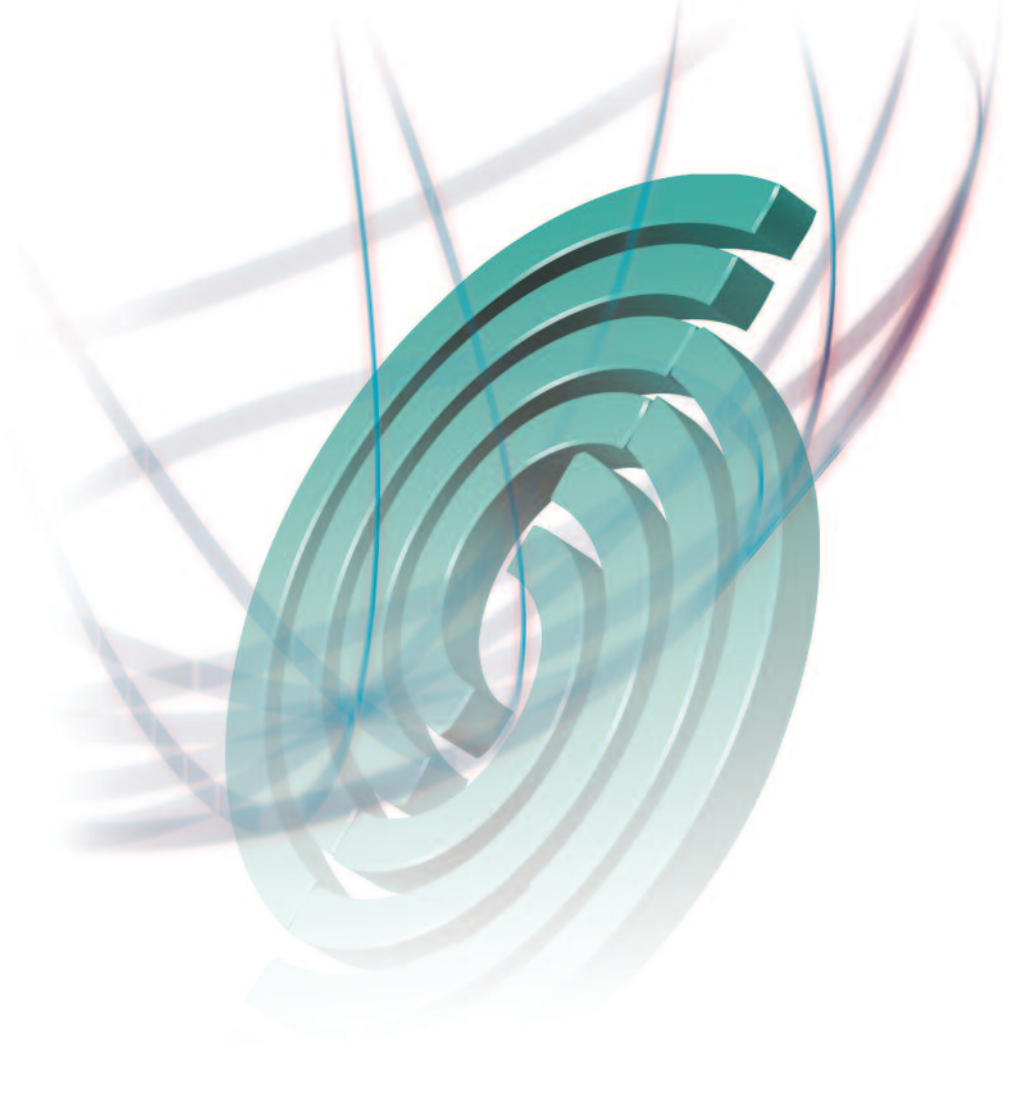




Standards Council of Canada  
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# Requirements for the Accreditation of Environmental Testing Laboratories

**CAN-P-1585**  
December 2008

Program Speciality Area – Environmental Testing (PSA-ET)



# **REQUIREMENTS FOR THE ACCREDITATION OF ENVIRONMENTAL TESTING LABORATORIES**

**PROGRAM SPECIALTY AREA - ENVIRONMENTAL TESTING  
(PSA-ET)**

## ***Exigences relatives à L'ACCRÉDITATION DES LABORATOIRES D'ANALYSE ENVIRONNEMENTALE***

***DOMAINES DE SPÉCIALITÉ DE PROGRAMME - ENVIRONNEMENT***

**CAN-P-1585  
December 2008**

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The following, issued separately from this document, are in integral part of these requirements:

CAN-P-1585 APPENDIX A - PSA-ET Directory of Acceptable Proficiency Testing Providers

CAN-P-1585 APPENDIX B - PSA-ET PT Cycle Summary Report

CAN-P-1585 APPENDIX C - Definitions for the PSA-ET Program

## **About the Standards Council of Canada**

The Standards Council of Canada (“SCC” or “the Council”) is a crown corporation established by an Act of Parliament in 1970, amended in 1996, to foster and promote efficient and effective voluntary standardization in Canada. It is independent of government in its policies and operations, although it is financed partially by Parliamentary appropriation. The SCC Governing Council consists of members from government and the private sectors.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public-private sector cooperation in relation to voluntary standardization in Canada, coordinate and oversee the efforts of the persons and organizations involved in the National Standards System, foster quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develop standards-related strategies and long-term objectives.

In essence, the Council promotes efficient and effective voluntary standardization in Canada in order to advance the national economy, support sustainable development, benefit the health, safety and welfare of workers and the public, assist and protect consumers, facilitate domestic and international trade and further international cooperation in relation to standardization.

The Council serves as the government’s focal point for voluntary standardization and represents Canada in international standardization activities, sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of standards development organizations, of product certification bodies, of testing and calibration laboratories, of quality and environmental management systems registration bodies and of quality management systems and environmental auditor certifiers and training course providers, and promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of multiple assessments and audits, both in Canada and with Canada’s trading partners.

This document is one of several issued by the Standards Council of Canada to define the policies, plans, and procedures established by the Council to help achieve its mandate.

Requests for clarification and recommendations for amendment of this document, or requests for additional copies should be addressed to the publisher directly.

## PREFACE

The Program Specialty Area – Environmental Testing (PSA-ET) program is operated and managed by the SCC through its Program for Accreditation of Laboratories - Canada (PALCAN). The assurance that an environmental testing laboratory adheres to recognized practices and standards can be achieved through accreditation in this program. Accreditation under the PSA-ET program is the formal recognition by the Standards Council of Canada of the competence of an environmental testing laboratory to perform a specific list of environmental tests in this Program Specialty Area (PSA). It is not a guarantee that test results will conform to standards or agreements between a testing laboratory and its customers; business transactions between an accredited testing laboratory and its customers are legal matters between the two parties.

Environmental testing includes the measurement of biological, chemical, physical, or toxicological characteristics of either the receiving environment or discharges to the receiving environment, and includes as appropriate, biological, chemical and physical fields of testing.

The Task Group Laboratories (TG Labs) is constituted by and reports to the Advisory Committee on Conformity Assessment (ACCA). The TG Labs is responsible for applications for accreditation from laboratories, assessments of applicant laboratories and reassessments of accredited laboratories and making recommendations, as required, to the ACCA and the Council.

The specific requirements for environmental testing laboratories in these requirements were developed through the Environmental Testing Working Group (ETWG) that is constituted by and reports to the TG Labs. The technical basis is drawn from published principles, practices and procedures used or promoted by national and international organizations.

This document was designed to meet International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Standard 17025 requirements. Rather than serving as a "stand alone" document, it was designed to harmonize with and complement the SCC document CAN-P-4E (ISO/IEC 17025:2005), "*General Requirements for the Accreditation of Testing and Calibration Laboratories*", which is ISO/IEC 17025:2005 verbatim, and to follow the standard SCC assessment protocol. These requirements are also based on the ISO/IEC Guide 43-1:1997(E), "*Proficiency Testing by Interlaboratory Comparisons - Part 1: Development and Operation of Proficiency Testing Schemes*" and the other SCC, International Laboratory Accreditation Cooperation (ILAC), Asia Pacific Laboratory Accreditation Cooperation (APLAC) and ISO documents and references.

Accreditation by the SCC requires an on-site assessment of the laboratory to demonstrate competence and conformance with the requirements of CAN-P-4E as well as prior and continued participation and satisfactory performance in acceptable proficiency testing program(s) for each test accredited, where applicable, as outlined in this document.

The scope of these requirements will be evaluated periodically to respond to customer, laboratory and accreditation requirements, as well as improvements in the available science and technology or regulatory changes.

This Preface is not an integral part of this document.

## INTRODUCTION

The general requirements for the competence of testing and calibration laboratories are described in CAN-P-4E (ISO/IEC 17025:2005). These requirements are designed to apply to all types of calibration and objective testing and therefore need to be interpreted with respect to the type of calibration and testing concerned and the techniques involved. CAN-P-1510E (Assessment Rating Guide) is the tool used to assess conformance to requirements in CAN-P-4E. The SCC policy documents (CAN-P-1630, CAN-P-1570, etc.) also apply.

This PSA-ET document provides an elaboration, interpretation and additional requirements to those requirements in CAN-P-4E that are required for laboratories involved in performing environmental testing analysis. It is expected that where no elaborations, interpretations or additional requirements are stipulated in this document for the elements of the standard, that the SCC PALCAN Policy documents (CAN-P-1630, CAN-P-1570, etc.) and best scientific practices in the area of environmental testing will guide the assessment process.

The program is designed to ensure environmental testing laboratories meet minimum quality and reliability standards and to ensure a demonstrated uniform level of proficiency among these environmental testing laboratories. This document identifies the minimum requirements for accreditation of laboratories supplying environmental testing services. This includes, but is not limited to, the measurement of biological, chemical, physical, or toxicological characteristics of either the receiving environment or discharges to the receiving environment, and includes as appropriate, biological, chemical and physical fields of testing on the environmental surroundings (air, water, soil, flora and fauna) and waste (gaseous, liquid and solid) samples.

This document does not re-state all the provisions of CAN-P-4E and laboratories are reminded of the need to comply with all of the relevant criteria detailed in CAN-P-4E and the current edition of the CAN-P-1570 *"PALCAN Handbook"*. The main clause numbers in this document generally follow those of CAN-P-4E but since not all clauses require interpretation the numbering of clauses may not be continuous. Clause 6, the specific requirements for the evaluation of laboratory performance by proficiency testing, is unique to this document.

