Standards Council of Canada
Conseil canadien des normes

Accreditation Services

Accreditation Program Overview

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Introduction

Standards Council of Canada

The Standards Council of Canada (SCC) is a Crown Corporation established by an Act of Parliament in 1970 to foster and promote efficient and effective voluntary standardization in Canada. SCC's services include the accreditation of Standards Development Organizations (SDOs) and the approval of National Standards of Canada (NSCs); the promotion of the use of standards in regulations, legislation; and the various programs offered by the Accreditation Services branch.

SCC also administers the OECD Good Laboratory Practice (GLP) initiative in Canada. GLP requirements were developed by the Organization for Economic Co-operation and Development (OECD). In this document, where the term "accreditation" is used, it is understood that this includes GLP recognition. As well, where the term "assessment" or it derivatives is used, it is understood that this includes GLP inspections.

Accreditation

ISO/IEC 17000 defines accreditation as "third-party attestation (5.2) related to a conformity assessment body (2.5) conveying formal demonstration of its competence to carry out specific conformity assessment tasks." SCC, as an accreditation body, uses a formal process to independently assess the capabilities of conformity assessment bodies.

The SCC is delivering accreditation services primarily to Canadian customers working in Canada and abroad and international customers doing business in Canada. As a national organization and by statute, SCC is required to provide services in two official languages - English and French. These are the only languages in which SCC's Accreditation Services operate.

Benefits of Accreditation

There are many reasons why an organization may consider accreditation. Although all accreditation programs are by definition voluntary, in some instances, there may be regulatory or legislative requirements for being accredited, sometimes even specifically for SCC accreditation. In other cases, market forces may dictate that business should go predominately to organizations that are accredited. Apart from these two factors, accreditation can be of great value to an organization. Accredited organizations often find that working under an accredited Quality Management System improves the efficiency of its staff and operations, and the quality of its products or services. As well, being accredited by a recognized Accreditation Body such as SCC instills increased consumer confidence in the value, quality, and safety of products, services, and test results.

Benefits of SCC Accreditation

SCC currently has approximately 500 customers in Canada, the U.S., and around the world, and is renowned for the thoroughness and value of its accreditation programs. Internationally, SCC is an active member of several Mutual Recognition Arrangements, including the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC), the Inter American Accreditation Cooperation (IAAC), and the Asia Pacific Accreditation Cooperation (APAC). These organizations arrange for peer evaluations of SCC and its accreditation programs once every four years. SCC also participates in the peer evaluations of accreditation bodies around the world. SCC staff persons are friendly, knowledgeable, and professional, and offer full services in both English and French. As well, the OECD performs a Mutual Joint Visit of SCC's GLP program every ten years.

Cost of Accreditation

Although SCC is a non-profit Crown Corporation, there are fees for its accreditation programs. Each applicant pays an application fee, and once accredited, a customer pays an annual fee, and is responsible for the fees of the assessment activities carried out by SCC, including travel and accommodation. Travel and accommodation costs are carried out following SCC Travel Policy, which is in alignment with Treasury Board guidelines. These fees are presented more specifically in the Fee Structure annexes of each program's respective Accreditation Licence Agreement.

Enquiries

Potential applicants should visit the SCC website (www.scc.ca), where further information on the various SCC accreditation programs may be found. This will help prospective applicants make a decision that fits the accreditation needs of their organization.

The information includes descriptions of SCC's ten accreditation programs:

- Management Systems Certification Body Accreditation
- Product, Process, and Service Certification Body Accreditation
- Certification Body Operating in Certification of Persons Accreditation
- Greenhouse Gas Validation and Verification Body Accreditation
- Inspection Body Accreditation
- Testing and Calibration Laboratory Accreditation
- Medical Laboratory Accreditation
- Proficiency Testing Provider Accreditation
- Good Laboratory Practice Recognition
- Standards Development Organization Accreditation

SCC's website also contains information of various sub-programs, program specialty areas, and schemes that are available within these ten programs. As well, the website has information on all SCC accredited organizations in all programs, accessible via a searchable database.

While this document applies to all ten programs mentioned above, each program has its own unique differences, such as Accreditation Cycle periods. This information is detailed in individual appendices at the end of this document.

Application

Once a potential customer is ready to apply, they may request an application package through SCC's website. The application package will request basic information on the operations of the customer, as well as the submittal of some basic documentation.

