
(b) The measurement technique.
(c) The ambient conditions.
(d) The behaviour of the measured device during the measurement.
(e) The condition of the measured device at the time of measurement.
(f) Other uncertainties that may be identified.

4.0 Environmental Considerations

4.1 General

Calibration equipment and reference standards will be affected by changes in a number of influencing parameters such as temperature, pressure, and relative humidity. The reference environmental conditions listed below are gradually being adopted internationally.

Although it is possible for standards laboratories to work under other environmental conditions and to correct their measurement results so as to represent the calibration information at the reference conditions, considerable extra work and meticulous data processing is necessary to ensure that correct results are reported. The overall operation of a standards laboratory or of a test equipment calibration laboratory is simplified when the same reference environmental conditions are maintained in calibration laboratories and in external client laboratories. This decreases the probability of errors when writing or implementing reports.

4.2 In-House Laboratories

For those calibration laboratories that do not offer their services to external clients, it may be more economical to establish a set of reference environmental conditions suitable to the local scene. This requires that appropriate attention be paid to calibration data from other sources with other environmental conditions.

4.3 Environmental Stability

Although the set points of variables, such as temperature, are important, a more important aspect is the stability of the environment during the time taken to make a calibration measurement. Limits on the rates of change of the environmental conditions are important to all laboratories, and should be established and maintained in all calibration laboratories.

The requirement for temperature stability applies only to the space occupied by the standards and the comparison or measuring equipment, although the larger the volume in which the conditions are stable the greater would be the confidence in the measurement results. It sometimes happens that a minor relocation of work space will improve conditions of measurement appreciably.

4.4 Micro-Climates

As far as temperature conditions are concerned, there are a number of artifact standards such as standard cells and standard resistors in the electrical/electronic field whose expected high precision performance can only be achieved when the devices are maintained in much more closely controlled temperature enclosures, such as oil baths or air baths, where stability of temperature of ± 10 mK or better can be maintained. Many precision measurements can only be made when these micro-climates are present to overcome the instabilities of temperature normally found in even the best-controlled laboratories. If the laboratory work is restricted to the use of such micro-climates the ambient temperature may change without affecting the compatibility of the measurement results.

4.5 Effects of Relative Humidity

It is known that relative humidity greater than approximately 65% can lead to corrosion effects in some instruments or standards, or to degradation of electrical insulation in other cases. Below approximately 20%, electrostatic effects begin to manifest themselves in many ways, one of which may be electrostatic discharge problems that can easily damage some sensitive electrical circuits.

4.6 Air Cleanliness

For many calibration laboratories, air cleanliness is an important factor. One of the ways to improve air cleanliness is to maintain a positive air-pressure differential of at least 12 Pascal (0.05 inches of water) between the inside of the laboratory and the adjacent area outside the laboratory, to reduce the influx of dust-laden air. Whether or not the recommended air cleanliness limits can be met without a positive pressure differential is very largely associated with the general cleanliness of the space surrounding the laboratory. If the air cleanliness limits can be met without a positive air pressure differential, there is no need to complicate the installation. Experience has indicated that 50,000-class and 100,000-class laboratories need the addition of positive air pressure.

A 50,000-class laboratory is one in which, under normal working conditions and with normal laboratory staff complement, the number of particles of 0.5 micrometer and larger does not exceed 1.8 million particles per cubic metre of air. This is equivalent to 50,000 particles per cubic foot of air.

Activities within the laboratory not directly related to the calibration activities and which tend to contribute to the generation of airborne particles should not be allowed. Such activities include soldering, smoking, eating, and drinking.

4.7 Lighting

A lighting level appropriate to the task being performed, and preferred by the people doing the specialized work, should be maintained in the work space. A lighting level of 500 to 1000 lux will be suitable for many laboratory work areas.

4.8 Vibration

The natural or induced vibrations present in the laboratory should not compromise the validity of the measurement results or affect the life of standards and associated equipment.

4.9 Acoustic Noise

In order to provide a more pleasant work environment, the ambient acoustic noise should be kept below 65 dB, "A" weighting.

4.10 AC Power

A reliable source of electrical energy is necessary. This source should be of suitable frequency and voltage, and with minimal distortion so as not to compromise the validity of the measurement results or affect the life of standards and associated equipment. It may be necessary to provide conditioned and regulated supplies for certain types of measurements.

4.11 Electromagnetic Interference

Electrical and magnetic fields must be kept to a level that will not compromise the validity of the measurement results.

4.12 Barometric Pressure

The barometric pressure can influence some measurements but is difficult to control in a laboratory environment. Metrologists should be aware of this influence and make any adjustments that are necessary to avoid compromising the validity of the measurement results.

4.13 General Facilities

In order to provide better operational conditions for the measurements being performed in a laboratory, it is desirable that a laboratory providing Type I or Type II calibration services should be physically divided into two distinct work areas.

4.14 Receiving and Cleaning Area

This area should be equipped so that equipment can be cleaned and prepared to enter the laboratory. The equipment should be cleaned and dismantled as required to ensure that dirt, dust, protective greases, or unnecessary covers or packing boxes are excluded from the calibration area.

