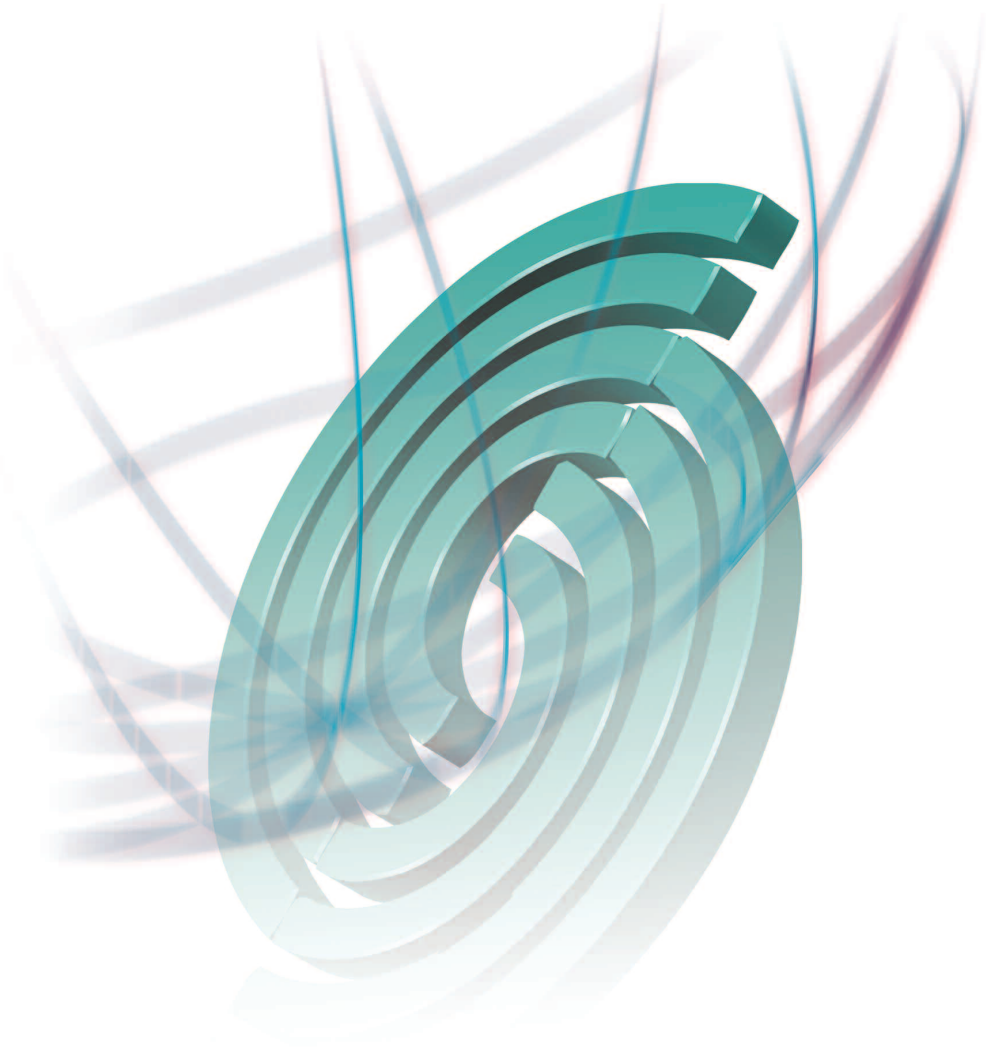

Standards Council of Canada
Conseil canadien des normes

Program for the Accreditation of Laboratories – Canada (PALCAN) PALCAN Handbook

CAN-P 1570
June 2010
Program Requirements for Applicant and Accredited Laboratories

Canada

PROGRAM FOR THE ACCREDITATION OF LABORATORIES – CANADA (PALCAN)

PALCAN HANDBOOK

Program Requirements for Applicant and Accredited Laboratories

PROGRAMME D'ACCRÉDITATION DES LABORATOIRES – CANADA (PALCAN)

GUIDE DU PALCAN

Exigences du programme applicables aux laboratoires candidats et accrédités

CAN-P-1570
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This document supersedes and replaces CAN-P1570 dated December 2008.

Standards Council of Canada
Conseil canadien des normes

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The following documents are issued separately and are available at: http://www.scc.ca/en/edocs/criteria-and-procedures/laboratory-accreditation

FOREWORD

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 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 organisations 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.

In addition, 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 organisations, product and services certification bodies, testing and calibration laboratories, proficiency testing providers, management systems certification bodies, personnel certification bodies and inspection bodies. In addition SCC administers the OECD Good Laboratory Practice (GLP) initiative on behalf of Health Canada and Environment Canada. SCC 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 at info.palcan@scc.ca .

INTRODUCTION

What is "Accreditation"?

The accreditation of an organisation within the PALCAN program is third party attestation, of the organisation, conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

For accredited testing and/or calibration laboratories, the Standards Council of Canada formally recognises the ability of the laboratory to produce competent results for the specific tests or calibrations that are listed on its Scope of Accreditation. A list of accredited laboratories and their scopes of accreditation is available to the public on the SCC web site at

http://palcan.scc.ca/SpecsSearch/SpecsSearchAction.do

Accredited laboratories are deemed to have all of the following in place in order to produce competent results:

i) technically competent staff with the requisite skills and knowledge;
ii) the environment with the requisite facilities and equipment;
iii) the requisite procedures; and
iv) the requisite quality control.

For accredited proficiency providers, the Standards Council of Canada formally recognises the ability of the organisation to provide proficiency samples for specific parameters that are listed on its Scope of Accreditation. A list of accredited proficiency providers and their scope of accreditation is available to the public on the SCC web site at:

http://palcan.scc.ca/SpecsSearch/SpecsSearchAction.do

The accredited organisation must sign an accreditation agreement that commits the organisation to conform to the specific program requirements set out in this document, CAN-P-1570 – PALCAN Handbook, as well as the Policies, Procedures, and Guidance documents contained or referenced herein; and agrees to pay all fees associated with accreditation.

