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Conseil canadien des normes

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

CAN-P-1570

November 2006

Program Requirements for Applicant and Accredited Laboratories

national standards system

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
November 2006

This document supersedes and replaces D92.6 PALCAN Handbook Edition 3 (December 2001) and CAN-P-1515 Conditions for the Accreditation of Calibration and Testing Laboratories, and CAN-P-1516 Guidelines for the Presentation of a Scope of Measurement or Testing for Applicant Laboratories.

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The following documents are issued separately and are available at:
http://www.scc.ca/en/publications/criteria/labs/index.shtml

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 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.

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 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 at info.palcan@scc.ca .

Laboratories accredited by the Standards Council of Canada are qualified to the requirements contained in the most recent editions of CAN-P-4E (ISO/IEC 17025: 2005) and CAN-P-1510E and the Policies, Procedures and Guidance documents contained or referred to in this document (CAN-P-1570).

INTRODUCTION

What is "Accreditation"?

The accreditation of a laboratory within the PALCAN program is a formal agreement between the Standards Council of Canada and the accredited laboratory. This agreement covers three specific aspects:

a. 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 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.

b. The accredited laboratory formally agrees to conform with 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 Laboratory"?

In addition to meeting the SCC requirements (CAN-P-4E) and Policies, Procedures and Guidelines contained or referred to this document, the PALCAN Handbook (CAN-P-1570), an applicant that is an *Accreditable Laboratory* must be:

- located at a single site;
- 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; this means that the SCC accreditation covers a distinct corporate entity and is limited to that entity within clear and distinguishable corporate boundaries; and
- subject to one quality management system, where the laboratory conducts testing and/or measurements 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 off-site (away from the main facility) satellite facility accreditation within the accredited unit. These are rare and must be reviewed on a case by case basis.

Disclaimer

Accreditation under CAN-P-4E is a demonstration of confidence in the laboratory'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 laboratory.

ACCREDITATION PROCESS

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

All PALCAN testing and calibration laboratory program requirements are contained in this Handbook or identified by reference to the applicable documents. Separate materials are available for Good Laboratory Practice Recognition and Proficiency Testing Provider programs. Technical requirements are defined in CAN-P-4E as supplemented with SCC specific interpretations for accreditation requirements as well as SCC specific Policies, Procedures and Guidelines. These are divided into two (2) principle categories that are defined in Section 5 of this document:

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

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

1.1 The PALCAN 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 Organisation receives the application and conducts the assessment of the applicant as well as the maintenance and surveillance activities. The Partner Organisation forwards a recommendation for accreditation to SCC. SCC retains the authority and right for the approval and granting of accreditation. Laboratories seeking SCC accreditation in the program specific areas that are serviced by SCC Partner Organisations (refer to Sections 1.1 a, b or c) should contact the relevant Partner Organisation(s) for additional instructions and interpretations of accreditation requirements. Contact information for the relevant Partner Organisations is given in 1.1 a, b and c below. In those cases, applications and fees are processed directly through the Partner organisation rather than through the SCC.

Where the activities of a laboratory seeking accreditation do not fall within the Partner Organisation activities as described in this section, the laboratory will be served by SCC directly. In these cases, 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-15. Mandatory withdrawal of a laboratory'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 laboratory 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, successful applicant calibration laboratories are eligible for CLAS certification and are eligible for a license to use the CLAS logo. Those interested in learning more 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. The Canadian Association for Environmental Analytical Laboratories (CAEAL)

CAEAL is the Partner organisation for environmental laboratories licensed to conduct drinking water testing under Ontario's Safe Drinking Water Act (OSDWA). Information for application through CAEAL can be obtained from the CAEAL website at:

http://www.caeal.ca

NOTE: All other environment testing (other than OSDWA) is accredited through the SCC PSA-ET program.

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

BNQ-EL is the Partner organisation for those laboratories in Quebec who may wish to participate in the SCC's PALCAN through BNQ-EL. Consult the BNQ-EL website for details:

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

1.2 To become accredited, laboratories shall meet the general requirements outlined in CAN-P-4E as well as applicable Policies, Procedures and Guidelines contained in or referred to in this document. Those Policies, Procedures and Guidelines not contained in this document are outlined in Section 5. The PALCAN accreditation process will allow the laboratories to demonstrate their competence and establish compliance with the requirements. Laboratories must demonstrate competence to perform the specific tests, types of tests or measurements 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 SCC and the Partner organisations will be treated in the strictest of confidence. 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 laboratory's name, along with the Scope of Accreditation, is posted on the SCC web-site.