4.15 Calibration Area

Calibration activities should be conducted in an area established for and dedicated to this purpose. It should be separated from receiving, cleaning, and other such activities. Equipment for calibration should be conditioned and stabilized to the calibration environment before calibration is attempted.

4.16 Repair and Adjustment

If repair and adjustment are carried out by the calibration laboratory, it should be done in the stabilized calibration area. However, the environmental quality of the calibration area should not be compromised by activities that create unwanted particulate matter.

4.17 Mobile and On-Site Calibration Operations

It is difficult to accomplish such separation of functions in a mobile or on-site calibration operation. In a mobile vehicle, particular care should be taken with housekeeping, to decrease the accumulation of dirt, dust, and grease.

5.0 Environmental Practices

5.1 General

To be deemed capable of making adequate measurements, calibration laboratories should provide a facility with adequate environmental controls, appropriate for the level of measurements to be made. Table I summarizes recommended environmental conditions for Type I and Type II mechanical/dimensional, electric/electronic and other laboratories, and recommended environmental conditions for Type III laboratories in general.

5.2 Control of Environmental Conditions

Type I and Type II calibration laboratories should have continuous control of the operating environment according to the recommendations in Table 1.

The nature of the Type III operation will require special consideration of the environmental factors listed above. Bear in mind that for Type III operations, some of the auxiliary or support equipment used in the calibration ensemble may be supplied by the client.

Type III laboratories should meet the environmental recommendations outlined in Table 1. However, it is recognized that this may not be possible at all times.

NOTES:
(1) If these conditions are not maintained at all times, a stabilization period of at least three hours during which the conditions are met is recommended before calibrations are carried out.

(2) Without continuous control of environmental conditions, it is possible that unusual ambient conditions may invalidate some of the calibration reports on the reference standards or on the reference instruments, or even damage the instruments. As a guideline, the conditions during uncontrolled storage should not exceed limits of 5ºC to 35ºC for temperature or 5% to 70% for relative humidity without special protection.

(3) When the suggested environmental conditions cannot be established, the calibration report must include an appropriate allowance for the uncertainties introduced by the difficult conditions and the associated effects on the reference standards and instruments as well as on the instruments being calibrated.

TABLE I RECOMMENDED ENVIRONMENTAL CONDITIONS FOR TYPE I, II, AND III CALIBRATION LABORATORIES

LABORATORY TYPE	FIELD	TEMPERATURE (DEGREES CELCIUS) SET POINT AND LIMITS	TEMPERATURE (DEGREES CELCIUS) MAXIMUM RATE OF CHANGE (K/HOUR)[a]	RELATIVE HUMIDITY (%)	AIRBORNE PARTICLE COUNT[b]
I	MECHANICAL/ DIMENSIONAL	20 ± 1	0.5	30 - 55	50 000
I	ELECTRIC/ ELECTRONIC	23 ± 1	1.0	30 - 55	100 000
I	OTHER	The environmental conditions for other fields of measurements should be developed and assessed with respect to appropriate applicable influencing factors.			
II	MECHANICAL/ DIMENSIONAL	20 ± 2	1.0	30 - 55	150 000
II	ELECTRIC/ ELECTRONIC	23 ± 2	1.5	30 - 55	250 000[c]
II	OTHER	The environmental conditions for other fields of measurements should be developed and assessed with respect to appropriate applicable influencing factors.			
III	GENERAL	Range of 18 - 28 with preferred setpoint of 23	1.5 (1.0 - for Mechanical/ Dimensional)	10 - 60	**d**

a Certain measurement or comparison equipment may require more stringent control.
b Measured in accordance with U.S. Federal Standard No. 209, "*Clean Room and Work Station Requirements, Controlled Environment*".
c There should be no accumulation of particles on or under benches, cabinets, equipment, instrumentation, etc.
d Careful housekeeping with no accumulation of particles on or under benches, cabinets, equipment, instrumentation, etc.

6.0 Documentary and Operational Protocols

6.1 Quality Control System

The laboratory should establish and maintain an effective quality control system that will include documentation of quality control procedures, work instructions, calibration procedures and records.

6.2 Traceability of Measurements

Reference standards of measurement, reference materials, and all measurements made by the laboratory should be traceable to appropriate designated standards.

6.3 Uncertainty List

The uncertainty list of the measurements made in the laboratory should be related to appropriate designated standards and kept up to date for all measurement processes undertaken. The component uncertainties in the list should be combined in an appropriate way to arrive at an estimate of the total uncertainty. The method of combining these uncertainties should be recorded. See CLAS Requirements Document 5 *General Guidelines for Evaluating and Expressing the Uncertainty of Measurement Results*.

6.4 Measurement Process Control

Each measurement process should have available adequate supporting data to demonstrate a state of control, e.g. through techniques such as Statistical Process Control (SPC), using check standards, or other means.

6.5 Calibration System

The laboratory should implement and maintain a suitable calibration system. Procedures should be available for the calibration of test equipment and measurement standards, with appropriate analysis of the uncertainties introduced by the calibration procedures.