What is an "Accreditable Organisation"?

To be accreditable, an organisation must be:

- managed by a suitably qualified professional authorised to approve and sign its test reports or calibration certificates;
- *a legal entity* as per the interpretation in CAN-P-1630 section 4.1.1; i.e. the SCC accreditation covers a distinct corporate entity and is limited to that entity within clear and distinguishable corporate boundaries; and
- under one quality management system, when the organisation provides testing and/or measurements and/or proficiency samples in more than one product area or operates in different fields of testing or measurement.

NOTE: There are exceptional situations where an accredited laboratory can be considered for on-site (away from the main facility) and satellite facility accreditation within the accredited unit. In those situations, the organisation will need to comply with the requirements of the applicable SCC documents.

Disclaimer:

Accreditation is a demonstration of confidence in the organisation's technical competence. It is not an assurance. It does not imply the acceptance by the SCC of any responsibility toward any person or organisation for the effects of the services provided by an accredited organisation.

ACCREDITATION PROCESS

1 Getting Ready for an Application to PALCAN or through a PALCAN Partner Organisation

All PALCAN testing and calibration laboratory program and proficiency providers program requirements are contained in this Handbook or identified by reference to the applicable documents. Separate materials are available for Good Laboratory Practice Recognition. Organisations are evaluated against the applicable requirements of latest version of:

- CAN-P-4 for testing and calibration laboratories
- CAN-P-11 for medical laboratories
- CAN-P-12 for Point of Care Testing
- CAN-P-43 for proficiency testing providers.

These requirements may be supplemented by SCC specific interpretations for accreditation requirements as well as SCC specific Policies, Procedures, Requirements and Guidelines. These are divided into two (2) principle categories that are defined in Section 5 of this document:

- General Program Policies, Procedures, Requirements and Guidelines
- Program Specific Policies, Procedures, Requirements and Guidelines

The SCC Policies, Procedures, Requirements and Guidelines may be supplemented by documentation specific to Partner Organisations (Partner) as described or referenced in Section 1.1 below.

1.1 The SCC Partnership. Certain portions of the SCC Accreditation Program are provided in partnership with other organisations that are qualified and monitored on a regular basis by the SCC. In these cases, the Partner receives the application and conducts the assessment of the applicant as well as the maintenance and surveillance activities. The Partner forwards a recommendation for accreditation to the SCC. SCC retains the authority and right for the approval and granting of accreditation. Organisations seeking SCC accreditation in the program specific areas that are serviced by SCC Partner (refer to Sections 1.1 a, b or c) should contact the relevant Partner for additional instructions and interpretations of accreditation requirements. Contact information for the relevant Partner is provided in 1.1 a, b and c below. Applications and fees for accreditation through a partner are processed directly through the Partner rather than through the SCC.

Where the activities of an organisation laboratory seeking accreditation do not fall within the Partner Organisation activities as described in this section, the organisation will be served by the SCC directly. In these cases, the SCC conducts the assessment of the facility as well as the approval and granting of accreditation.

Complaints, appeals and suspensions related to accreditation are processed exclusively through the SCC and the requirements of CAN-P-15CA. Mandatory withdrawal of an organisation's accreditation or a facility's recognition may only be authorized by SCC.

PALCAN is directly responsible for the Laboratory Accreditation, Proficiency Testing (PT) Provider Accreditation, and Good Laboratory Practice (GLP) Recognition programs within the SCC. PALCAN also oversees the activities of the SCC Partner organisations with respect to accreditation.

PALCAN Partnerships include:

a. The Calibration Laboratory Assessment Service (CLAS) of the National Research Council of Canada (NRC)

NRC CLAS is the Partner organisation for calibration laboratories. In addition to accreditation, by SCC, CLAS certifies specific measurement capabilities or calibration laboratories of successful applicant in support of the Canadian National Measurement System and allowing the use of the CLAS logo. Those interested in learning more about this program should consult:

http://inms-ienm.nrc-cnrc.gc.ca/clas/clas_e.html or
http://inms-ienm.nrc-cnrc.gc.ca/clas/clas_f.html

b. Bureau de normalisation du Québec - Évaluation des laboratoires (BNQ-EL)

BNQ-EL is the Partner organisation for those organisations located in Québec who may wish to obtain SCC accreditation through BNQ-EL, against CAN-P-4 for testing laboratories, CAN-P-11 for medical laboratories, CAN-P-12 for Point of Care Testing and/or CAN-P-43 for PT providers. Consult the BNQ-EL website for details:

http://www.bnq.qc.ca/fr/index.html
http://www.bnq.qc.ca/en/index.html

c. Ontario Medical Association (OMA) – Quality Management Program-Laboratory Services (QMP-LS)

OMA is a Partner organization for medical laboratories and SCC accreditation against CAN-P-11 and/or CAN-P-12, for non Quebec based medical laboratories, may be obtained through OMA.

Information for application through OMA can be obtained from the OMA website at:

http://www.qmpls.org

1.2 Policies, Procedures and Guidelines that are not contained in this document are outlined in Section 5. The SCC's accreditation process requires organisations to demonstrate their competence and establish conformity with these requirements. Testing and/or calibration laboratories must demonstrate competence to perform the specific tests, types of tests or measurements for which they wish to become accredited. Proficiency providers must demonstrate competence to provide proficiency samples for specific parameters for which they wish to become accredited. Applicants must also agree to conform to the SCC conditions for accreditation found in this Handbook.

1.3 All information provided to the SCC and the Partner organisations will be treated as strictly confidential. The SCC keeps all application information confidential and the applicant's name is not divulged to a third party. Once the application for accreditation is approved, the organisation name, along with the Scope of Accreditation, is posted on the SCC website.