To obtain initial accreditation by SCC under the PSA-ET program, a laboratory shall successfully complete both a proficiency testing regimen and an on-site assessment by technical specialists. The assessments will be conducted using standard SCC assessment protocols such that:

- a comprehensive on-site assessment of the program will occur every two years; and
- surveillance questionnaires, including evaluation of the laboratory's quality manual and proficiency testing results, will be conducted in the intervening years.

For the initial assessment, the applicant shall complete and return the CAN-P-1570 Appendix A *"Application for Accreditation"* document as outlined in CAN-P-1570 *"PALCAN Handbook"* as well as placing in the right hand column of the *"Assessment Rating Guide"* (CAN-P-1510E) the appropriate references to their Quality System (QS) Quality Manual, any other Quality System documents and Standard Operating Procedures (SOP). Any requested copies of their specific SOPs or other documents shall be supplied at least two weeks prior to the on-site assessment visit. For every scope extension and/or re-assessment visit, the applicant shall follow the processes as



outlined in the CAN-P-1570 “*PALCAN Handbook*” including providing a completed “*Assessment Rating Guide*”, placing in the right hand column all the appropriate references to their QS Manual, any other Quality System documents and SOP’s as well as supplying any requested SOP or other document at least two weeks prior to the on-site re-assessment visit.

This PSA employs designated technical assessors, including those from provincial/federal regulatory agencies, for the assessment of the participating laboratories. These technical assessors have committed to adhere to the standard SCC assessment protocols and rules of confidentiality; however, they may be required by law to report to their own regulatory agency any contravention of the acts and regulations they are duty-bound to enforce.

Accreditation under the PSA-ET specific requirements is the formal recognition by SCC of the competence of an environmental testing laboratory to manage and perform this type of activity. It is not a guarantee that test results will conform to standards or agreements between a testing laboratory and its customers. Business transactions between an accredited testing laboratory and its customers are legal matters between the two parties.

Laboratories are also reminded of the need to comply with any relevant statutory or legislative requirements applicable to the jurisdiction in which they operate. With respect to health and safety legislation, this normally requires the establishment of a health and safety committee, or if the laboratory is small, an employee with responsibility for overall safety, as per Section 1.5 of CAN-P-4E.

This document has been approved by the Task Group Laboratories Environmental Testing Working Group (TG Labs ETWG), by the Task Group Laboratories (TG Labs) and the Advisory Committee on Conformity Assessment (ACCA) of the SCC.

## GENERAL AND ADDITIONAL REQUIREMENTS

Laboratories accredited through PALCAN shall meet all requirements in the international standard CAN-P-4E (ISO/IEC 17025:2005) *"General Requirements for the Competence of Testing and Calibration Laboratories"*, these PSA-ET requirements and Appendices to these requirements to qualify for the SCC Program Specialty Area - Environmental Testing accreditation. Environmental testing laboratories that do not meet these CAN-P-1585 requirements for their environmental tests will not be accredited by SCC for those environmental tests. The checklist that is used to assess the management and technical requirements of CAN-P-4E and these PSA requirements is the latest version of CAN-P-1510E, *"Assessment Rating Guide"*. The requirements of CAN-P-15 (*"Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings"*) also apply to all SCC accredited laboratories. For information on application and terms and conditions of accreditation, refer to the current edition of the SCC CAN-P-1570 *"PALCAN HANDBOOK Program Requirements for Applicant and Accredited Laboratories"*. If an accredited testing laboratory cannot maintain these requirements, it shall cease any publicity referring to the accredited status for the analysis of environmental materials, and inform the SCC in writing within five days. See the termination and withdrawal procedure in the current version of CAN-P-15.

All laboratories shall also meet all the pertinent provisions of the most recent editions of the SCC PALCAN Policy documents (CAN-P-16xx) defined in the normative references.

### 1 SCOPE

The PSA-ET program for environmental testing laboratories applies to all tests associated with the measurement of chemical, radio-chemical, biological, microbiological or toxicological and related physical characteristics of environmental samples (i.e., waste materials, air, water, soil, biological tissue, etc.).

Proficiency testing (including interlaboratory comparisons [ILCs]) is a demonstration of the ability of the laboratory to produce credible results. It is one of the important tools used by laboratories and accreditation bodies for monitoring test results and for verifying the accreditation process itself. The SCC Policy for participation in proficiency testing schemes is to comply with the general minimum proficiency testing requirements outlined in the ILAC P9:2005 *"ILAC Policy for Participation in National and International Proficiency Testing Activities"* as well as the more specific proficiency testing benchmark participation frequency guidelines for all its accredited environmental laboratories of two (2) proficiency testing rounds/year for the environmental sub-discipline as outlined in the APLAC PT 006:2008 *"Proficiency Testing Frequency Guidelines"*.

The SCC also complies with the responsibilities of an accreditation body for APLAC testing interlaboratory comparisons outlined in the APLAC PT 002:2008 *"Testing Interlaboratory Comparisons"*.

Accreditation in this PSA-ET program requires ongoing continued participation and demonstrated satisfactory performance in acceptable proficiency testing schemes(s) for each test accredited, where applicable. Proficiency testing requirements specified in clause 6 of this document shall apply to all testing under this PSA.

Applicant and accredited laboratories shall identify to the SCC the specific environmental testing proficiency testing provider(s) and their specific proficiency testing scheme(s) they shall employ for the accredited environmental tests and associated specific measurands in this PSA-ET program. The laboratory shall obtain specific SCC approval of the proficiency testing provider(s) and their specific proficiency testing scheme (s) for their accredited scope accordingly prior to using them for their specific accredited environmental tests under this PSA. The SCC will maintain a CAN-P-1585 Appendix A (*“PSA-ET Directory of Acceptable PT Providers”*) containing specific SCC acceptable proficiency testing providers and their specific proficiency testing scheme(s) for this PSA-ET program. Only specific SCC acceptable proficiency testing providers and their specific proficiency testing scheme(s) shall be employed for this PSA-ET program. This CAN-P-1585 Appendix A does not imply endorsement by SCC or its ETWG of any specific proficiency testing provider listed in this Appendix.

Multi-measurand methods can be included in the scope even if not all of the measurands are included in a proficiency testing scheme(s). Not all of the measurands may be included in a specific proficiency testing providers’ test group. However, if the measurand is available from any SCC acceptable proficiency testing provider then the laboratory will be required to participate in proficiency testing rounds from more than one proficiency testing providers, if necessary, to cover all the measurands in the multi-measurand method(s) in their scope.

There is also recognition that some testing is not conducive to a formalized proficiency testing scheme and, therefore, other mechanisms, such as in-house proficiency programs, blind splits, ILCs etc., shall be used to evaluate the laboratory performance.

Specifically for Ontario environmental laboratories accredited under the SCC-MOE (Ministry of Environment) accreditation agreement for the conduct of specific drinking water tests in Ontario, as required by the Act and Ontario Regulation 248/03 (Drinking-Water Testing Services) (*“Regulation 248”*). The SCC shall also base its recommendation for a laboratories’ accreditation to the MOE on a testing standard or standards prescribed by regulation under the Act, including the Protocol of Accepted Drinking-Water Testing Methods dated January 2008, as amended and incorporated by reference by Regulation 248.

## **2 NORMATIVE REFERENCES**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CAN-P-4E (ISO/IEC 17025:2005), General Requirements for the Competence of Testing and Calibration Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-15, March 2000, Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P- 43 (ISO/IEC Guide 43:1997), November 2001, Proficiency Testing by Interlaboratory Comparisons. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1510E, Assessment Rating Guide. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1570 PALCAN Handbook, Program Requirements for Applicant and Accredited Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1623, PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing (APLAC T005). Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1624, PALCAN Policy on the Use of Proficiency Testing as a Tool for Accreditation in Testing (ILAC G22:2004). Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1625, Policy on Guidelines and Procedures for Laboratories with Serious and Critical Non-Conformities. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1626, PALCAN Policy on Traceability Requirements for Calibration Sources Used by Accredited Testing Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1627, PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1628, PALCAN Policy on the Use of Information Technology in Accredited Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1629, PALCAN Guidance for the Validation of Test Methods. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1630, PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories. Standards Council of Canada, Ottawa, Ontario, Canada.

CAN-P-1631, PALCAN Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status (ILAC G14:2000). Standards Council of Canada, Ottawa, Ontario, Canada.

ILAC P9:2005, ILAC Policy for Participation in National and International Proficiency Testing Activities.

APLAC PT 002:2008, Testing Interlaboratory Comparisons.

APLAC PT 006:2008, Proficiency Testing Frequency Guidelines.

(VIM) 3<sup>rd</sup> ed.:2007, International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM) (ISO/IEC Guide 99, First edition 2007).

### 3 TERMS AND DEFINITIONS

All definitions in CAN-P-4E, and VIM 3<sup>rd</sup> ed. [e.g. laboratory, testing laboratory, calibration laboratory, calibration, test, calibration method, test method, verification, quality system, quality manual, reference standard, reference material, certified reference material, traceability, proficiency testing, (accreditation) requirements] and those applicable from ISO/IEC Guide 43-1, ISO 9000 [e.g. quality assurance, quality control] apply. Some of these definitions are reproduced for convenience in the document CAN-P-1585 Appendix C (*“Definitions for the PSA-ET Program”*)

**To ensure clarity and consistency, for the purposes of this PSA-ET program the definitions in CAN-P-1585 Appendix C (*“Definitions for the PSA-ET Program”*) shall apply and shall be employed by all environmental testing laboratories accredited under this PSA.**

**NOTE:** there are new or revised definitions for many terms in VIM 3<sup>rd</sup> Ed. 2007. Laboratories shall update all their Quality System documents to reflect these revised definitions as defined in CAN-P-1585 Appendix C.

### 4 MANAGEMENT REQUIREMENTS

All the requirements in Section 4 of CAN-P-4E and all other relevant CAN-P series documents apply to all accredited laboratories. This section of these requirements is to be used in conjunction with the CAN-P-4E document. The intent of this section is to provide elaboration, interpretation, and additional requirements to some of the clauses of CAN-P-4E for which procedures specifically applicable to environmental testing will be used. **Some sub clause numbering will be unique to this section.** The following section numbers correspond directly to the clauses in CAN-P-4E.

#### 4.2 Quality system

4.2.5 Documentation shall be maintained and include or make reference to the following:

- All test methods and standard operating procedures
- Protocols for method development and validation
- Chain of custody
- Quality assurance, audit records (internal and external) and proficiency testing as applied to each scope of testing

### **4.3 Document control**

4.3.1 The laboratory shall establish and maintain policies and procedures to document the responsibility for all procedures performed (internal and external), how these procedures are monitored and when corrective actions are taken.