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 conformance with each one;

b. to enable PALCAN staff or the Partner organisation to detect any potential non-conformance 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 laboratory.

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/lab/index.shtml

1.6 As a signatory to the Asia Pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (APLAC MRA – APLAC MR-001), 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-area of major disciplines of a laboratory's Scope of Accreditation every four years (preferably on a yearly basis)

NOTE 1: 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, European Co-Operation for Accreditation (EA), IAAC or equivalent) where these are available.

NOTE 2: Annual participation in PT is required where available.

NOTE 3: Laboratories should use proficiency testing programs which conform to the operational procedures detailed in ISO/IEC Guide 43-1 (1997).

1.7 Some Program Specialty Areas (PSAs) have specific requirements pertaining to proficiency testing participation; refer to the individual PSA CAN-P guidelines for additional information (refer to Section 7 of CAN-P-1570 Appendix B).

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-15.

1.9 Following the outcome of the complaint resolution by SCC, should the CAB believe that the complaint has not been satisfactorily addressed; the CAB 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 SCC policy that applicants first approach the ILAC member accreditation body in their own countries. Where SCC accreditation is required by the applicant, the application will be considered.

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

2.3 PALCAN or the appropriate Partner organisation will evaluate inquiries to determine their eligibility as an accredited laboratory and if applicable will forward an application package.

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

2.5 The applicant is encouraged to hold discussions with the PALCAN technical staff or the appropriate Partner organisation before submitting an application for accreditation.

3 Application

3.1 SCC Applications

The following applies to applications to PALCAN for accreditation as a testing laboratory. [1]

[1] If the applicant is seeking recognition under Good Laboratory Practice Recognition (GLP), please consult CAN-P-1583 and 1584 for the appropriate program and application information. If the applicant is seeking accreditation as a Proficiency Testing Provider, please consult CAN-P-1593 and 1594 for program and application information.

a. The Applicant submits a completed application package in accordance with CAN-P-1570 Appendix A of this document to the Program Officer Applications of SCC (PALCAN). The application is accompanied by the specified documentation and the proposed scope of accreditation. The proposed scope is prepared by the applicant in accordance with the guidance and criteria provided in CAN-P-1570 Appendix B. The proposed scope of accreditation is a list of the methods for which the applicant is seeking accreditation.

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 SCC will be treated in accordance with the terms outlined in the *Confidentiality Clause* as mentioned in section 1.3.

d. SCC will close any application that has been inactive for more than 180 days. An application will be considered inactive if written responses to SCC requests, such as required actions or requests for additional information are not received. 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.

e. SCC will formally acknowledge receipt of the completed application, review the contents and provide an estimate for the cost of the evaluation of the application, becoming accredited and maintaining accreditation. Upon receipt of the fee for evaluation and an acknowledgement accepting the estimate for the remaining cost, SCC will begin the evaluation of the application. Applicant laboratories should refer CAN-P-1570 Appendix C to determine the financial aspects related to accreditation.

3.2 SCC Partner Applications

The following applies to applications submitted to Partner organisations.

a. **BNQ-EL**. Applicant laboratories from Quebec that wish to acquire SCC accreditation through BNQ-EL must return a completed BNQ-EL application to BNQ-EL. BNQ-EL documentation can be obtained by contacting; Laboratory Assessment, Tel. 1-800-386-5114, Fax. (418) 652-2221, E-mail: bnqinfo@bnq.qc.ca. BNQ-EL information may also be obtained from the BNQ-EL website at http://www.bnq.qc.ca/en/labo/index.html.

b. **CAEAL** Applicant environmental laboratories testing drinking water under Ontario's Safe Drinking Water Act that wish to acquire SCC accreditation must follow the application process described on the CAEAL web page at http://www.caeal.ca. CAEAL information may also be obtained by telephone at (613) 233-5300.

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

http://inms-ienm.nrc-cnrc.gc.ca/clas/application_forms_e.html or
http://inms-ienm.nrc-cnrc.gc.ca/clas/application_forms_f.html

3.3 Group Accreditations

Group Accreditation is available to Organizations with multiple sites accredited by SCC and that meet the following 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

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

4 Evaluation of the Application

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 need to be resolved within 90 days of the receipt of the report and require the submission of an initial plan of action within 30 days. Their resolution will require that the applicant laboratory make changes to their documentation or provide clarification on how the requirement has been met. Formal response with supporting evidence is required. The concerns are potential required actions which the laboratory will need to review and discuss at the assessment visit.