NOTE: The Standards Council of Canada is a federal crown corporation and, as such, is subject to the "Access to Information Act". This Act provides exemptions so that the SCC may refuse to disclose records under the Act that

contain trade secrets or financial, commercial, scientific, or technical information, which, if released, could damage the competitive position. As such, the SCC will endeavour to maintain the confidentiality of all submitted documentation, but must abide by the provisions of the Act.

1.4 The information that is provided with a client application has several purposes:

a. to ensure that an applicant has examined each of the requirements and is reasonably confident of conformity with each requirement;

b. to enable PALCAN staff or the Partner to detect potential non-conformity and advise the applicant, thus providing reasonable assurance of a successful on-site assessment;

c. to provide the on-site assessment team with the background information needed to carry out an effective assessment; and

d. to provide the basis for confirming consistency between the documented and assessed capability of the organisation.

1.5 SCC is a signatory to a number of bilateral and multi lateral recognition arrangements. The purpose of these arrangements is to enhance the value of accreditation through international recognition achieving harmonization of the interpretations and uniformity in the rigor of application. The Mutual Recognition Arrangements (MRA) to which SCC is a signatory are identified on the SCC website at:

http://www.scc.ca/en/programs-services/laboratories

1.6 The SCC must ensure that calibration and/or testing laboratories demonstrate technical competence by satisfactory participation in proficiency testing activity where such activity is available. The international minimum amount of appropriate proficiency testing required per laboratory is:

a. one activity prior to gaining accreditation; and
b. one activity relating to each major sub discipline of a laboratory's Scope of Accreditation within four years.

The proficiency testing requirements for medical laboratories can be found on the QMP-LS website.

NOTE 1: SCC's policy on proficiency testing meets the requirements of the mutual recognition agreements of ILAC, APLAC and IAAC that SCC is a signatory to.

NOTE 2: Appropriate proficiency testing activity includes international or national inter-laboratory comparisons or measurement audits run or approved by the accreditation body itself. Preference should be given to international inter-laboratory comparisons (i.e. APLAC, IAAC or equivalent) where these are available.

NOTE 3: Annual participation in PT is required where available.

NOTE 4: Laboratories should use proficiency testing programs which conform to the operational procedures detailed in ISO 17043.

1.7 Some Program Specialty Areas (PSAs) have specific requirements pertaining to proficiency testing participation; refer to the individual PSA CAN-P documents for additional information (refer to Section 8 of CAN-P-1570 Appendix A).

1.8 SCC Conformity Assessment Programs operate in accordance with ISO/IEC 17011 - *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*. Accordingly, the SCC Policies and Procedures are designed to meet the impartiality, non-discriminatory and conflict of interest requirements of the standard. Any Conformity Assessment Body (CAB) that believes that it has not been treated by the SCC in a manner that meets these requirements should submit a complaint in accordance with CAN-P-15CA.

1.9 Following the outcome of the complaint resolution by the SCC, should the CAB believe that the complaint has not been satisfactorily addressed; it has the option to forward the complaint and the SCC response to ILAC for further consideration.

2 Inquiries from Potential Applicants

2.1 SCC may provide accreditation services in any country within the WTO. By virtue of our membership in ILAC (International Laboratory Accreditation Cooperation), it is the SCC policy to notify the applicant if there is an ILAC member accreditation body in their own countries that can provide the accreditation. Where SCC accreditation is required by the applicant, the application will be considered.

2.2 An inquiry from a potential Applicant on becoming an accredited laboratory, PT provider, or a recognized GLP facility can be made directly to SCC or a Partner. Applicants seeking SCC accreditation through one of the Partner organisations listed in 1.1 above are referred to the appropriate Partner organisation.

2.3 The SCC or the appropriate Partner will evaluate inquiries to determine their eligibility as an accreditable organisation and if applicable will forward an application package to the potential Applicant.

2.4 SCC or the appropriate Partner will respond to questions from the potential Applicant prior to the submission of a formal application.

2.5 The potential Applicant is encouraged to hold discussions with the technical staff of the SCC or the appropriate Partner before submitting an application for accreditation.

3 Application

3.1 SCC Applications

The following applies to applications to the SCC for accreditation as a testing laboratory and PT provider. [1]

a. The Applicant submits a completed application package in accordance with *F0200-Application for Accreditation-PALCAN* to the PALCAN Administration. The application must be

[1] If the applicant is seeking recognition under Good Laboratory Practice Recognition (GLP), please consult CAN-P-1583 for the appropriate program and application information.

accompanied by the specified documentation and the proposed scope of accreditation listing the testing methods, disciplines or parameters (for PT providers) for which the applicant is seeking accreditation. The proposed scope is prepared by the applicant in accordance with the guidance and criteria provided in CAN-P-1570 Appendix A.

b. This application must include all the items specified in the application form. An application package that is missing any one of these items is not considered complete and will result in a delay in processing.

c. The Applicant agrees to provide any additional information needed for its evaluation. All information provided to the SCC will be treated in accordance with the terms outlined in the *Confidentiality Clause* in section 1.3.

d. The SCC will formally acknowledge receipt of the completed application, review the contents and provide an estimate for the cost of the accreditation process and the maintenance of accreditation. Upon receipt of the fee for evaluation and an acknowledgement accepting the estimate for the remaining cost, the SCC will begin the evaluation of the application. Applicant organisations should refer to the *F0800 series-PALCAN Fee Structure* to determine the financial aspects related to accreditation.

e. The SCC will close any application that has been inactive for more than 180 days (6 months). An application will be considered inactive if written responses to SCC requests, such as required actions or requests for additional information are not received. The SCC will provide a 30-day written notice prior to closing an applicant file. The reactivation of a closed application will require the submission of a new application package including the application fee, applicable at the time of re-application.