**NOTE:** see also CAN-P-1630 interpretative note.

### **4.6 Purchasing Services and Supplies**

4.6.2.1 New reagents and standards shall be verified against old ones or verified by other means (ex. CRM, analytical QC etc), and records maintained.

4.6.4.1 List and records of investigation of all approved suppliers shall include subcontractors.

### **4.13 Control of Records**

4.13.1 Technical records shall include reagent preparation logs. Reagent preparation logs shall include, as appropriate: supplier, grade, batch number; dates of preparation or verification; analyst preparing the reagent, measurement of weights, volumes, time intervals, temperatures and related calculations; relevant processes (e.g. pH adjustment, sterilization etc); verification results; and, discard or expiry date.

#### **4.13.2.1**

- a) The laboratory shall have documented procedures to ensure that it maintains a coordinated record keeping system for its technical records. The information that is to be included shall be documented and may include items such as records of telephone conversations, evidence receipts, descriptions of evidence packaging and seals, subpoenas, records of observations and test/examination results, reference to procedures used, diagrams, print-outs, photographs, etc. In general, the records required to support the technical data shall be such that in the absence of the analyst, another competent analyst could evaluate what had been performed and interpret the data.
- b) Where instrumental analyses are conducted, operating parameters shall be appropriately recorded.
- c) Where appropriate, all observations or test results shall be preserved. Electronic records, photocopies, tracings or hand-drawn facsimiles shall also be preserved (e.g. tape, CD or DVD backup of electronic files).
- d) When a test result or observation is rejected, the reason(s) shall be recorded.

- e) Test results, calculations and manual data transfers or electronic transfers, excluding those that form part of a validated electronic transfer process, shall be checked by at least a second person. The record shall include an indication when the results and any corrective actions needed were performed and when such checks have been carried out and by whom.
- f) Each document in the record shall be traceable to the analyst and where appropriate, to a uniquely identified laboratory number. It shall be clear from the record who has performed all stages of the analysis/examination and when each stage of the analysis/examination was performed (e.g. relevant date(s)).
- g) Laboratory generated examination records and reports shall be paginated using a page numbering system which indicates the total number of pages.
- h) The laboratory shall have documented policies and procedures for the review of records, including test reports.
- i) Where independent checks on non-conformances are carried out by other authorized personnel, the records shall indicate when each non-conformance has been checked and agreed and by whom the checks were performed. This may be indicated in a number of ways including entries against each finding, entry on a summary of findings etc.

#### **4.14 Internal Audits**

4.14.1 The SCC policy requires that internal audits shall be conducted at least on an annual basis. Every part of their quality system shall be audited annually (including a representative sampling of test methods); however, it is not necessary to audit each person or each testing /measurement procedure, or to audit every aspect at one time.

#### **4.15 Management Reviews**

4.15.1 The SCC policy requires that management reviews shall be conducted at least annually even though the wording of the standard might appear to allow for a longer periodicity. Management reviews are often a series of events/meetings that percolate upwards.

### **5 TECHNICAL REQUIREMENTS**

All the requirements in Section 5 of CAN-P-4E and all other relevant CAN-P-series documents apply to all accredited laboratories. This section of these requirements is to be used in conjunction with the CAN-P-4E document. The intent of this section is to provide elaboration, interpretation, and additional requirements to some clauses of CAN-P-4E for which procedures specifically applicable to environmental testing will be used. The following section numbers correspond directly to the clauses in CAN-P-4E. **Some sub clause numbering will be unique to this section.**

## 5.2 Personnel

5.2.1 The laboratory shall have a defined policy that ensures that all staff working in the laboratory is competent to perform the work required. The term ‘competent’ implies demonstrating the requisite knowledge, skills and abilities to perform the job. The laboratory’s policy shall also include procedures for documenting training, retraining and maintenance of skills, expertise and demonstrated competence.

Where test or technique specific training is given, acceptance criteria shall be assigned e.g. observation of the relevant tests or analyses by an experienced officer, satisfactory performance in the analysis of quality control/quality assurance samples, correlation of results with those obtained by other trained staff. The appropriate sign off shall be recorded.

Qualifications generally required in an environmental testing laboratory are as follows:

- key supervisors: appropriate degree, diploma, or equivalent and at least 3 years laboratory experience
- analysts: appropriate technical diploma or equivalent and variable years laboratory experience depending on technical complexity of duties, which is relevant to the test(s) being accredited

5.2.2 The laboratory shall maintain personnel training and qualification records and certificates.

In addition to the above criterion, some provinces may have additional legislated requirements. The Quality Manual or other QS documents shall reflect these requirements.

5.2.5 A laboratory shall have clear statements of the competencies required for all jobs and records shall be maintained to demonstrate that all staff is competent for the jobs they are asked to perform.

Records of demonstrated competence are analogous to documented evidence of analyst proficiency.

Laboratories shall have a formal policy of cross training staff so that each task can be assigned to a second staff member should the primary staff to which the task has been assigned be unable to perform their duties.

Each laboratory or section shall maintain an up-to-date record of the training that each member of staff has received. These records shall include academic and professional qualifications, external or internal courses attended and relevant training (and retraining, where necessary) received whilst working in the laboratory.

Records shall be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability and demonstrated competence to perform these tests has been formally assessed.



### 5.3 Accommodation and Environmental Conditions

5.3.1 Accommodations and environmental conditions will depend on the type and volume of work being performed, and may include (as required):

- adequate lighting at work areas
- controlled photoperiods of adequate quality and intensity in specific laboratory areas as required
- adequate power
- sufficient appropriately grounded outlets which are free of surges and have voltage regulators in use
- back-up emergency power supply available
- sufficient sinks with hot and cold running water
- suitable reagent water supply
- dilution water supply (marine or fresh water) suitable for use in toxicity testing and culturing test organisms; incorporate suitable piping with dechlorination and filtration as required
- air supply free of dust, fumes and oil and suitable for sample aeration and/or purging
- vacuum source is able to maintain sufficient vacuum
- bench tops are adequate
- adequate bench space
- adequate floor area
- temperature is controlled in specific laboratory areas as required
- humidity control in specific laboratory areas as required
- appropriate air quality in specific laboratory areas as required (e.g. biological sterility); otherwise ensure the laboratory is well ventilated (once through ventilation, where appropriate) and free of dust and/or fumes
- sufficient fume hoods, able to maintain appropriate face velocity
- appropriate refrigerated storage, including freezer storage, available for samples and other materials
- measures to avoid cross contamination in areas in which trace levels of environmental contaminants are evaluated and analyzed

5.3.2 The laboratory shall have procedures for monitoring, controlling and recording environmental conditions where applicable, such as:

- acceptable lighting
- replenishment of consumables used in reagent water and/or dilution water treatment
- water quality characteristics as required, especially conductivity on a daily or as used basis and corrective actions taken for non-conformance
- temperature
- humidity
- storage temperatures and corrective actions taken for non-conformance

5.3.4 Access to the operational area of the laboratory (including the office and areas where records are stored) shall be controllable and limited. Visitors shall not have unrestricted access to the operational areas of the laboratory. A record shall be retained of all visitors to the operational areas of the laboratory.

5.3.5 Procedures shall be in place to ensure that the use of materials used in cleaning and/or pest control do not cause interference with testing.

## 5.4 Test Methods and Method Validation

5.4.1 All methods shall be fully documented including procedures for quality control (which includes the use of reference materials).

5.4.2 a) All laboratory developed methods or methods adopted by the environmental testing laboratory shall be fully validated or verified by the laboratory for “fitness of purpose” before being used on customer samples. This validation or verification shall be fully documented by the appropriate procedures as defined in CAN-P-1629.

b) Where a laboratory introduces a new validated or verified method, it shall first demonstrate the ability to adequately perform the method against any documented performance characteristics of that procedure. All method validation and verification records shall be maintained for future reference.

c) Laboratories shall institute a procedure to identify infrequently performed tests or analyses (i.e. where the test is not performed for > 6 months). For these tests or analyses, there are methods of demonstrating competence. These include but are not limited to the following:

- i) regular analysis of control samples and use of control charts even when ‘real’ samples are not being analyzed
- ii) before the test or analysis in question is performed on a real sample re-verification involving at least the use of an appropriate reference material, followed by replicate testing or analysis of the real sample
- iii) continued demonstrated satisfactory performance in a proficiency testing scheme(s)

d) The quality of standard materials and reagents shall be adequate for the procedure used. Lot/batch numbers of standard materials and critical reagents shall be recorded. All critical reagents shall be tested for their reliability. The reagent preparation logbook shall record the identity of the preparer. Standard materials and reagents shall be labelled with:

- name
- concentration, where appropriate
- received date as well as preparation date and expiry date (if necessary)
- storage conditions, if relevant
- hazard warning, where necessary

**NOTE:** see also CAN-P-1630 interpretative note.

## 5.4.5 Validation of Methods

**NOTE:** The Eurachem Guide “*Fitness for Purpose of Analytical Methods - A Laboratory Guide to Method Validation and Related Topics*” document is a very valuable resource for method validations. In addition to using that guide, the following are additional requirements to ensure all elements are considered in validating methods.

5.4.5.2 All technical procedures and laboratory methods used by an environmental testing laboratory for measurand determinations, whether modified even slightly or applied outside its intended scope (i.e. applied to another matrix) from national/ international methods (5.4.2) or in-house methods (5.4.3, 5.4.4) shall be validated by the laboratory for “fitness of purpose” prior to implementation. This validation shall be fully documented by the appropriate procedures and at a minimum meet the requirements in CAN-P-1629.

Methods may be validated or verified by comparison with other established methods using certified reference materials (where available) or materials of known characteristics.

In validating quantitative test methods, the following issues (among others) shall be documented, as appropriate:

- matrix effects
- sample homogeneity
- specificity
- sensitivity
- detection limit
- limit of quantitation
- accuracy
- repeatability
- robustness
- bias
- intra laboratory variations
- analysis of reference materials
- interferences
- concentration ranges
- long term stability of measured compounds
- cross sensitivity
- reporting limit
- linearity range
- precision (including intermediate precision)
- reproducibility
- trueness
- measurement of uncertainty
- inter laboratory variations
- recovery studies

In validating qualitative test methods, the following issues (among others) shall be documented, as appropriate:

- matrix effects
- sample homogeneity
- specificity
- inclusively
- contaminated controls
- specificity
- artificially contaminated samples
- false negative rate
- detection limit
- repeatability
- robustness
- intra laboratory variations
- interferences
- cross sensitivity
- sensitivity
- exclusivity
- inoculating cultures
- sensitivity
- naturally contaminated samples
- false positive rate
- reporting limit
- reproducibility
- measurement of uncertainty
- inter laboratory variations

- analysis of reference cultures
- inter laboratory collaborative study
- pre collaborative study
- sensitivity

- a) Evidence of measurand determinations, its separation from interfering substances (cross sensitivity), and the applicability of the method for measuring the measurand in the particular matrix, consistent with the required reporting limits, shall be demonstrated. Methodology shall also provide documented acceptable accuracy and precision.
- b) The validation of a method is only applicable to the methodology as written and any variation in procedure, analyst, instrumentation (ex addition of a new instrument) or application is subject to revalidation or re-verification. A number of techniques may be used for determining trueness, a part of method validation, including comparison with a recognized method, the analysis of a certified reference material (CRM), comparison of results with a second laboratory or another reliable demonstration of method validity as might be available.