4.2 In cases where the evaluation identified that substantial amendments to the quality management system documentation would be required, a laboratory will be required to agree to a pre-assessment visit. The purpose of this visit will be to review the required actions with the laboratory to ensure the required corrective actions are warranted and understood. The cost of this visit will be in addition to the fees previously estimated.

4.3 Upon resolution of the required actions, PALCAN will determine a mutually agreeable date to conduct the assessment visit and will notify the laboratory 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. Formal notification of the assessment visit will be provided at least four (4) weeks 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 listed on the scope of accreditation for the team and other additional records and documents as determined during the application evaluation.

5 Policies, Procedures and Guidelines

In addition to the requirements of CAN-P-4E and this document, SCC has published a number of Policies, Procedures and Guidance documents that also contain criteria and specific interpretations of CAN-P-4E.

All documents of the CAN-P-1500/1600 Series are available without charge from the SCC web site at http://www.scc.ca/en/programs/lab/publications.shtml by selecting "Criteria & Procedures".

5.1 General Program Policies, Procedures and Guidelines

CAN-P-4E is supplemented with interpretations of specific requirements. These interpretations apply to all testing laboratories, as well as calibration laboratories in certain cases, and are contained in separate documents as follows:

CAN-P-1623 *PALCAN Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing (APLAC TC-005)*
CAN-P-1624 *PALCAN Policy on the Use of Proficiency Testing as a Tool for Accreditation in Testing (ILAC G22:2004)*
CAN-P-1625 *PALCAN Policy on Serious and Critical Non-Conformities*
CAN-P-1626 *PALCAN Policy on Traceability Requirements for Calibration Sources Used By Accredited Testing Laboratories*
CAN-P-1627 *PALCAN Policy on the Selection of Physical Measurement Calibration Sources for Testing Laboratories*
CAN-P-1628 *PALCAN Policy on the Use of Information Technology in Accredited Laboratories*
CAN-P-1629 *PALCAN Guidelines for Validation of Test Methods*
CAN-P-1630 *PALCAN Interpretations for Conducting Assessments of Testing and Calibration Laboratories*
CAN-P-1631 *PALCAN Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status (ILAC G14:2000)*

5.2 Program Specific Policies, Procedures and Guidelines

CAN-P-4E is supplemented with program specific interpretations of requirements and includes the interpretations specific to Partner Organisation areas of activity. Calibration 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 7 of CAN-P-1570 Appendix B.

6 Assessment

6.1 PALCAN will select an assessment Team usually composed of a Team Leader and at least one appropriate Technical Assessor. Generally, assessment teams may be led by an SCC Senior Program Officer (SPO) or alternatively by a contracted Team Leader (TL). 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 conformance with the requirements of CAN-P-4E, the Policies, Procedures and Guidelines in this document, as well as any applicable program specific documentation (refer to section 5 above). 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 where relevant. There are specific proficiency testing requirements for some Partners organisations such as CLAS and CAEAL, and for some Program Specialty Areas (PSA's).

6.3 Assessment teams will normally consist of a PALCAN-qualified Team Leader and at least one Technical Assessor for each field of testing (see CAN-P-1570 Appendix B) 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. 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 required actions, which must be addressed within six months of the visit, and the recommended actions, 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 The assessment team will produce a final report of the assessment visit and PALCAN 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 follow-up report usually within 10 days of the visit.

6.6 Applicants have the right to challenge any action cited in a visit follow up report. An applicant must submit a challenge in writing to the PALCAN Manager, Laboratory Accreditations no later than 10 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 PALCAN, 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 follow-up report.

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

7 Approval

7.1 The final team report is forwarded for an independent technical review. Approval is confirmed through balloting.

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

7.3 All applicant laboratories 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 laboratory will receive an interim letter of accreditation signed by the Director of Conformity Assessment. The laboratory will also be required to sign an accreditation agreement (refer to CAN-P-1570 Appendix D). The SCC will forward a Certificate of Accreditation accompanied by a letter of accreditation from the Chair of SCC to the newly accredited laboratory. The accreditation certificate can be made available in electronic format on request. In the case of successful calibration laboratory applicants, the Certificate of Accreditation is issued jointly with the National Research Council of Canada and dually serves for CLAS Certification. Similarly, accreditation certificates for environmental laboratories testing drinking water under Ontario's Safe Drinking Water Act are issued jointly with CAEAL, and accreditation certificates for laboratories assessed by BNQ-EL are also issued jointly.

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 laboratory from applying again at a later date.