6.6 Calibration Records

A separate record should be maintained for each in-house standard and item of test equipment. These records should be retained for the life of the equipment and should include the following information:

(a) Description of equipment and unique identification.
(b) Date received and placed in service.
(c) Condition when received (new, used, reconditioned).
(d) Current location, if appropriate.
(e) Copy of the manufacturer's instructions, where available.
(f) Dates on which the standards and calibration equipment were calibrated and, if in-house, the identity of personnel performing the calibration(s).
(g) Calibration interval.
(h) Calibration results and, for measurement standards, the data obtained.
(i) Designated limits on the ranges or functions of the equipment.
(j) Source of calibration.
(k) The environmental conditions during the calibration.
(l) A statement of the cumulative uncertainties in the data obtained in the calibration.
(m) Details of any maintenance (servicing, adjustment, repairs) or modifications, malfunctions, or damage that could have affected the calibration status.
(n) Any limitations in use.
(o) Reference to calibration procedure(s) used, when done in-house.

6.7 Client Reports

Although certificates of conformity to manufacturer or other organization specifications (e.g. ASTM) are frequently provided to clients, calibration certificates with actual measured values or correction factors are the most meaningful and are preferred.

Reports and original test data should be retained for five years or five calibration intervals, whichever is longer, and made available when requested for review by the client or by a calibration laboratory accrediting agency. See CLAS Requirements Document 6 *Requirements for Calibration Certificates issued by CLAS Laboratories* for additional requirements related to calibration reports and certificates.

6.8 Intervals of Calibration

Test equipment and measurement standards should be calibrated at periodic intervals established and maintained to assure acceptable measurement uncertainty and reliability. Intervals should be shortened or may be lengthened when the results of previous calibrations indicate such action is necessary or sufficient to maintain acceptable reliability. ISO 10012-1 Annex A and NCSLI RP-1 *Establishment and Adjustment of Calibration Intervals* contain guidelines for the determination of calibration intervals for measuring equipment.

Reliability means the probability of equipment remaining in tolerance during the calibration interval, and for standards, the probability of the assigned value of the standard not changing by more than the list of uncertainties. In the client's laboratory, the list of uncertainties should include any uncertainty associated with drift rate. The procedure for assigning calibration intervals and adjusting them should be fully documented. The laboratory should have a fully-documented recall system for all its test equipment and standards to assure timely recalibrations. The recall system may allow temporary extension of the calibration due date for limited periods of time under specific conditions such as the completion of a test in progress.

6.9 Labelling and Calibration Status

Test equipment and measurement standards should be sealed for integrity using a tamper-proof seal, where possible. The test equipment and measurement standards should be labelled to indicate calibration status and function and should have on the seal, as a minimum, the name of the organization performing the calibration, the calibration date, the calibration due date, and the calibration status. When the client is from the same organization, a reference to who performed the calibration can be used to replace the name of the organization. The seal or a separate label should indicate the function of the equipment or measurement standard by using a code format or by spelling out the function. Acceptable function names include: Reference Standard, Transfer Standard, Travelling Standard, Check Standard, Test Equipment, and Measurement Equipment. Where a function code is used, it must be documented. For items that are too small or where it would be impractical to affix a label, then the label should be affixed to the container of the item, or some other suitable form of labelling should be used. The labelling procedure should be fully documented and the documentation should include instructions on disposition of items with broken seals. See also CLAS Requirements Document 4 *Requirements for Identifying Measurement Equipment and its Calibration Status*.

6.10 Labelling of Limitations of Use

Items of test equipment and measurement standards not calibrated to their full capability or which have other limitations of use should be labelled or otherwise identified as to the limitations. Limitation labels available should include:

(a) Limited Use - used when not all instrument parameters have been calibrated or when the instrument no longer meets all original specifications.

(b) No Calibration Required - indicates that the instrument to which it is attached does not require calibration.

(c) Calibrate on Demand - indicates that the instrument to which it is attached is not on a regular instrument-recall system and is calibrated only as and when required by the user.

(d) Invalidated Calibration - label acts as a visual identifier to prevent use of any instrument that has failed in operation; is past its calibration due date; is suspected of being, or known to be, outside its designated limits; or shows evidence of physical damage that might affect measurement accuracy.

7.0 Measurement Capabilities

The laboratory should maintain a listing of its capabilities including parameters, ranges, and uncertainties along with details of the measurement equipment to support these claims. Such listings are available as examples on the CLAS website. These are prepared and published by CLAS for all CLAS certified laboratories (see CLAS Directory of Accredited Calibration Laboratories).

8.0 Personnel

The laboratory should maintain a staff of sufficient size so as not to cause unnecessary delays in the service it provides to its customers. Staff members should possess, at a minimum, the training and skills necessary to perform their assigned duties. Training should be, at a minimum, a planned activity and “fit for purpose”. For example, if a technician is responsible for performing a statistical analysis of data collected during the calibration process, then he/she should possess the necessary skills to perform such an evaluation. These skills may be obtained from a variety of sources, such as formal education, formal training, on the job training, or any other suitable means. Some laboratories may also require their staff to demonstrate their competency by a variety of methods such as qualification testing, performance testing, ongoing proficiency audits, or review of results of laboratory proficiency tests.