**NOTE:** Changes in conditions that have been shown through ruggedness testing to not have a significant effect on the results of a method (e.g. different operator or instrument) can be made without having to revalidate a method. Those specific conditions shall be clearly identified in the method.

- c) The extent of validation or verification data required prior to using a method routinely will depend on the type and the purpose of the method and the performance related documentation already available for the particular method. All requirements shall be documented in the Quality Manual, individual method or covered in a specific laboratory SOP and at a minimum meet the requirements in CAN-P-1629.
- d) For most methods used in the environmental testing laboratory, the absence of significant interferences (cross sensitivity) shall be demonstrated by running matrix and reagent blanks during the validation process, if applicable.
- e) If CRM analyses suggest a bias then the laboratory shall check all steps to isolate the problem and take corrective action.
- f) During the validation or verification of a method the analytical range is assessed by using calibration standards covering at least the minimum range of expected sample results but preferably encompassing the orders of magnitude characteristic of the instrument. The sensitivity of the method, defined as the detector response per unit measurand concentration, is given by the slope of the calibration curve. Examination of this calibration curve will demonstrate the number and concentrations of the standards acceptable for routine analysis. Acceptability will depend upon linearity and intercept values as well as the overall shape of the calibration curve (or in the case of LC-MS-MS analyses, the value of a couple of coefficients from the quadratic equations from the calibration).

All technical procedures and laboratory methods used by an environmental testing laboratory for measurand determinations, once validated or verified, shall have the following prior to implementation:

- i. formal, complete, approved “**Method Validation Summary Report**” document (however named). This Method Validation Summary Report document shall include a clear definition of the method/purpose. It shall also contain a clear list of the method validation definitions and, at a minimum, all the summary data for the appropriate or pertinent items in above. It shall also contain a statement signed by the appropriate technical staff that this laboratory method is “fit for purpose” prior to implementation.
- ii. All resulting values obtained from the method validation or verification data shall be clearly reflected (listed) in the specific analytical method documentation.
- iii. The Quality Control for a particular analysis shall be based on the method validation data (Eurachem Guide Section 8.).

All technical procedures and laboratory methods used by an environmental testing laboratory for measurand determinations, once validated or verified, shall be periodically reviewed (at least once every two years) to confirm the ongoing “fitness for purpose” of that procedure or method.

#### 5.4.5.3

- a) The detection limit (LOD) is the lowest concentration of measurand in a real sample matrix that can be reliably detected using a specific analytical procedure (test method) which is statistically different from the response obtained from a reagent blank carried through the complete method. When repeated analyses of reagent blanks show a positive response for the measurand, the LOD is defined as:  $LOD = S_b + 3 \text{ S.D.}$  where  $S_b$  is the average signal for the reagent blanks and S.D. is the standard deviation of the blanks. If the reagent blanks do not show a positive response for the measurand, the S.D. is obtained from replicate analysis ( $n=7$  or more) of a typical sample spiked at a level within 2 to 3 times the estimated LOD.
- b) The continuing improvement in technology has made available methodology that can measure smaller and smaller element concentrations in different samples. However, the detection of very low levels may not always be essential and it may be acceptable in some circumstances to define a "practical" reporting limit based on customer requirements and the proposed use of the analytical data. This would have the advantage of reducing the technical difficulty of obtaining data and of reducing costs.

### 5.4.6 Estimation of uncertainty of measurement

5.4.6 Laboratories shall demonstrate implemented use of adequate procedures consistent with GUM (and its’ supplemental document ISO/IEC Guide 98-1) as well as the CITAC/Eurachem Guide CG4 (QUAM: 2000) for estimation of the uncertainty of measurement associated with all accredited tests.

Irrespective of the type of testing, the laboratory shall identify the significant components of measurement uncertainty.

For quantitative tests, numerical estimates are expected for those tests which produce numerical results. At a minimum, this shall include the calculations for standard uncertainty, combined standard uncertainty and expanded uncertainty (normally at a coverage factor of  $k=2$ ).

**NOTE:** The definitions for standard uncertainty, combined standard uncertainty and expanded uncertainty shall be those defined in VIM 3rd Ed: 2007 (which are the definitions employed by GUM and QUAM). Refer to CAN-P-1585 Appendix C.

For qualitative tests the laboratory shall identify and control major sources of uncertainty.

## 5.6 Measurement Traceability

All the requirements for traditional measuring and testing equipment, where applicable, shall be met. The equipment shall receive adequate calibration and have valid measurement traceability on critical equipment as defined in CAN-P-1626.

**NOTE:** see also CAN-P-1626 note 4.2 for the definition for critical equipment.

5.6.1 Individual calibration programs shall be documented and controlled for the specific requirements of the testing or analytical work being carried out. It will normally be necessary to check instrument calibration after any shut down, whether deliberate or otherwise and following service or other substantial maintenance. In general, calibration intervals should not be less stringent than manufacturers' recommendations.

5.6.2 Items that laboratories need to consider ensuring conformance to measurement traceability shall include the following:

- the availability of Class S or Class 1 weights used for balance calibrations; laboratories shall have traceability for the item in its possession
- the accuracy of volumetric measurements by using Class A glassware, where appropriate
- the availability of a thermometer, traceable as per CAN-P-1626 used for calibrations; laboratories shall have traceability for the item in its possession
- certificates for certified weights and thermometers maintained on file
- certificates for reference materials, standards or reagents used in preparing reference materials or standards (e.g., certified reference materials and calibration standards) maintained on file

5.6.2.2.1 Method calibration procedures shall include, as appropriate: use of a reagent blank to establish a calibration baseline; use of equivalent standard/sample reagent background; use of an adequate number of standards; establishment of linearity and calculation of slope and/or RRF; use of a control standard to monitor calibration stability/accuracy; use of control charting; and, identification of calibration non-conformance criteria.

5.6.3 Reference and calibration materials or standards of stated purity shall be obtained from a reliable source as outlined in CAN-P-1626 and 1627. These materials or standards shall be traceable to national or international sources. If such materials or standards are not certified, the laboratory shall develop procedures for verifying their purity and identity as outlined in CAN-P-1627.

Reference and certified calibration materials or standards and their documentation shall be stored in such a way as to maintain their integrity and be labelled as to content, date received, date prepared or opened and expiration date. The reagent preparation logbook shall include the analyst's initials or name. These materials or standards shall be replaced at appropriate intervals depending upon stability and storage conditions. To maintain their traceability, they shall not be used after the expiry date specified by the supplier and they shall meet the conditions specified in CAN-P-1627. If these materials or standards have expired they may be used as QC material or in-house reference materials.

In-house reference materials may be made traceable to Certified Reference Materials by running them along side of each other and documenting the results providing the procedures in CAN-P-1626 and CAN-P-1627 are followed. This shall be repeated with a frequency that will be determined by the stability of the reference materials or standards. Acceptable uncertainty shall be documented in the Quality Manual, method documentation or SOP.

Documentation allowing all dilutions to be traced to the primary reference material or standards shall be maintained.

## **5.7 Sampling**

5.7 The laboratory shall monitor the reliability of its sampling of submitted samples to ensure any sub-sample taken is reliably and demonstrably representative of the original sample submitted. This shall be documented in the quality documentation and acceptable limits defined, controlled and maintained.

5.7.1 The laboratory shall provide the customer, where requested, with field supplies (e.g. sample bottles, filters, preservatives) and maintain appropriate records of field supplies provided or provide the customer with specifications for sampling.

## **5.8 Handling of Test and Calibration Items**

5.8.3 The laboratory shall ensure any abnormalities and deficiencies are recorded upon receipt of the sample. Abnormalities and deficiencies may include:

- damaged sample
- insufficient sample for analysis
- deficiencies related to field filtration, chemical preservation, sample container, temperature on arrival, exclusion of air, elapsed time subsequent to sampling

5.8.4 The laboratory shall have appropriate facilities and environmental conditions to protect the integrity of the sample once the sample is received at the laboratory.

The laboratory shall follow any customer or regulatory directives to ensure sample integrity is maintained.

## **5.9 Assuring the quality of tests and calibration results**

5.9 Accreditation by SCC in this PSA requires the laboratory to demonstrate competence with these requirements by continued participation and satisfactory performance in the proficiency testing scheme outlined in section 6 of this document, as well as other proficiency testing schemes as appropriate.

Unsatisfactory results shall be followed up with an investigation and if necessary corrective or preventive actions. See also CAN-P-1630.

5.9.1 Records of instrument calibration and performance parameters shall be maintained. The records shall clearly indicate the calibration data that is associated with the specific samples analyzed.

Appropriate quality control procedures shall include, but not be limited to:

- appropriate level of quality control effort (i.e., duplicate samples, duplicate analysis, replicate analysis, replicate tests, matrix duplicates, reference materials, measurand/surrogate spikes, method blanks, control cultures, and control samples)
- use of control charting and the analysis of these charts such that long term trends are detected
- identification of non-conformance in method performance
- participation in proficiency testing
- and/or analysis of independently prepared check samples

The laboratory shall review their control chart data for all measurands for the appropriateness of the established mean and SD at appropriate intervals (ex. 3-6 months depending on the number of data points) and update those values as appropriate.

5.9.2 Whenever possible in the quality control system, compliance with statistical control shall be monitored through techniques such as control charting such that long term trends are detectable. The results of quality control analyses (e.g. Control Reference Materials, duplicate samples, duplicate analysis, replicate analysis, replicate tests, matrix duplicates) are indicators of the performance of the analytical system and their interpretation depends partly on the concept of statistical control. Statistical control corresponds to stability of operation. Specifically, it implies that quality control results can be interpreted as arising from a normal population with mean  $\mu$  and variance  $\sigma^2$ .