Once the applicant has compiled the necessary documentation, they submit it, with the completed application form to SCC. Payment of the applicable application fee is required at this time in order for the application process to begin. Please note that submitting an application does not automatically guarantee that the application will go forward. If, following the initial review the application is not accepted, the initial application fee is non-refundable.

All application information submitted by the applicant will be considered confidential. It will not be disclosed outside of SCC or its contracted resource base[1].

If the applicant is based in another economy[2] with an accreditation body that is a member of IAF and/or ILAC, SCC will recommend the applicant seek accreditation from the local or regional body. It will ultimately be the applicant's decision as to whether to continue with SCC accreditation.

The application will then be processed and an Account Manager (AM) will be assigned. An initial review of the application package will be performed. If any information is missing or incomplete, the applicant will be contacted.

Part of the initial review will involve the AM determining whether or not the assessment can be carried out within SCC's required timelines. As well, they will perform a risk assessment of the applicant, which may include, but is not limited to, a credit check.

[1] SCC is a federal crown corporation and as such, is subject to the "Access to Information Act". This Act provides exemptions for commercial information which allows SCC to refuse to disclose records that contain trade secrets or financial, commercial, scientific or technical information which if released, could damage the customer's competitive position. As such, SCC will endeavor to maintain the confidentiality but must abide by the provisions of the Act. Where law requires information to be disclosed to a third party, the customer shall be informed of the information provided.
[2] If the customer is not based in an economy that is a WTO member economy, the application will be rejected.

Once it is determined that the application may proceed, the applicant will be informed and the accreditation process will begin. If the application is not accepted, the AM will communicate with the applicant and share the details as to why the application was not accepted. SCC shall recommend a pre-assessment visit if it feels it is necessary following the identification of significant deficiencies with the submitted information. The applicant themselves can also request a pre-assessment visit.

Assessing Customer Readiness

Once the application is accepted, the next step is the document review. SCC will perform a review of the documents submitted by the applicant to verify whether its management system, policies, and procedures meet the relevant requirements of the accreditation program applied for and the applicant's readiness. If any nonconformity arises from this review, the reviewer will contact the applicant and request the applicant submit responses to the required actions.

Assessment

When all of the nonconformities that arose from the document review have been resolved, the AM will contact the applicant to set up the assessment visit plan. Depending on the program, the applicant could be subject to head office assessments, fixed office location assessments, witness audits, and other surveillance activities, as deemed appropriate. SCC staff will work with the applicant to find mutually agreeable dates for all applicable activities.

For the initial assessment, SCC will visit all fixed office locations where key activities are performed and/or managed, or from which remote personnel performing key activities are managed, and/or where records are maintained. Where appropriate, SCC will also visit fixed office locations where other activities covered by the requirements of the relevant conformity assessment standard(s) are performed, or from which personnel performing these activities are managed.

The next step is the formation of the assessment team, or teams if more than one activity is required. The team will include a team leader, referred to as a Lead Assessor[3], as well as other assessors, technical experts, and observers, if needed, and an independent reviewer (the independent reviewer is not participating in the on-site assessment). The applicant will be informed of all team members ahead of time. If the applicant objects to any of the team members, they must inform the AM in writing, with justification, within two (2) business days of being notified of the team. The AM will then review the provided justification and may change the makeup of the team if they determine that it is a valid objection.

[3] Note that for the GLP program, Lead Assessors and Assessors are referred to as Lead Inspectors and Inspectors.

The AM will work with the Lead Assessor to review any significant items and issues that were identified during the document review. The Lead Assessor will then prepare the assessment plan for the activities and the plan will be sent to the applicant for review. It will provide an outline of which areas of the applicant's operations will be reviewed at various points during the assessment schedule. The assessment plan will also inform the applicant of which areas will be reviewed at what times of the day, so as to provide as minimal disruption to the applicant's operations as possible. These assessment activities are to give SCC a representation of how each operation normally runs.

At the beginning of the first day of the assessment, the Lead Assessor will hold an opening meeting. The entire assessment team will be present at this meeting, and the applicant should include whatever staff it feels is appropriate.

During the opening meeting, the Lead Assessor will outline the scope of the assessment and introduce the team members, as well as which areas they will be focusing on. The applicant should take this opportunity to introduce its key personnel, and provide any safety or administrative information to the assessment team as necessary. If possible, it's often useful to provide the assessment team with some orientation of your facilities. A brief tour of the facility follows the opening meeting. This helps the team members orient themselves within the facility and provides an overview of specific activities.