3.2 SCC Partner Applications

The following applies to applications submitted to Partner organisations.

a. **BNQ-EL**. Applicant organisations from Québec that wish to obtain SCC accreditation through BNQ-EL must return a completed BNQ-EL application to BNQ-EL. Information and documentation on BNQ-EL programs can be found on the BNQ-EL website at http://www.bnq.qc.ca/en/labo/index.html or can be obtained by contacting; Laboratory Assessment, Tel. 1-800-386-5114, Fax. (418) 652-2221, E-mail: bnqinfo@bnq.qc.ca.

b. **NRC CLAS** Applicant calibration laboratories must return a completed CLAS application form and documents to CLAS. The CLAS application documents, instructions and CLAS fee schedule are published at

http://www.nrc-cnrc.gc.ca/eng/services/inms/calibration-laboratory/application-form.html
or
http://www.nrc-cnrc.gc.ca/fra/services/ienm/laboratoires-etalonnage/formulaire-demande.html

c. **OMA/QMP-LS** SCC accreditation against CAN-P-11 and/or CAN-P-12, for non Quebec based medical laboratories, may also be obtained through OMA. Applicants must return a completed OMA application to OMA.

Information and documentation on OMA programs can be found on the OMA/QMP-LS website at

http://www.qmpls.org

3.3 Group Accreditations

Group Accreditation is available to Organisations with multiple sites accredited by the SCC and that meet the following minimal conditions:

a. All sites belong to a single legal entity

b. All sites operate under a common Quality System

c. The relationship between the sites is documented

Organisations that wish to apply for Group Accreditation should refer to Appendix B, The SCC Policy on Group Accreditations.

4 Evaluation of Applications Submitted to SCC

4.1 The Senior Program Officer will assess the application against program requirements. Applicants will be provided with a detailed report of the findings. The findings are divided into two principle categories: required actions and concerns. The required actions are findings that will normally require the organization to make changes in their documentation or provide clarification on how the procedure requirements of the conformity standard have been met. Concerns are potential required actions that represent areas of concerns that are identified during the evaluation of the application. A substantially complete response to the required actions must be provided before proceeding with the initial assessment. A formal response to the concerns are not explicitly required before the initial assessment visit.

4.2 In cases where the evaluation of the application identified that substantial amendments to the quality management system documentation would be required, an organisation may be required to agree to and undergo a pre-assessment visit. The purpose of this visit will be to review the actions required to bring the quality system into conformity. The fees incurred by this visit will be in addition to those previously estimated.

4.3 Upon resolution of the required actions, PALCAN will determine a mutually agreeable date to conduct the initial assessment visit and will notify the organisation in writing, of an assessment date and the team composition. The date needs to be scheduled within 3 months of the completion of the evaluation process; substantial resolution of the required actions resulting from the application evaluation must have been achieved before a visit is scheduled. Notification of the initial assessment visit will be provided prior to the scheduled date. The applicant will be asked to provide copies of quality management system documentation including, as required, copies of relevant test methods and procedures for the team and other additional records and documents as determined during the application evaluation.

5 Policies, Procedures and Guidelines

SCC has published a number of Policies, Procedures and Guidance documents that also contain criteria and specific interpretations of requirements.

All documents of the CAN-P-1500/1600 Series are available without charge from the SCC web site at http://www.scc.ca/en/edocs/criteria-and-procedures/laboratory-accreditation.

5.1 General Program Policies, Procedures, Requirements and Guidelines

Accreditation program requirements are outlined in specific program documents found on the PALCAN section of the SCC website at
http://www.scc.ca/en/edocs/criteria-and-procedures/laboratory-accreditation.

5.2 Program Specific Policies, Procedures, Requirements and Guidelines

The requirements above may be supplemented by program specific interpretations of requirements and includes the interpretations specific to Partner areas of activity. Calibration and medical laboratories have specific interpretations that are required. However, the remainder only apply to testing laboratories that voluntarily seek or specifically require recognition for these criteria. Each Program Specialty Area (PSA) has separate documents defining the criteria and interpretations. These programs and corresponding documents are detailed in Section 8 of CAN-P-1570 Appendix A *Guidelines for Presentation of Testing Scopes.*

5.3 PT Provider Program Policies, Procedures, Requirements and Guidelines

CAN-P-43 is supplemented with interpretations of specific requirements. The documents listed in 5.1 apply to all PT providers organisations.

6 Initial Assessment

6.1 SCC will select an assessment team usually composed of a Team Leader and at least one appropriate Technical Assessor. Initial assessment teams will be led by an SCC Senior Program Officer (SPO) or the SCC PALCAN Manager. In exceptional circumstances a contracted Team Leader (TL) may be used. The selection is based on expertise, location and the availability of the individuals.

6.2 The assessment team will conduct an on-site assessment of the applicant to confirm full conformity with the specific applicable program requirements the Policies, Procedures and Guidelines in this document, (refer to section 5 above for testing laboratories). The assessment will focus on evaluation of technical competence in the specific scopes for which accreditation is sought. This includes a review of proficiency testing results for testing/calibration laboratories where relevant. There are specific proficiency testing requirements for some Partners programs such as CLAS, BNQ and OMA/QMP-LS and for some Program Specialty Areas (PSA's). For PT providers, the assessment will focus on evaluation of competence to provide proficiency samples in the specific scopes listed as parameters for which accreditation is sought.

6.3 Assessment teams will normally consist of a SCC-qualified Team Leader and at least one Technical Assessor for each field of testing (see CAN-P-1570 Appendix A) or Program Specialty Area. Additional assessors may be required for multi-discipline Fields of Testing. Technical Assessors may be drawn from regulatory agencies and "authorities having jurisdiction" within

the public sector. While these regulatory personnel, who are experts in the scientific discipline and testing field under assessment, have committed to adhering to the SCC rules of confidentiality, they are also required by law to report any contravention of the laws they are duty-bound to enforce.