The range of quality control activities expected to be incorporated into environmental testing protocols on a routine basis includes the use of:

- reference collections of previously analyzed samples or reference materials (matrix duplicates);
- certified reference materials and internally generated reference materials;
- positive and negative controls;
- control charting of reference material results;
- duplicate sampling and analysis;
- replicate analysis and tests;
- range control charting of duplicate sample and replicate analysis results;
- repeat testing;
- independent checks (verification) by other authorized personnel;
- independent checks on commercial calibration solutions;
- participation in proficiency testing schemes.

5.9.3 Every analytical batch shall be accompanied by quality control measures that demonstrate the analytical system control status (e.g. determinations on quality control samples, water quality, balance tolerances, furnace temperatures). The ISO 7870 and 7873 documents include information on the design and implementation of control charting.

5.9.4 Reagent blanks will be run with each set of samples and shall represent at least 10-20% of the samples analyzed. However, in instances where a large number of samples of a given commodity require analysis, the frequency of matrix blanks could be significantly reduced if, after analysing a number of samples, most (greater than 90%) are negative. Under these circumstances, the samples serve as adequate blanks.

5.9.5 Reagent quality shall be monitored. Reagents are to be purchased, where possible, from ISO 9001 certified suppliers that provide reagents of required quality. Laboratories shall test each lot or batch and compare the results to the previous analysis. Records are to be kept as to which samples are run using each batch.

5.9.6 Laboratory reagent grade water shall be tested, monitored, controlled and these results shall be documented. It is required that each data set collected shall be related to the appropriate water quality data for the period of time that the test certificates are required to meet traceability requirements.

## **5.10 Reporting the Results**

5.10.2 Results shall be reported, usually in a test report, and shall include all the information requested by the customer and necessary for the interpretation of the test result and all information required by the test method used.

The requirements for reporting test results to customers shall apply not only to hard copy reports but also electronic reporting of results by such methods as Excel spreadsheets, e-reporting, database files, web-based reporting etc.

Certificates of Analysis and/or test reports shall be signed by the authorized personnel as described

in the Quality Manual and other quality documents, where appropriate. Certificates of Analysis are often used for legal purposes. As such, information contained in these reports is directed by the appropriate laws of the land.

(b) The laboratory shall be able to track the location at which the test was carried out, if tests were carried out at different locations. The lab shall put this information on the test report. The location and identity of subcontractors does not need to be identified on the test report.

(e) The laboratory shall have the capability to provide the identification of the test method and shall place this information on the test report.

(g) The laboratory shall be able to trace the date of analysis and shall include it on a test report.

(i) Test reports shall contain the test result, with units. Appropriate significant digits shall be used in reported results.

(j) The test report shall include at least the name of the person authorizing the report. The actual signature of the person authorizing the report need not be on the report, but shall be maintained on file. An electronic signature is sufficient, provided that the laboratory has procedures in place to guard against improper use of the electronic signature.

5.10.2.1 Incorrect quantifications or identifications on any customer sample(s) are unacceptable. The laboratory is obliged to notify the customer and implement corrective action(s) as outlined in CAN-P-4E (ISO/IEC 17025:2005).

5.10.3 Test reports shall include information necessary for the interpretation of results, such as:

- flags when data is reported below the detection limit (or other specified limit)
- flags when a result is qualified due to a non-conformance related to test method variance, sample history, method performance, interference or data validation
- flags when there is no result due to damaged or insufficient sample
- maximum allowable concentrations or standards

5.10.6 Test reports shall identify tests that were subcontracted but laboratories are not required to identify the subcontractor on the test report.

## **6 EVALUATION OF LABORATORY PERFORMANCE BY PROFICIENCY TESTING**

All the requirements in CAN-P-4E and all other relevant CAN-P series documents apply to all accredited laboratories. This section contains the specific requirements for the evaluation of environmental testing laboratory performance by proficiency testing. It is unique to this document and it provides the elaboration, interpretation, and additional requirements for some of the clauses of CAN-P-4E for which proficiency testing requirements specifically applicable to environmental testing shall be applied.

The SCC Policy for participation in proficiency testing schemes is to comply with the general minimum proficiency testing requirements outlined in the ILAC P9:2005 “*ILAC Policy for*

*Participation in National and International Proficiency Testing Activities*” as well as the more specific proficiency testing benchmark participation frequency guidelines for all its accredited environmental laboratories of two (2) proficiency testing rounds/year for the environmental sub-discipline as outlined in the APLAC PT006:2008 “*Proficiency Testing Frequency Guidelines*”.

The SCC also complies with the responsibilities of an accreditation body for APLAC testing interlaboratory comparisons outlined in the APLAC PT002:2008 “*Testing Interlaboratory Comparisons*”.

## **6.1 General Criteria for Proficiency Testing**

6.1.1 Accreditation in this PSA-ET program requires ongoing continued participation and demonstrated satisfactory performance in acceptable proficiency testing scheme(s) for all environmental tests appearing in the laboratory’s Scope of Accreditation, where such proficiency testing scheme(s) exist.

It is recognized that for some specialized tests a formalized proficiency testing scheme may not exist and, therefore, other mechanisms, such as in-house proficiency programs, blind splits, Inter Laboratory Comparisons etc., shall be used to evaluate the laboratory performance.

6.1.2 All procedures associated with the handling and testing of proficiency testing samples (items) by the laboratory shall be carried out to the extent possible in a manner identical to routine method(s) of testing that applied to customer samples.

6.1.3 Laboratories shall analyze the proficiency testing samples using the test method listed in their Scope of Accreditation. If their scope contains more than one (1) accredited test method or analytical technique for the same measurand in any proficiency testing test group (e.g. zinc in water by FAAS and also ICP and/or ICP/MS) then each test shall have its own proficiency testing result.

6.1.4 Laboratories shall declare their test method detection limit for each measurand of every accredited test method employing the current version of CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document (refer to section 6.3.1.9).

6.1.5 If the proficiency testing sample concentration for any measurand falls below the test method detection limit the laboratory shall advise the proficiency testing coordinator for that specific measurand/test method in that specific proficiency testing sample (refer to section 6.3.2.3).

6.1.6 Laboratories shall, employing the current version of CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document, declare which “proficiency testing program” for each accredited test has been approved for by SCC (refer to sections 6.2.2, 6.2.3.1 a) and 6.2.4.1 a)).

## 6.2 Proficiency Testing Requirements

### 6.2.1 Prior to becoming accredited

A laboratory shall successfully complete two (2) proficiency testing rounds from an SCC acceptable proficiency testing provider(s) listed in CAN-P-1585 Appendix A. This shall cover all areas of environmental testing (e.g. inorganic, organic, toxicology, microbiology etc), sample matrix (e.g. drinking water, ground water, waste waters, sludge, soils, hazardous wastes, oil, pulp and paper, air filters, vegetation etc) and concentration range of the measurand appropriate for each test which accreditation is requested.

6.2.1.1 This requires participation as follows:

- a) each proficiency testing round contains sample sets consisting of a minimum of four (4) samples per test group offered. These sample sets shall have four (4) different concentrations spanning a predetermined concentration range that covers the concentration range of the accredited test requested and concentrations that are above the laboratory's declared detection limit for the measurand for at least three (3) of the four (4) samples.

**NOTE:**

- i) an acceptable proficiency testing scheme having generally equivalent frequency (e.g. 2 sample sets per round, 4 times per year) is acceptable provided over the course of a year the concentrations span a predetermined concentration range that covers the concentration range of the accredited test
  - ii) where specific environmental regulatory requirements stipulate additional proficiency testing requirements (e.g. more samples/set or higher frequency of proficiency testing rounds) those regulatory requirements shall be met to maintain accreditation
- b) there is a minimum of eight (8) proficiency testing samples per accredited test with concentrations that are above the laboratory's declared detection limit for the measurand for at least seven (7) of the eight (8) samples.

**NOTE:** The laboratory shall identify to the SCC circumstances where it is not possible to find an acceptable proficiency testing scheme which has seven (7) of the eight (8) proficiency testing samples for the year above its detection limit for the measurand. The SCC may give special consideration to these situations

- c) there is a minimum of 10 participants (i.e. "n"  $\geq$  10) reported results for that measurand in any particular proficiency testing round

**NOTE:** The laboratory shall identify to the SCC the very special circumstances where the specific test in a matrix is very specialized and it is not possible to find an acceptable proficiency testing scheme which has n  $\geq$  10 for that specific measurand in that particular matrix. The SCC may give special consideration to these situations

6.2.1.2 To pass a set of proficiency testing samples, analysis shall be completed and results reported within the time period specified by the proficiency testing coordinator after receipt of each proficiency testing round of samples by the laboratory.

6.2.1.3 A laboratory that fails the first set may be provided with a replacement set of four (4) samples [having different concentrations for the previous sets], after corrective action has been taken.

6.2.1.4 If the replacement set is not analyzed satisfactorily, further corrective action(s) shall be taken. The laboratory shall not request a third set of four (4) samples [having different concentrations for all previous sets] for at least 6 months.

**NOTE:** The SCC strongly suggests a thorough investigation of the root cause of these failures and the appropriate corrective action(s) be taken prior to requesting the third set of proficiency testing samples.

## **6.2.2 The “2 x 4 Proficiency Testing Program”**

**Once accredited**, in order to maintain accreditation, the laboratory shall maintain demonstrated satisfactory performance in acceptable proficiency testing scheme (s) covering all areas of environmental testing (e.g. inorganic, organic, toxicology, microbiology etc), sample matrix (e.g. drinking water, ground water, waste waters, sludge, soils, hazardous wastes, oil, pulp and paper, air filters, vegetation etc) and concentration range of the measurand(s) appropriate to each accredited test on their scope.

6.2.2.1 This requires participation in a “**2 x 4 proficiency testing program**” as follows:

- a) participation in a minimum of two (2) proficiency testing rounds annually for each accredited test from an SCC acceptable proficiency testing provider(s) listed in CAN-P-1585 Appendix A.
- b) each proficiency testing round contains sample sets consisting of a minimum of four (4) samples per test group offered. These sample sets shall have four (4) different concentrations spanning a predetermined concentration range that covers the concentration range of the accredited test and concentrations that are above the laboratory’s declared detection limit for the measurand for at least three (3) of the four (4) samples.

**NOTE:**

- i) an acceptable proficiency testing scheme having generally equivalent frequency (e.g. 2 sample sets per round, 4 times per year) is acceptable provided over the course of a year the concentrations span a predetermined concentration range that covers the concentration range of the accredited test
  - ii) where specific environmental regulatory requirements stipulate additional proficiency testing requirements (e.g. more samples/set or higher frequency of proficiency testing rounds) those regulatory requirements shall be met to maintain accreditation
- c) there is a minimum of eight (8) proficiency testing samples per year per accredited test with concentrations that are above the laboratory’s declared detection limit for the measurand for at least seven (7) of the eight (8) samples.