8.3 The accredited laboratory is encouraged to make use of the SCC accreditation mark to publicise its accreditation. A copy of the Trademark License Agreement (see sample in CAN-P-1570 Appendix E) is provided to the newly accredited laboratory 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 laboratory. 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

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

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

b. In the years between reassessment visits, the laboratory 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 laboratory 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.

c. The reassessment visits conducted by PALCAN or the appropriate Partner organisation 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 laboratory will be formally notified when a reassessment is due and the notification will provide requirements for pre-visit submission. The laboratory shall provide PALCAN with the updated information.

e. PALCAN and the appropriate Partner Organisations follow the same process as for an assessment, per section 6 of this document, with the following exceptions:

- The accredited laboratory has 90 days, in lieu of 180 days, to resolve any required actions group A;

- The accredited laboratory is notified in writing of continued accreditation, along with a revised scope, and when necessary, a new certificate will be issued.

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 initially scheduled 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 initially scheduled 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, 2005
2. Accreditation granted	March 07, 2007
3. First Reassessment Visit	**May 26, 2007**
4. Surveillance Questionnaire	May 26, 2008
5. Next Reassessment Visit	**May 26, 2009**
6. Surveillance Questionnaire	May 26, 2010

In addition to these criteria, the following conditions also apply:

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 laboratory staff. The visits MUST take place within 3 calendar months of the due date.

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

9.2.2 Changing the Scheduled Due Dates

The laboratory 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. Laboratories 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 a laboratory 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 laboratory may request a further delay.

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

A laboratory authorized representative can request a change in visit due date by contacting the Senior Program Officer (SPO) responsible for the laboratory 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 PALCAN or the appropriate Partner organisation to confirm that specified requirements have been fulfilled. Verification visits are conducted as a follow up visit to an assessment or reassessment visit when it was found that there were serious and critical non-conformities in accordance with CAN-P-1625. The reasons that such confirmation may be required include:

a. Verification of the implementation of corrective actions that cannot be satisfactorily substantiated through a simple documentation review. Verification visits may be the result of a laboratory 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 laboratory as indicated in the current Fee Structure in CAN-P-1570 Appendix C.

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

c. Substantial findings requiring corrective action related to the quality management system documentation were identified during the assessment or reassessment visit.

Laboratories that are unwilling to undergo such a visit within the specified time frame will normally be suspended until such time as a visit provides evidence of the continued competence of the laboratory to conduct the tests 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 to conduct a verification or surveillance visit of the laboratory. An on-site visit of generally no more than one day will take place to assess the maintenance of the quality management system, and/or technical activities of the laboratory, and to confirm that recommendations of the previous on-site visit are being implemented. The laboratory 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 about the technical competence of the laboratory or the implementation of its quality management system relating to the Scope of Accreditation cannot be thoroughly addressed by submission of documentation.

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

11 Scope Extensions

11.1 Accredited laboratories may apply for scope extensions or modifications to their existing Scope of Accreditation, to SCC or to the applicable Partner organisation. This request may take the form of a formal application for Scope Extension, per CAN-P-1570 Appendix A. The SCC SPO or Partner organisation responsible for the file of the accredited laboratory 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 Major and Minor Scope Extensions are as follows:

Minor Scope Extension: The additional capabilities requested are not a departure from the laboratory'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. An on-site visit is not required.

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 laboratory 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 consenting to a minor scope extension.

When the evaluation confirms that the request is for a **minor** extension of the scope, the PALCAN staff member or the appropriate Partner Organisation shall then produce a *Minor Scope Extension* Report for submission to the Chair, TG Labs, with a recommendation to grant the minor extension. The Chair, TG Labs shall provide a recommendation to the Director, Conformity Assessment. PALCAN shall make the decision known to the appropriate Partner Organisation when applicable and shall communicate the decision to the accredited laboratory 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 laboratory requires the visit to be carried out sooner than the next scheduled reassessment, additional fees will apply. See CAN-P-1570 Appendix C for visits conducted by PALCAN, and applicable Partner Organisation documentation for their fee information.

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

12 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-15 *Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings.* This document is available on the PALCAN website at

http://www.scc.ca/en/publications/criteria/index.shtml.

12.1 Suspensions

a. The suspension, or even withdrawal, of accreditation of a specific scope does not, of itself, represent suspension or withdrawal of the whole laboratory where a laboratory has multiple scopes with SCC. Individual tests can be suspended following 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. Laboratories may also voluntarily withdraw certain tests from their scopes on written notification to SCC.

b. An entire laboratory may be suspended. This may result, for example, from the laboratory's non-conformance to the requirements of accreditation, or for non-payment of outstanding invoices. The laboratory's 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. A laboratory's full "accredited" status would be reinstated only after satisfactory resolution of the reason(s) for suspension.