NOTE: Regulatory requirements that are outside the assessment scope of the SCC will not be cited in any assessment or reassessment report authored by a PALCAN Team Leader, but may be reported to the appropriate regulatory agency by the assessor.

6.4 The assessment team will produce a draft report of the Group A required actions, which must be fully addressed within six months of the visit, and the Group B, which must be addressed prior to the next reassessment visit. This report will be presented to the applicant and will be reviewed during an exit briefing at the end of the assessment visit.

6.5 In the case where TL is not the assigned Senior Program Officer (SPO), the assessment team will produce a final report of the assessment visit and SCC will forward it to the applicant. This report is reviewed and approved by the Senior Program Officer (SPO) assigned to the file and the client will receive the final report usually within 14 calendar days of the visit.

6.6 Applicants have the right to challenge any action cited in a visit report. An applicant must submit a challenge in writing to the PALCAN Manager, Laboratory Accreditations no later than 14 calendar days after the conclusion of the visit.

6.7 The applicant shall reply within 30 days of receipt of the final follow-up report with a "plan" to address the required actions. This plan includes a proposed completion date not exceeding 180 days from the exit meeting. If completion is delayed beyond these dates without prior agreement from SCC, the applicant may be required to reapply for accreditation. Upon completion of all required actions, the applicant shall submit objective evidence of completion as stated in the final report.

6.8 The assessment team will verify the applicant's responses for completeness and suitability, and will prepare an assessment report. SCC will advise the applicant if another visit is necessary for verification/surveillance purposes.

7 Approval

7.1 The assessment report is forwarded for an independent technical review, if necessary.

7.2 If there are any negative ballots, they must be resolved before proceeding to the next level of approval.

7.3 All applicant organisations that meet program criteria are approved for accreditation by the Director, Conformity Assessment, on behalf of the SCC Council.

8 Accreditation

8.1 Accreditation is granted to successful applicants effective on the date of approval of the accreditation by the Director, Conformity Assessment. At that time, the organisation will receive a letter of accreditation signed by the Director of Conformity Assessment. They are required to

sign an accreditation agreement. The SCC will forward a Certificate of Accreditation accompanied by a letter of accreditation from the Chair of SCC to the newly accredited organisation. The accreditation certificate can be made available in electronic format on request. The SCC Certificate of Accreditation for organisations assessed by a Partner is jointly issued with the Partner.

8.2 The SCC advises the applicant of the accreditation approval decision. In the event of rejection of an application, the applicant will be advised of the reasons. An appeal of this decision may be made in accordance with Section 11. A rejected application will not preclude an applicant organisation from applying again at a later date.

8.3 The accredited organisation is encouraged to make use of the SCC accreditation mark to publicise its accreditation. A copy of the Trademark License Agreement is provided to the newly accredited organisation for signature. Some Partner organisations have similar requirements for the use of their logos and marks and these requirements are detailed in their specific documentation.

8.4 The scopes of accreditation are published on the SCC website, and a notification is posted on the website identifying the newly accredited organisation. In the case of calibration laboratories, CLAS will update the Directory of the Canadian Calibration Network on the CLAS website.

9 Reassessments Visits and Surveillance Questionnaires

9.1 Reassessments and Surveillance Questionnaire

SCC or the applicable Partner ensures continued compliance with accreditation requirements by conducting reassessment visits of each accredited organisation. Interim to the reassessment visits, organisations are required to complete and respond to a surveillance questionnaire.

a. The first reassessment is generally conducted one (1) year after being granted accreditation and subsequent reassessments every two (2) years thereafter (refer to section 9.2.1a). If applicable, and whenever possible, on-site visits are co-ordinated with the SCC Partner Organisations to occur concurrently.

b. In the years between reassessment visits, the organisation is required to complete a **Surveillance Questionnaire** to provide confirmation that the assessed quality management system and accredited activities continue to meet the requirements of accreditation. The organisation will be required to identify any significant changes that have been made to the quality management system, key staff, procedures, facilities and equipment. Completing the surveillance questionnaire in a timely manner is essential to maintaining the conditions of accreditation. The Surveillance Questionnaire is then reviewed by a Senior Program Officer who will confirm if the information provided is acceptable. If deficiencies are identified, the Senior Program Officer will follow-up with the organisation.

c. The reassessment visits conducted by SCC or the appropriate Partner will take place on a mutually agreeable date within the criteria of section 9.2.1c) of this document and will follow a process similar to the initial assessment as described in section 6 of this document.

d. The organisation will be formally notified when a reassessment is due and the notification will provide requirements for pre-visit submission. The organisation shall provide SCC with the updated information.

e. The reassessment process is the same process as for an assessment, per section 6 of this document, with the following exceptions:

- The accredited organisation has 90 days, to resolve any required actions group A;
- The accredited organisation is notified in writing of continued accreditation, and is provided with a revised scope, and when necessary a new certificate.

9.2 Due dates for Reassessment and Surveillance Questionnaire

9.2.1 Initially Scheduled Due Dates

The due dates for Reassessments and Surveillance Questionnaires are initially scheduled based on the following criteria and conditions:

a. The due date for the first reassessment is one (1) year after being granted accreditation or two (2) years after the assessment visit, **which ever is sooner**.

b. The due dates for all subsequent activities are based on the month and date of the due date determined in 9.2.1a) above: subsequent reassessments are every two (2) years and Surveillance Questionnaires are sent in between reassessments every two (2) years.

The following **example** illustrates a typical resulting visit/questionnaire due date profile:

1. Initial Assessment Visit	May 26, 2008
2. Accreditation granted	March 07, 2010
3. First Reassessment Visit	**May 26, 2010**
4. Surveillance Questionnaire	May 26, 2011
5. Next Reassessment Visit	**May 26, 2012**
6. Surveillance Questionnaire	May 26, 2013

c. The actual date of the reassessment visit should be as close as possible to the due date based on availability of SCC team members and organisation's staff. The visits MUST take place within 3 calendar months of the due date.

d. The Surveillance Questionnaires will be sent one (1) month before the due date. Responses MUST be received at SCC on or before the due date.