**NOTE:** The laboratory shall identify to the SCC circumstances where it is not possible to find an acceptable proficiency testing scheme which has seven (7) of the eight (8) proficiency testing samples for the year above its detection limit for the measurand. The SCC may give special consideration to these situations

d) there is a minimum of 10 participants (i.e. “n” ≥ 10) reported results for that measurand in any particular proficiency testing round.

**NOTE:** The laboratory shall identify to the SCC the very special circumstances where the specific test in a matrix is very specialized and it is not possible to find an acceptable proficiency testing scheme which has  $n \geq 10$  for that specific measurand in that particular matrix. The SCC may give special consideration to these situations.

6.2.2.2. To pass a set of proficiency testing samples, laboratories shall correctly report, for each accredited test, the measurand(s) result or identification along with the specific test method employed within the timelines outlined by the proficiency testing provider.

6.2.2.3 Proficiency testing results are due within the time period specified by the proficiency testing coordinator after receipt of proficiency testing samples by the laboratory. Laboratories not reporting results on time shall be subject to the suspension procedure described in sub-section 6.4 (Procedures for Unsatisfactory Laboratory Performance).

### **6.2.3 The “2 x 2 Performance Based Proficiency Testing Program”**

Accredited laboratories with a **two (2) year history** (i.e. 4 proficiency testing rounds under the “2 x 4 proficiency testing program” after accreditation) with demonstrated satisfactory performance results for each accredited test over that 2 year period are eligible for the **“2 x 2 performance based proficiency testing program”** for that specific accredited test.

6.2.3.1 This **“2 x 2 performance based proficiency testing program”** requires participation as follows:

- a) the laboratory shall, for each accredited test, seek and be granted prior approval from the SCC to convert to this program for that specific accredited test.
- b) participation in a minimum of two (2) proficiency testing rounds annually for each test approved for this program from an SCC acceptable proficiency testing provider(s) specifically approved for this performance based program as listed in CAN-P-1585 Appendix A.
- c) each proficiency testing round contains sample sets consisting of two (2) samples per test group offered. These sample sets shall have different concentrations for each measurand and concentrations that are above the laboratory’s declared detection limit for the measurand for all samples.
- d) there is a minimum of four (4) proficiency testing samples per year for each accredited test approved for this program. These sample sets over two (2) proficiency testing rounds shall have different concentrations spanning a predetermined concentration range that covers the concentration range of the accredited test and all proficiency testing samples shall be above the laboratory’s declared detection limit for the measurand for all four (4) proficiency testing samples.

**NOTE:**

i) an acceptable proficiency testing scheme having generally equivalent frequency (e.g. 1 sample set per round, 4 times per year) is acceptable provided over the course of a year the concentrations span a predetermined concentration range that covers the concentration range of the accredited test

ii) where specific environmental regulatory requirements stipulate additional proficiency testing requirements (e.g. more samples/set or higher frequency of proficiency testing rounds) those regulatory requirements shall be met to maintain accreditation

e) there is a minimum of 10 participants (i.e. “n” ≥ 10) reported results for that measurand in any particular proficiency testing round.

f) Failure to maintain satisfactory performance for any measurand on any original proficiency test round or a remedial test for that accredited test may result in SCC requiring the laboratory to return to the “2 x 4 proficiency testing program” outlined in 6.2.2 above for that accredited test.

6.2.3.2 To pass a set of proficiency testing samples, laboratories shall correctly report, for each accredited test, the measurand(s) result or identification along with the specific test method employed within the timelines outlined by the proficiency testing provider.

6.2.3.3 Proficiency testing results are due within the time period specified by the proficiency testing coordinator after receipt of proficiency testing samples by the laboratory. Laboratories not reporting results on time shall be subject to the suspension procedure described in sub-section 6.4 (Procedures for Unsatisfactory Laboratory Performance).

Laboratories required to revert to the “2 x 4 proficiency testing program” shall have demonstrated satisfactory performance for a minimum of two (2) proficiency testing rounds (i.e. 8 proficiency testing samples) for that accredited tests prior to being considered for reinstatement to this “2 x 2 performance based proficiency testing program”.

#### **6.2.4 Accredited Laboratories under OSDWA and other Accredited Laboratories**

6.2.4.1 Laboratories accredited by SCC under the Ontario Safe Drinking Water Act (OSDWA) shall be eligible for the “2 x 2 performance based proficiency testing program” outlined in 6.2.3 above.

a) the laboratory shall, for each accredited test, seek and be granted prior approval from the SCC to convert to this program for that specific accredited test.

- b) the laboratory meets the requirements of a **two (2) year history** (i.e. 4 proficiency testing rounds under the “2 x 4 proficiency testing program” after accreditation) of demonstrated satisfactory performance results for that accredited test over the past 2 year period.
- c) the laboratory provides detailed documentary evidence of demonstrated satisfactory performance for that accredited test to SCC for all four (4) proficiency testing rounds.

6.2.4.2 Laboratories currently assessed by another Accreditation Body under the APLAC MRA and wishing to become an SCC accredited environmental testing laboratory will be given consideration by SCC for the “2 x 2 performance based proficiency testing program” outlined in 6.2.3 above. These accredited laboratories may convert to this program provided they meet the following requirements:

- a) the laboratory shall, for each accredited test, seek and be granted prior approval from the SCC to convert to this program for that specific accredited test.
- b) the laboratory meets the requirements of a **two (2) year history** (i.e. 4 proficiency testing rounds under the “2 x 4 proficiency testing program”, or equivalent after accreditation) of demonstrated satisfactory performance results for that accredited test over the past 2 year period.
- c) the laboratory provides detailed documentary evidence of demonstrated satisfactory performance for that accredited test to SCC for all four (4) proficiency testing rounds.

### **6.3 Proficiency Testing Program Responsibilities**

#### **6.3.1 Laboratory’s responsibilities**

6.3.1.1 Applicant and accredited laboratories shall identify to the SCC the specific environmental testing proficiency testing provider(s) and their specific proficiency testing scheme(s) they will employ for their accredited environmental tests and associated specific measurands under this PSA-ET program subject to the conditions below.

6.3.1.2 Laboratories may use any SCC acceptable proficiency testing provider(s) listed in CAN-P-1585 Appendix A for tests listed in their scope subject to sections 6.2.1, 6.2.2.1 a) and 6.2.3.1 b) above as well as 6.3.1.3, 6.3.1.6, 6.3.2 and 6.3.3.1 below.

For multi-measurand test methods, not all of the measurands may be included in a specific proficiency testing provider’s test group. If the measurand is available from any SCC acceptable proficiency testing provider listed in the current version of CAN-P-1585 Appendix A, then the laboratory shall be required to participate in proficiency testing rounds from more than one proficiency testing provider if necessary to cover all the measurands in the multi-measurand method(s) in their scope with the SCC.



6.3.1.3 The laboratory shall obtain specific SCC prior approval of the proficiency testing provider(s) specific scheme(s) they will employ for their accredited scope of environmental testing under this PSA. Once approved the laboratory shall not change their “current” proficiency testing provider(s) without obtaining prior approval from the SCC except for the specific instances of “remedial” testing as outlined in 6.4.4 a) below and the conditions in 6.3.1.6.

6.3.1.4 If the laboratory is required to participate in (or return to) the “2 x 4 proficiency testing program”, the laboratory shall immediately notify their approved proficiency testing provider that they must receive four (4) proficiency testing sample sets per round for that specific accredited test and all proficiency testing samples shall be above the laboratory’s declared detection limit for all measurands.

6.3.1.5 The laboratory shall, for each accredited test, seek and be granted prior approval from the SCC to convert to the “2 x 2 performance based proficiency testing program” for that specific accredited test.

6.3.1.6 If the laboratory is granted approval for the “2 x 2 performance based proficiency testing program”, the laboratory shall notify their approved proficiency testing provider that they may only receive two (2) proficiency testing sample sets per round for that specific accredited test and all proficiency testing samples shall be above the laboratory’s declared detection limit for all measurands.

However, if their currently approved proficiency testing provider cannot supply the required number of proficiency testing samples (i.e. 2 proficiency testing samples/round), for what ever reason, the laboratory shall employ one of the other proficiency testing providers listed in the current version of CAN-P-1585 Appendix A that can supply the required number of samples/round. The laboratory shall notify SCC of the change of proficiency testing provider for that specific accredited test employing the current version of CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document.

6.3.1.7 The laboratory shall make arrangements for their approved proficiency testing providers’ coordinator to provide a copy of their laboratories’ final “proficiency testing performance report” (however named) and date of delivery of this document to the SCC ETWG Secretary immediately after that report is released to the proficiency testing participants (refer to 6.3.2.6 below).

6.3.1.8 Laboratories shall provide the SCC ETWG Secretary, within 10 working days from the first date of receiving the proficiency testing provider final “proficiency testing performance report” (in what ever format first reported to the laboratory), a summary of their performance in that proficiency testing round. This shall be done by electronically reporting their proficiency testing performance employing the current version of CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document. (see 6.1.4 and 6.1.6 above)

Laboratories failing to accurately report their performance in any proficiency testing round within this timeline shall be immediately subject to suspension outlined in clause 6.4.3.

6.3.1.9 If the proficiency testing sample concentration for any measurand falls below the test method detection limit the laboratory shall clearly indicate that by reporting either a “<” or “< DL” on the “*PSA-ET PT Cycle Summary Report*” for that specific measurand/test method in that specific proficiency testing sample (refer sections 6.1.4 and 6.3.2.3).

6.3.1.10 Laboratories shall keep all proficiency testing provider final “proficiency testing performance report” documents (however named) relating to their scope under this PSA-ET for a minimum of 3 years. They shall provide copies of any final “proficiency testing performance evaluation report” to the SCC when requested by the SCC.

### **6.3.2 Proficiency Testing Provider’s responsibilities**

6.3.2.1 All proficiency testing providers seeking to have their specific proficiency testing scheme(s) recognized as an acceptable proficiency testing scheme in this PSA-ET and be listed in the current version of CAN-P-1585 Appendix A shall provide to the SCC documents which shall describe their specific proficiency testing scheme(s), its operations and requirements including the time lines for submission of results by participants, the issuing of proficiency testing reports, the measurands and concentration ranges. These documents shall have sufficient detail to permit the SCC to assess them as an acceptable proficiency testing provider with specific proficiency testing scheme(s) in accordance with the requirements outlined in these PSA-ET requirements.