12.2 Voluntary Withdrawal

An accredited laboratory 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. Partner Organisations will forward all laboratory notifications of voluntary withdrawal to the SCC for processing.

12.3 Enforced Withdrawals

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

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

12.4 Public Notification of Withdrawal

PALCAN will publicise all instances of voluntary as well as SCC enforced withdrawal of accreditation on the SCC website. In addition, CLAS publishes all suspensions and withdrawals of accreditation of calibration laboratories in the Directory of the Canadian Calibration Network on the CLAS website for a predetermined period.

12.5 Reapplication after withdrawal

Full withdrawal of accreditation will not preclude a laboratory from applying for accreditation again at a future date. Partial withdrawal of the accredited scope also does not prevent the laboratory 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.

12.6 Complaints

If a laboratory is dissatisfied with the actions taken by the SCC during the accreditation process, or disagrees with an interpretation made by SCC, that laboratory may submit a formal written complaint to the SCC. Please refer to clauses 7-12 of CAN-P-15 for the processing of complaints.

12. 7 Appeals/Hearings

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

13 Publicity Guidelines

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

13.1 SCC Sponsored Publicity

PALCAN and the Partner Organisations will publicise the accreditation of laboratories in several ways, such as the following:

a. an official Certificate of Accreditation, for public display, will be provided to each laboratory following accreditation;

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

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

d. 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;

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

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

13.2 Recommended Publicity Practices for Accredited Laboratories

a. Laboratories may publicise their accredited status in several ways. Accredited laboratories may include the following statement on their company letterhead and advertisements without further approval from SCC. An accredited laboratory 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 laboratories 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 and APLAC Mutual Recognition Arrangements, under clause 5.10.1 of ISO/IEC 17025: 2005, SCC accredited laboratories 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 organizations mentioned in the statement above, for the information of the laboratories:

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

13.3 Other Publicity Practices

Laboratories that promote their accredited status, or make any reference to their accredited status in a manner deviating from clause 12.2 a) may do so only with the prior approval of the Manager, Laboratory Accreditations, and the appropriate approval authority from a Partner Organisation where this is applicable. Advice and assistance for other laboratory initiated publicity are also available from the PALCAN Senior Program Officers.

13.4 Publicity Restrictions

The following restrictions apply to publicising an accredited status:

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

b. similarly, no statement or mark relating to laboratory accreditation may appear on any product, package or test report (except as allowed in clause 13.2b);

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

13.5 Guidelines for the use of Accreditation Certificates

a. The accredited organization 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 attached as CAN-P-1570 Appendix E.

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.

13.6 SCC Trademark License Agreement

Accredited laboratories 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 laboratory.

13.7 ILAC Mark Sublicensing Agreement

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.

13.8 Use of Partner Organisation Logos and Promotional Materials

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

14 Proficiency Testing Provider Accreditation (PT)

Proficiency Testing Providers that serve laboratories and groups of laboratories may seek formal accreditation of their competence in the provision of these services. Such formal recognition of competence from the SCC is provided under the PT PSA. Applicant organisations will normally be involved in the development and delivery of PT samples, and the analysis of PT results from these client laboratories. Accreditation will include examination of the competence of the laboratories and organisations involved in sample production. Accredited Proficiency Testing Providers comply with the requirements of ISO/IEC Guide 43 (Parts 1 and 2) and the SCC assessment criteria document (CAN-P-1594) is substantially based on ILAC G13

For this Program Specialty Area, interested parties are asked to complete the application form in CAN-P-1593 (Annex B) which is available on the SCC website at:
http://www.scc.ca/en/programs/lab/profictest.shtml

The PT Fee Structure is available upon request to SCC.

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

The Standards Council of Canada (SCC) GLP Compliance Recognition Program is recognized by the Canadian Pest Management Regulatory Agency (PMRA)
(http://www.hc-sc.gc.ca/pmra-arla/english/aboutpmra/about-e.html)
in its role as the Regulatory Authority for pesticide registration in Canada. It is therefore directed primarily towards domestic test facilities, including field sites involved in pre-registration human health and environmental safety testing of pest control products. The program's scope includes physical-chemical property, analytical, residue and toxicological or eco-toxicological studies as defined by the Regulatory Authority requiring GLP compliance. A comprehensive list of studies requiring compliance to the principles of GLP, and the corresponding implementation schedule for GLP compliance, is available from the PMRA.

The applicable Fee Structure for this Program is available upon request to SCC.

For this program, interested parties are asked to complete the application form in CAN-P-1584 (Annex A) which is available on the SCC website at:
http://www.scc.ca/en/publications/criteria/labs/glp.shtml