Note: The reassessment and surveillance schedules for National Metrology Institute (PSA NMI) can be found in CAN-P-1573.

9.2.2 Changing the Scheduled Due Dates

The organisation will be notified of the initially scheduled due date (per section 9.2.1) at the same time as they are notified that accreditation is granted. Organisations will be reminded of their due date every time maintenance of accreditation is confirmed (after the approval of a

reassessment visit report). The due date may be changed upon request any time after organisation has been granted accreditation; however, some restrictions apply:

a. Advancing Due Dates: Due dates may be advanced (new due date is sooner) by any number of months; HOWEVER, once approved, future requests for a change in due date will be based on this advanced due date. Requests for advancing the due date must be submitted at the latest three (3) months before the new proposed due date.

b. Delaying Due Dates: Due dates may be delayed (new due date is later) by up to three (3) months in a **one (1) time request within a 5 year period**. Five (5) years from the new due date, the organisation may request a further delay.

c. Conditions: the conditions stipulated in section 9.2.1 c) and d) apply to the new due dates.

An organisation's authorized representative can request a change in visit due date by contacting the Senior Program Officer (SPO) responsible for the file. If you do not know the contact information of the SPO, please feel free to contact info.palcan@scc.ca .

10 Verification and Surveillance Visits

10.1 Verification Visits

A verification visit allows SCC or Partner to confirm that specified requirements have been fulfilled. Verification visits are conducted as a follow up visit to an assessment or reassessment visit for the following reasons:

a. When it was found that there were serious and critical non-conformities in accordance with CAN-P-1625.

b. Verification of the implementation of corrective actions that cannot be satisfactorily substantiated through a simple documentation review. Verification visits may be the result of an organisation having so many required actions during the initial assessment, that verification of the implementation of the changes called for by the initial assessment team becomes necessary. Regardless of the requirement for an extra visit, the initial visit will be invoiced as an assessment visit. The costs associated with the verification visit will also be the responsibility of the applicant organisation as indicated in the current Fee Structure, available on the website.

c. Documented questions about the technical competence of the organisation or the implementation of its quality management system relating to the Scope of Accreditation cannot be thoroughly addressed by submission of documentation.

Organisations that are unwilling to undergo a verification visit within the specified time frame will be suspended until such time as a visit provides evidence of the continued competence of the organisation to conduct activities for which it is accredited.

10.2 Surveillance Visits

Surveillance Visits are conducted to confirm that specified requirements are being maintained. Reasons for surveillance visits can include:

a. In the instances where there are serious concerns of conformity by the assessment/reassessment team (refer to CAN-P-1625 – *PALCAN Policy on Serious and Critical Non-Conformities*) after an on-site visit has taken place, a recommendation may be made by the Team Leader and/or Senior Program Officer and/or Manager and/or Director to conduct a verification or surveillance visit of the organisation. An on-site visit of generally at least one day will take place to assess the maintenance of the quality management system, and/or technical activities of the organisation. The organisation is responsible for any additional fees to cover the travel costs of the Team Leader and Technical Assessors, if applicable, as well as any professional fees.

b. Documented questions, e.g. a complaint, about the technical competence of the organisation or the implementation of its quality management system relating to the Scope of Accreditation cannot be thoroughly addressed by submission of documentation.

c. An organisation moves to a new location. These visits must be conducted within three (3) months of relocation.

11 Scope Extensions

Accredited organisations may apply for scope extensions or modifications to their existing Scope of Accreditation, to SCC or to a Partner. Request for scope extensions must take the form of a formal application, per *F0200-Application for Accreditation-PALCAN*. The SCC SPO or Partner organisation responsible for the file of the accredited organisation shall assess the request and shall determine the appropriate course of action.

Scope Extension requests will be evaluated to determine if they are Minor or Major Scope Extensions. The definitions of Minor and Major Scope Extensions are as follows:

Minor Scope Extension: The additional capabilities requested are not a departure from the organisation's current activities or are compatible in technique to techniques witnessed at the assessment or reassessment visit. The effect of the requested change on existing supporting instrumentation, data acquisition/calculations, calibration, traceability, measurement uncertainty, personnel qualifications and equipment operation is assessed by the technical assessor from the field of testing that was at the previous visit. The Technical Assessors must formulate a recommendation to accept the request without a visit to the site and confirm that the change is not a departure from currently accredited activities.

Major Scope Extension: When the assessor can not, based on the information provided to support the application, consent to a minor scope extension or the requested capabilities represent a change in activity or the change can have an impact as a result on the ability of the organisation to produce competent results. These conditions need to be verified by an on-site visit. The breadth and depth of the visit will depend on the additional capabilities requested. The Assessor is to provide justification for not classifying it as a minor scope extension.

When the evaluation confirms that the request is for a **minor** extension of the scope, the SCC or the Partner shall then produce a *Minor Scope Extension* Report for submission to the Manager PALCAN, with a recommendation to grant the minor extension. The Manager PALCAN and or Technical Expert assigned by the Manager shall provide a recommendation to the Director, Conformity Assessment. SCC shall make the decision known to the Partner when applicable

and shall communicate the decision to the accredited organisation and provide a new Scope of Accreditation.

When the evaluation confirms that the request is for a **major** scope extension, an on-site assessment will be necessary. If the organisation requires the visit to be carried out sooner than the next scheduled reassessment, additional fees will apply. See *PALCAN Fee Structure* for visits conducted by SCC, and applicable Partner documentation for their fee information.

If applicable, and whenever possible, all organisations within the SCC Partnership shall co-ordinate scope extension visits to occur concurrently with biennial reassessments of the organisation.