Every approved proficiency testing provider under this PSA-ET program shall declare to SCC their normal number of proficiency testing samples/round and whether they are capable of supplying samples under the SCC “2 x 2 performance based proficiency testing program”. If their current proficiency testing scheme is not capable of supply the required number of proficiency testing samples (i.e. 2 proficiency testing samples/round), for what ever reason, this proficiency testing provider’s program shall be listed in the current version of CAN-P-1585 Appendix A as being restricted to providing samples for only the “2 x 4 proficiency testing program”.

To become an acceptable proficiency testing provider, in general:

a) the proficiency testing provider shall be accredited to the SCC PSA-PT program or another equivalent proficiency testing accreditation program from an Accreditation Body having a Mutual Recognition Agreement with SCC and meet the requirements in sub-sections 6.3.2.2 to 6.3.2.8 below.

OR

b) if the proficiency testing provider is not accredited to the SCC PSA-PT program (or its equivalent) then that providers’ proficiency testing scheme shall comply with principles of ISO/IEC Guide 43 (CAN-P-43:1997), ILAC G13:2007 and ISO/IEC 13528 and shall meet the requirements below and all the requirements in all sub-sections of 6.3.2.2 to 6.3.2.8 below. In addition, the proficiency testing providers’ specific scheme(s) may be subject to 3rd party assessment to the SCC PSA-PT program.

Specifically, the proficiency testing providers' documentation to the SCC shall include, but not be limited to, the following information:

- demographic contact information of the proficiency testing provider, its' coordinator and the technical competencies of their personnel
- proficiency testing providers quality system program including proficiency testing provider accreditation status or adherence to international proficiency testing guidelines (ISO/IEC Guide 43, ILAC G13, ISO/IEC 13528)
- information provided to the participants that describes their specific proficiency testing scheme(s), its operations and requirements
- all sample preparation and handling protocols including unique identification of proficiency testing samples
- proficiency testing sample verification protocols including stability and homogeneity testing and statistical analyses
- frequency of the specific proficiency testing scheme(s) including the number and type of sample sets per test group per proficiency testing round for each matrix and area of testing as well as the number of times per year the specific proficiency testing rounds are offered
- specific proficiency testing scheme(s) sample details including areas of testing, matrix of samples, test group(s) and test code including specific measurands, analytical concentration ranges and units, etc.
- requirements for participants to identify test method(s) for specific measurands
- time lines and details on the submission of results by participants
- statistical analyses of the participants results including the method(s) and assessment criteria for evaluation of participants performance. This includes criteria of how the consensus mean value (assigned value) and acceptable SD limits (estimate of variability or acceptance limits) are determined
- a copy of the "proficiency testing performance evaluation report" (however named) for each specific proficiency testing test group including time lines and details of the test and test method for specific measurands

6.3.2.2 SCC acceptable proficiency testing providers shall employ the "z-score" method (ISO/IEC Guide 43 and ISO 13528) for the evaluation of laboratory performance for all quantitative tests and the appropriate evaluation methodology for qualitative tests.

For quantitative tests, performance on each single measurand result calculation of the z-score shall be as follows:

$$z = \frac{x - X}{\sigma_{pt}}$$

where:

- the quantity  $(x - X)$  is called the "estimate of laboratory bias" in ISO 13528
- "x" is the participant's result
- "X" is the "assigned value" (i.e. the consensus value which is the consensus proficiency testing mean)

-  $\sigma_{pt}$  is the “standard deviation for proficiency assessment”, an appropriate measure of variability which is selected to meet the requirements of the proficiency testing scheme.

As described in ISO 13528,  $\sigma_{pt}$  can be determined in a variety of ways:

- i) a traditional or robust standard deviation
- ii) a fitness for purpose goal for performance as determined by expert judgement

If consensus is used to determine  $\sigma_{pt}$ , the estimates of variability should be reliable; that is, based on enough observations to reduce the influence of outliers and achieve sufficiently low uncertainty.

6.3.2.3 All test results that are reported by the laboratory as lower than that laboratory’s declared detection limit shall be treated as “non-detects”. The proficiency testing provider shall not assign a z-score for those “non-detect” specific test results and the proficiency testing provider shall report those results as either “<” or “< DL”.

6.3.2.4 For proficiency testing provider whose **normal proficiency testing scheme protocol** consists of providing more than two (2) proficiency testing sample sets per round (i.e. three (3) or more sample sets per round), shall for any SCC accredited laboratory that has been granted approval by SCC for its “2 x 2 performance based proficiency testing program” for specific accredited test(s):

a) provide, irrespective of the proficiency testing providers “normal” protocol, only two (2) proficiency testing sample sets per round for that specific test(s) to that laboratory and all proficiency testing samples shall be above the laboratory’s declared detection limit for all measurands.

b) provide, irrespective of the proficiency testing providers “normal” protocol, only four (4) proficiency testing samples per year per identified accredited test to that laboratory. These sample sets over two (2) proficiency testing rounds shall have different concentrations spanning a predetermined concentration range that covers the concentration range of the laboratory’s accredited test and all proficiency testing samples shall be above the laboratory’s declared detection limit for the measurand for all four (4) proficiency testing samples.

6.3.2.5 The proficiency testing provider shall specify the time period within which the proficiency testing results are due after receipt of proficiency testing samples by the laboratory. Laboratories not reporting results within this timeline shall be subject to the suspension procedure described in sub-section 6.4 (Procedures for unsatisfactory laboratory performance).

6.3.2.6 The proficiency testing provider shall issue to the laboratory a final “proficiency testing performance report” (however named) outlining its specific performance evaluation results for the laboratory including the actual “z-scores” the laboratory received for the individual measurand(s) (refer section 6.3.2.3) as well as general performance evaluation information for all participants.

Specifically, all the reports issued (in what ever format reported) to participants by the proficiency testing coordinator shall adhere to the ILAC Guide 13:2007 guidelines (section 3.6.3) as well as contain the following minimum information:

- a) participants reported value (x)
- b) assigned value (X)
- c)  $\sigma_{pt}$  – i.e. the standard deviation for proficiency assessment including how it was calculated
- d) z-score and evaluation criteria. The evaluation criteria shall adhere to ISO/IEC Guide 43 and ISO/IEC 13528 (refer to 6.3.3.2 below)

6.3.2.7 The proficiency testing coordinator shall provide a copy of each accredited SCC PSA-ET laboratory’s final “proficiency testing performance report” and date of delivery of this document was reported to the laboratories (in what ever format first reported) to the SCC ETWG Secretary immediately after it is released to the proficiency testing participants.

6.3.2.8 Any appeal by a laboratory regarding the assessment of reported results shall be administered by the proficiency testing providers normal appeal protocols.

### 6.3.3 SCC responsibilities

6.3.3.1 The SCC will review potential CAN-P-1585 proficiency testing providers’ document(s) that describes their specific proficiency testing program(s), its operations and requirements and determine if the proficiency testing providers’ specific proficiency testing scheme(s) are acceptable for use in this PSA-ET program.

The SCC will maintain a CAN-P-1585 Appendix A (“*PSA-ET Directory of Acceptable PT Providers*”) containing specific SCC acceptable proficiency testing providers, their specific proficiency testing scheme (s) and their status concerning the SCC “2 x 2 performance based proficiency testing program” for this PSA-ET program. Only specific SCC acceptable proficiency testing providers and their specific proficiency testing scheme (s) shall be employed for this PSA-ET program. This CAN-P-1585 Appendix A does not imply endorsement by SCC or its ETWG of any specific proficiency testing provider listed in that document.

6.3.3.2 The SCC criteria employed for the evaluation of performance in quantitative test results shall be the interpretation of the z-score for each measurand as follows (ISO/IEC Guide 43):

$ z  \leq 2.0$	“Satisfactory” performance
$2.0 <  z  < 3.0$	“Questionable” performance
$ z  \geq 3.0$	“Unsatisfactory” performance

**NOTE:** As outlined in section 6.2 above, the number of participants the laboratory is evaluated against shall be  $\geq 10$ .

For qualitative analyses, any false positive or false negative identification shall be deemed unsatisfactory performance.

## **6.4 Procedures for unsatisfactory laboratory performance**

6.4.1 Failure of a laboratory to comply with any aspect of accreditation requirements including these requirements may lead to suspension or withdrawal of accreditation in accordance with the standard SCC suspension and withdrawal procedures documented in CAN-P-15. In addition, the laboratory shall be subject to the suspension or withdrawal procedures below, when its proficiency testing performance does not meet the specified performance criteria outlined in sub-section 6.3.3.2 above.

All instances of withdrawal of accreditation will be publicized by the SCC on their website. When suspension action is taken, customers, potential customers and the public will be notified by the posting of a Suspension Notice on the SCC website. In the case of accredited laboratories, this notice shall take the form of an amended scope of accreditation.

For Ontario environmental laboratories accredited under the SCC-MOE accreditation agreement for the conduct of specific drinking water tests in Ontario, as required by the Act and Ontario Regulation 248/03 (Drinking-Water Testing Services) (“Regulation 248”), the SCC shall also notify the Ontario Ministry of Environment authorized representative in writing of the proposed suspension or revocation of a laboratories’ accreditation.

6.4.2 SCC will consider several factors in determining whether the suspension of a test from the scope of an applicant laboratory or withdrawal of accreditation of an accredited laboratory is necessary:

- a) unsatisfactory performance or failure to participate in a proficiency testing round
- b) failure to take immediate corrective action(s) on unsatisfactory proficiency testing performance(s)
- c) failure to properly correct the unsatisfactory proficiency testing performance(s) in a timely manner
- d) failure to report proficiency testing results within the timeline outlined by the proficiency testing provider
- e) failure to report proficiency testing results to the SCC ETWG Secretary within the timelines outlined in section 6.3.1.8
- f) failure to accurately report their performance in any proficiency testing round

6.4.3 Failure of a laboratory to participate in an acceptable proficiency testing scheme(s) round or to accurately report their performance in any proficiency testing round will result in immediate suspension. The laboratory will not be reinstated until demonstrated satisfactory proficiency testing performance is confirmed.

6.4.4 Incorrect quantitation or identifications on any proficiency testing sample are unacceptable for any measurand for which a laboratory is accredited and will result in initiation of action (s) outlined in clause 6.4.5.

6.4.5 The first date of “Receipt of notification” by the laboratory of any unsatisfactory result from the proficiency testing provider in that proficiency testing round places the onus directly upon the laboratory to immediately initiate corrective action(s). Any final “proficiency testing performance report” issued by whatever means by the proficiency testing provider and in what ever format first reported to the laboratory constitutes this “receipt of notification” of the proficiency testing results to the laboratory.