12 Scope retention times for routine tests conducted infrequently

The definitions for "routine tests conducted infrequently" and "non-routine testing" are found in Appendix A section 2.

To retain listing of "Accredited routine tests conducted infrequently" the testing laboratory shall comply with the following three critical elements:

- Test Equipment -- Maintain and have available the latest documentation of test equipment and instrumentation utilized for all the standards listed in their accredited scope. In addition critical reagents or supplies; test jigs etc required to perform the test(s) shall be readily available to perform the test(s).

- Qualified Staff -- Have qualified testing staff (not trainees) that can perform all the tests listed in their accredited scope. The training records should indicate the various qualified level(s) of competency achieved by the individual in performing the test(s). This also includes any retraining or demonstration of proficiency in advance of performing or reinstating a test(s).

- Documentation -- Maintain and have available the latest test report(s) or representative test report (s) for the all the tests listed in their accredited scope.

Note: 1. - The requirements of 5.4.2-'Selections of methods' must be met. The test lab needs to keep informed of changes to industry requirements, regulations, and improvements to technology used in the test such as improvements to the instrumentation. For example, if a test lab conducts a standard test method infrequently they need to keep informed about the status of the test method. The test lab may need to revalidate a non –standard test procedure at some point.

2. - Provide a documented procedure for re-instating an infrequently used or archived test, including any necessary validation /verification, calibration of equipment, training or proficiency demonstration of analyst.

3. –The Test Lab shall participate in external PT or ILC where it is available and have appropriate quality control procedures to assure the quality of the test results.

13 Suspensions, Withdrawals, Complaints, Appeals and Hearings

The PALCAN requirements and procedures for suspension or withdrawal of accreditation by the SCC, for the voluntary withdrawal of its accredited status by an accredited organisation, and for

lodging of formal complaints by any interested party, are included in CAN-P-15CA *SCC Conformity Assessment Accreditation Program Requirements and Procedures for the Suspension and Withdrawal of Accreditation and the Resolution of Complaints, Disputes and Appeals. T*his document is available on the SCC website at

http://www.scc.ca/en/edocs/criteria-and-procedures/laboratory-accreditation.

13.1 Suspensions

a. The suspension, or even withdrawal, of accreditation of a specific scope does not, of itself, represent suspension or withdrawal of the whole organisation where it has multiple scopes with SCC. Individual tests can be suspended following an initial proficiency testing failures. These tests may be withdrawn should unsatisfactory proficiency testing results persist. Suspended or withdrawn tests may be reinstated following successful proficiency testing results. Organisations may also voluntarily withdraw certain tests from their scopes on written notification to SCC.

b. An entire organisation may be suspended. This may result, for example, from the non-conformity to the requirements of accreditation, or for non-payment of outstanding invoices. The Scope of Accreditation, which is posted on the SCC website, would be amended to "Suspended Scope of Accreditation" and their listing in the SCC website's Directory of Accredited Laboratories would be amended to show the word "Suspended" before their name. In the event that laboratory is accredited through a partnership, SCC's scope is amended to "Suspended Scope of Accreditation" and the scope/certificate is removed from the partner's website. A full "accredited" status would be reinstated only after satisfactory resolution of the reason(s) for suspension.

13.2 Voluntary Withdrawal

An accredited organisation may voluntarily withdraw its accreditation either in full or for specific tests and/or calibrations, at any time, by providing written notice to the SCC. The SCC exclusively processes voluntary withdrawals. The Partner will forward all notifications of voluntary withdrawal to the SCC for processing.

13.3 Enforced Withdrawals

Accreditation shall only be withdrawn by the SCC for cause. . Withdrawal normally follows a period of suspension. The enforced withdrawal may be initiated on the recommendation of a Partner.

The inability to satisfactorily resolve a suspension will result in the subsequent withdrawal of accreditation for the organisation as a whole. Under such circumstances, the SCC is the sole authority for the withdrawal of the accreditation of the entire organisation.

13.4 Public Notification of Withdrawal

SCC will publicise all instances of voluntary as well as SCC enforced withdrawal of accreditation on the SCC website. In addition, Partners will publish all suspensions and withdrawals of accreditation on their specific website for a predetermined period.

13.5 Reapplication after withdrawal

Full withdrawal of accreditation will not preclude an organisation from applying for accreditation again at a future date. Partial withdrawal of the accredited scope also does not prevent from applying for, in this instance, a scope extension to include the withdrawn tests on their Scope of Accreditation at a later time. Granting of accreditation will be contingent on the resolution of the factors that led to the withdrawal.

13.6 Complaints

If an organisation is dissatisfied with the actions taken by the SCC during the accreditation process, or if an organisation disagrees with an interpretation made by the SCC, that organisation may submit a formal written complaint to the SCC. Please refer to clauses CAN-P-15CA for the processing of complaints.

13.7 Appeals/Hearings

Organisations have the right to appeal SCC notification of intent to suspend or withdraw within thirty (30) days of receiving the notice advising the organisation of the intent to suspend or withdraw. For further information on the appeals and hearing process, please refer to CAN-P-15CA.

14 Publicity Guidelines

A significant benefit of SCC accreditation is that an organisation may publicise its competence based on an internationally recognised accreditation program. The SCC encourages such activities; however, certain restrictions apply to prevent misunderstanding about the significance of accreditation. A condition of accreditation is that the organisations agree to abide by these restrictions as outlined below.