The laboratory shall respond to the SCC ETWG Secretary within 10 working days from the first date of this “receipt of notification” (in what ever format first reported to the laboratory) with an initial corrective actions report (CAR). This initial CAR shall include a description of the unsatisfactory performance or failure and clearly indicating the corrective actions(s) being taken. This initial CAR shall indicate whether the laboratory has requested a “remedial” set of samples for that measurand(s).

a) if a “remedial” set of samples has been requested then:

- these “remedial” set of samples (either 2 or 4 samples) shall be a different set of samples (samples with the concentrations blind to the laboratory, in different concentrations to the original set and the same or more number of samples as in the original round) from that of the current proficiency testing round
- the “remedial” set may be obtained from the same proficiency testing provider or any another SCC acceptable proficiency testing provider
- upon receipt of this set of “remedial” samples from the proficiency testing provider(s), the laboratory shall analyze them in a timely fashion and report the results to the proficiency testing provider
- the proficiency testing provider shall judiciously evaluate the results using their normal protocols and provide a final “remedial proficiency testing performance report” (however named) to the laboratory and SCC. As outlined in section 6.2 above the number of participants the laboratory is evaluated against shall be  $\geq 10$
- the laboratory shall then report to the SCC ETWG Secretary within 10 working days of first receiving the final “remedial proficiency testing performance report” (in what ever format first reported to the laboratory) with the final CAR which shall clearly include root cause analyses and all the corrective actions(s) taken. The laboratory shall also electronically report their proficiency testing performance by providing a summary of that “remedial” proficiency testing set employing a new copy of the CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document and a copy of the proficiency testing providers final “remedial proficiency testing performance report”
- this total process should generally not take longer than the normal SCC protocols for CARs (i.e. 30 working days)

b) if no “remedial” set of samples are required, the laboratory shall respond to the SCC ETWG Secretary within 30 working days with the final CAR which shall clearly include root cause analyses and all the corrective actions(s) taken.

The SCC will evaluate the results of this final CAR(s) to determine if satisfactory proficiency testing performance has been achieved. The SCC may request additional information to substantiate satisfactory proficiency testing performance has been achieved.

**NOTE:** The proficiency testing provider has no responsibility for monitoring the laboratory’s proficiency testing performance as it relates to the maintenance of SCC accreditation under this PSA-ET. This is the sole responsibility of the SCC.

6.4.6 Failure to provide the final CAR response, the CAN-P-1585 Appendix B (“*PSA-ET PT Cycle Summary Report*”) document or a copy of the proficiency testing providers final “remedial proficiency testing performance report” (in what ever format first reported to the laboratory) as required by sub-section 6.4.5 following unsatisfactory proficiency testing performance on any test in any proficiency testing cycle shall result in suspension or withdrawal of accreditation. The CAR(s) shall provide sufficient evidence that the problem has been identified, root cause analyses has been conducted and all the corrective actions(s) taken. An unsatisfactory CAR(s) may also initiate an on-site visit by the SCC.

6.4.7 Failure to obtain satisfactory performance for any measurand in that “remedial” set of proficiency testing sample(s) shall initiate the SCC ETWG Convener to recommend to the SCC ETWG Secretary an immediate suspension of that test(s). The SCC ETWG Secretary will advise the Manager Laboratories - PALCAN to immediately suspend that test(s). The laboratory’s test(s) will not be reinstated until substantiated proof of demonstrated satisfactory performance has been confirmed by the next scheduled round of the proficiency testing providers’ scheme for that test(s).

6.4.8 Should the SCC initiate action to suspend the laboratory's accreditation for the specific test(s), the laboratory's official status will become "suspended" according to normal SCC protocol until such time that demonstrated satisfactory proficiency testing performance is confirmed and the suspension is lifted.

6.4.9 Continued unsatisfactory proficiency testing performance over three (3) proficiency testing rounds will trigger SCC to initiate withdrawal according to the procedure in the current version of CAN-P-15.

6.4.10 A laboratory whose accreditation has been withdrawn may reapply according to normal SCC protocol.



## **BIBLIOGRAPHY**

The following is an extensive list of recommended references:

APLAC PT 002:2008, Testing Interlaboratory Comparisons. (<http://www.aplac.org/index.php?id=86>)

APLAC PT 003:2008, APLAC Proficiency Testing Directory. (<http://www.aplac.org/index.php?id=86>)

APLAC PT 006:2008, Proficiency Testing Frequency Guidelines. (<http://www.aplac.org/index.php?id=86>)

CITAC/EURACHEM ECTRACE, 2003, Traceability in Chemical Measurement, a guide to achieving comparable results in chemical measurement. (<http://www.citac.cc/>)

CITAC/EURACHEM Guide, English Edition 1.0, December 1998 (currently under revision 2008), The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics. ISBN 0-948926-12-0 (<http://www.citac.cc/>)

CITAC/EURACHEM Guide, Edition 2002, Guide to Quality in Analytical Chemistry. An Aid to Accreditation. (<http://www.citac.cc/>)

CITAC/EURACHEM Guide CG2, English Edition 2nd internet version, November 1998, Quality Assurance for Research and Development and Non-routine Analysis (CAN-P-1595 July 2001). (<http://www.citac.cc/>)

CITAC/EURACHEM Guide CG4, Second Edition, 2000 (**QUAM: 2000.P1**). Quantifying Uncertainty in Analytical Measurement. (<http://www.citac.cc/>)

ILAC Guide 13:08/2007, ILAC Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes.

ISO 3534-1:1993(E/F), Statistics - Vocabulary and Symbols Part 1: Probability and General Statistical Terms.

ISO 5725-1:1994(E) (amendment 1998), Accuracy (trueness and precision) of Measurement Methods and Results-Part 1: General Principles and Definitions.

ISO 5725-2:1994(E) (amendment 2002), Accuracy (trueness and precision) of Measurement Methods and Results-Part 2: Basic Method for the Determination of Repeatability and Reproducibility of a Standard Measurement Method.

ISO 5725-3:1994(E) (amendment 2001), Accuracy (trueness and precision) of Measurement Methods and Results-Part 3: Intermediate Measures of the Precision of a Standard Measurement Method.

ISO 5725-4:1994(E), Accuracy (trueness and precision) of Measurement Methods and

Results-Part 4: Basic Methods for the Determination of the Trueness of a Standard Measurement Method.

ISO 5725-5:1998(E) (amendment 2005), Accuracy (trueness and precision) of Measurement Methods and Results-Part 5: Alternative Methods for Determination of the Precision of a Standard Measurement Method.

ISO 5725-6:1994(E) (amendment 2001), Accuracy (trueness and precision) of Measurement Methods and Results-Part 6: Use in Practice of Accuracy Values.

ISO 7870:1993, Control Charts - General Guide and Introduction.

ISO 7873:1993, Control Charts for Arithmetic Average with Warning Limits.

ISO 9000:2000, Quality Management Systems - Fundamentals and Vocabulary.

ISO Guide 30:1992, Terms and definitions used in connections with reference materials.

ISO Guide 33:1989, Uses of Certified Reference Materials.

ISO/IEC Guide 2:1996, General terms and their definitions concerning standardization and related activities.

ISO/IEC Guide 43-1:1997(E), Proficiency Testing by Interlaboratory Comparisons - Part 1: Development and Operation of Proficiency Testing Schemes.

ISO/IEC Guide 43-2:1997(E), Proficiency Testing by Interlaboratory Comparisons - Part 2: Selection and Use of Proficiency Testing Schemes by Laboratory Accreditation Bodies.

ISO/IEC Guide 98-1:2008 (draft 09/2007), Uncertainty of measurement – Part 1: Introduction to the expression of uncertainty in measurement.

ISO/IEC Guide 98-3:2008, Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995).

ISO/IEC Guide 99, First edition 2007, International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM). (VIM) 3<sup>rd</sup> ed.:2007).

ISO Standard 13528:2005(E), 1st Edition, Statistical Methods for use in Proficiency Testing by Interlaboratory Comparisons.

ISO/IEC Standard 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories.

ISO/IEC CD 17043:2008, Conformity assessment – General Requirements for proficiency testing.

ISO/TS 19036:2006 (E), Technical Specification First Edition, Microbiology of food and animal feeding stuffs – Guidelines for the estimation of measurement uncertainty for quantitative determinations.

Guide to the Expression of Uncertainty in Measurement (**GUM**), 1993 (amended 1995), published by ISO in the name of BIPM, IEC, IFCC, IUPAC and OIML (ISBN 92-67-10188-9). (Note: the new ISO/IEC Guide 98-1:2008 supplement)

AOAC International Methods Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis, Philip Feldsine, Carlos Abeyta & Wallace H. Andrews, Journal of AOAC International, Vol. 85, No. 5, 2002. (<http://www.aoac.org/vmeth/MICGUIDE.pdf>)

Guidance Notes C&B and ENV002, July 2002, Method Validation of Microbiological Methods, Singapore Accreditation Council (SAC-SINGLAS) (<http://www.sac-accreditation.gov.sg/documents.asp?type=1#others>)

Harmonised Guidelines for Internal Quality Control in Analytical Chemistry Laboratories, Pure Appl. Chem., Vol. 67, pp 649-666, 1995. (<http://www.iupac.org/publications/pac/1995/pdf/6704x0649.pdf>)

Harmonized Guidelines for Single-laboratory Validation of Methods of Analysis (IUPAC Technical Report) 2002 - Pure Appl. Chem., Vol. 74, No. 5, pp 835-855, 2002. (<http://www.iupac.org/publications/pac/2002/pdf/7405x0835.pdf>)

Nomenclature, symbols, units and their usage in spectrochemical analysis - II Data Interpretation, IUPAC 1975, Spectrochim. Acta B 33B, 1978, p.241-245,

Quality Assurance of Chemical Measurements, John Keenan Taylor, Lewis Publishers, p85, 1987,

Standard Practice for Dealing with Outlying Observations, ASTM E178-80.

The Expression of Uncertainty and Confidence in Measurement, UKAS M3003, Edition 2, January 2007. (<http://www.ukas.com/Library/downloads/publications/M3003.pdf>)

The International Harmonized Protocol for the Proficiency Testing of Analytical Chemistry Laboratories (IUPAC Technical Report) Prepared for publication by Michael Thompson, Stephen L.R. Ellison, Pure Appl. Chem., Vol. 78, No. 1, pp 145-196, 2006. (<http://www.iupac.org/publications/pac/2006/pdf/7801x0145.pdf>)