14.1 SCC Sponsored Publicity

SCC and its Partners publicise the accreditation of organisation in several ways, such:

a. an official Certificate of Accreditation, for public display, is provided to each organisation following accreditation;

b. a list of accredited organisations and the details of the Scope of Accreditation is published on the SCC website at
http://palcan.scc.ca/SpecsSearch/SpecsSearchAction.do?language=en

c. a list of organisations accredited through the Partnership with BNQ-EL is published on the BNQ website at

http://www-es.criq.qc.ca/pls/owa_es/bnqw_labo.liste_labo_accr?p_lang=fr

d. the details of the Scope of Accreditation of calibration laboratories are published on the CLAS website at:
http://infoex.nrc-cnrc.gc.ca/inms/search_clas_e.html

e. the details of the Scope of Accreditation for medical laboratories accredited to CAN-P-11 and/or CAN-P-12 through the Partnership with OMA are published on the OMA website:
http://www.qmpls.org/ola/ola_accredited.htm

f. notices of accreditation or withdrawal, announcing the accreditation status of each affected laboratory, will be published on the SCC website and made available to the public;

g. periodic press releases announcing the accreditation, and general news items dealing with accreditation program including any withdrawal of accreditation, will be released to the media from time to time;

h. other publicity programs may be developed to promote accreditation activities and increase public awareness of the program.

14.2 Recommended Publicity Practices for Accredited Organisations

a. Organisations may publicise their accredited status in several ways. Accredited organisations may include the following statement on their company letterhead and advertisements without further approval from the SCC. An accredited organisation that is part of a larger organisation may use this statement on the organisational letterhead, providing that the accredited laboratory is identified by name, immediately preceding or following the statement:

"Accredited by the Standards Council of Canada as a [testing] [and] [calibration] laboratory for specific [tests] [and] [measurements]".

b. Accredited organisations may also make reference to their accredited status in [testing] [and/or] [calibration] reports, **provided non-accredited tests and calibrations are clearly identified**. The reference shall read as follows:

"This [testing] [and] [calibration] laboratory is accredited by the Standards Council of Canada for specific tests or calibrations as listed on www.scc.ca.".

c. As a signatory to the ILAC, IAAC and APLAC Mutual Recognition Arrangements, under clause 5.10.1 of ISO/IEC 17025: 2005, SCC accredited laboratories (**at the moment excludes PT providers**) may use the following statement on reports/certificates:

"The Standards Council of Canada is one of the signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for the mutual recognition of test reports and/or calibration certificates (whichever is relevant)."

Following are the websites for the two organisations mentioned in the statement above, for the information of the laboratories:

http://www.ilac.org
http://www.aplac.org
http://www.iaac.org.mx

14.3 Other Publicity Practices

Organisations that promote their accredited status, or make any reference to their accredited status in a manner deviating from clause 13.2 a) may do so only with the prior approval of the Manager, Laboratory Accreditations, and the appropriate approval authority from a Partner where this is applicable. Advice and assistance for other organisations initiated publicity are also available from the PALCAN Senior Program Officers.

14.4 Publicity Restrictions

The following restrictions apply to publicising an accredited status:

a. reference to the accredited status may not be part of any promotional endorsement of products or services;

b. similarly, no statement or mark relating to accreditation may appear on any product, package or test report (except as allowed in clause 14.2b);

c. should accreditation be voluntarily withdrawn, or suspended or withdrawn by the SCC, the organisation shall immediately cease issuing all reference to its former accredited status for that test or calibration. Upon reinstatement of its suspended or recently withdrawn, PT area, test or calibration accreditation, an organisation may resume its publicity program.

14.5 Guidelines for the use of Accreditation Certificates

a. The accredited organisation may use Certificates of Accreditation issued by the SCC in any reasonable manner while the recipient's accreditation is valid.

b. Certificates may be duplicated and/or manipulated as long as the entire certificate is visible and the original intent of the Certificate is not corrupted or its nature in any way changed.

c. These guidelines will in no way abrogate the instructions, conditions, standards of quality and specifications contained in the Trademark License Agreement, available from PALCAN.

d. The recipient may not use the Certificate in advertising without the prior consent of the SCC.

e. The recipient may not authorise a third party to use the Certificate.

14.6 SCC Trademark License Agreement

Accredited organisation may request the use of the SCC accreditation mark. To do so, they should forward an email request for a Trademark License Agreement to: info.palcan@scc.ca. Upon return of a duly signed copy of the agreement, the SCC will issue an electronic accreditation mark that may be used by the accredited organisation.

14.7 ILAC Mark Sublicensing Agreement – At the moment this is not applicable to PT providers.

The SCC is a signatory to the ILAC MRA. As such, accredited laboratories may enter into a sublicense agreement with the SCC for the use of the ILAC-MRA Mark. To request a copy of the agreement and the conditions of use, please send an email request to: info.palcan@scc.ca.

14.8 Use of Partner Organisation Logos and Promotional Materials

The use of the logos and promotional materials of SCC Partner is strictly controlled by those partners and their issuing agencies. Organisations that participate in PSAs or Partner programs must obtain permission from the Partner in order to make use of these materials.

15 Good Laboratory Practice Recognition (OECD – *Organisation for Economic Co-operation and Development*)

The Standards Council of Canada (SCC) GLP Monitoring Authority (GLP MA) has Memoranda of Understanding with Health Canada (HC) and Environment Canada (EC) allowing it to act as the GLPMA for determining GLP compliance of facilities within Canada. Compliance with the OECD Principles of GLP is required by the respective Canadian regulatory authorities: HC, Health Products and Food Branch (HPFB) and the Pest Management Regulatory Authority (PMRA); and EC New Substances Division. Canadian regulatory authorities expect non-clinical study submissions to be GLP complaint: HPFB, pharmaceuticals, radiochemicals, biologics; PMRA, pesticides and biocides; EC, industrial chemicals. A comprehensive list of studies requiring compliance to the Principles of GLP, and the corresponding implementation schedule for GLP compliance is available from the respective receiving authorities.javascript:wOpen('http://www.hc-sc.gc.ca/pmra-arla/','b');

The application form, applicable fee structure and CAN-P-1583, *SCC Monitoring Authority Requirements for the Recognition of GLP Complaint Facilities* are available on the SCC website at:

http://www.scc.ca/en/programs-services/laboratories/glp