During the on-site assessment, the team will require access to information demonstrating conformity to the accreditation requirements. Where nonconformities (NCR) are found, copies demonstrating evidence of the NCR may be requested by the assessment team. Applicants shall ensure the availability and retrievability of the required information. If the applicant has specific confidentiality issues that may interfere with this requirement, they are requested to discuss this ahead of time with their assigned SCC AM, so that arrangements can be made ahead of time. That said, all assessment team personnel are required to sign confidentiality agreements.

The assessment team will take detailed notes on their observations of the applicant's operations, as well as their review of the applicant's documents and records. When interviews with personnel and review of records have been completed, the team will meet to consolidate their notes and findings in the form of the Findings Report, for presentation to the customer at the closing meeting, As well, the team may, as appropriate, provide the customer with a brief update at the end of each day onsite of any nonconformities uncovered during that day. This will give the customer the opportunity to provide any follow-up documentation that may resolve the nonconformity before the Findings Report is compiled.

At the end of the last day of the assessment, the Lead Assessor will lead the closing meeting. The Lead Assessor will present the Findings Report and ensure that it is understood by the customer. The applicant will be requested to formally acknowledge the receipt of the Findings

Report. If there is disagreement between the team and the customer regarding any of the findings, they should be discussed and resolved, if possible while the team is on-site. If not resolved, all opinions shall be recorded and reported to SCC. The applicant is encouraged to involve their senior management in both the opening and closing meetings.

Addressing Nonconformities

At the conclusion of the closing meeting, or shortly thereafter, the applicant will be provided with an electronic copy of the Findings Report. The applicant will be instructed to respond to the findings with an initial plan of actions within one month (30 days) of receipt of the Findings Report, and evidence of corrections and implementation of corrective actions so that closure of nonconformities have been approved by SCC within three months (90 days) of the receipt of the Findings Report.[4]

Once the applicant has submitted their initial plan of action relative to each finding, SCC will have ten business days to review and respond to the plan. If the plan is deemed incomplete or unsatisfactory, the applicant will have up to two more attempts at their plan, before additional actions may be taken by SCC, noting that they must still complete the required actions within the 3 month (90 days) timeframe.

Once the plan has been accepted, the applicant will have the remainder of the original three month timeframe to complete the corrections, implement their corrective actions, and obtain SCC approval for closure. This evidence should be submitted to SCC (through the Findings Report) in advance of the deadline, to allow SCC assessors appropriate time to assess the evidence. As with the initial plan, the applicant will have three attempts at delivering appropriate evidence. If, with either the initial plan or the implementation evidence, the applicant's submissions are deemed unsatisfactory, or the applicant exceeds the timelines, the applicant may be subject to the withdrawal of the application (for an applicant customer) or the customer may be subject to suspension (for an accredited customer).

If there is still disagreement between the applicant and the assessment team on a particular finding at any point in the process, and the applicant wishes to formally challenge them, please refer to the Complaints section of this document.

[4] For GLP, no initial plan is required within 30 days. Only the 90 day timeline applies.

Decision

At the time that all nonconformities have been resolved to the satisfaction of the Lead Assessor, the team will prepare the final Accreditation Report. The report will contain the recommendation of the Lead Assessor as to whether the applicant has met the requirements of accreditation.

SCC will then call upon the Accreditation Review Team (ART) to review the report and other supporting documentation to ensure that SCC's accreditation procedures have been fulfilled, and that the resolution of the nonconformities has met all requirements for accreditation. The ART will typically be made up of one or more technically qualified staff in the program and/or applicable sub-programs in which the customer operates, including experts in the areas of quality management and accreditation if applicable. The ART may be comprised of both SCC or contracted staff. No member of the original assessment team for the activity will participate in the ART. If the ART finds that the report is not sufficient, they may request further information and may request additional assessment activities.

The result of the ART review will be a recommendation to the Vice President, Accreditation Services, as to whether or not the applicant has met the requirements for accreditation. The Vice President or delegate will review the ART's recommendation, along with the Accreditation Report and other supporting documentation, and make the final decision to grant accreditation (or continued accreditation, for an already accredited customer). The Vice President has been granted this decision-making authority by SCC's governing council.

SCC will advise the applicant on the decision, and provide documented justification if the result is to not grant accreditation. The applicant has the option to appeal this decision, as per the Appeals section of this document.

Publication of Accreditation

Once the final accreditation decision has been made, SCC's Finance department will verify that the customer has fully paid all invoices issued. Those payments must be made before the actual accreditation can be granted.

SCC staff will prepare an Accreditation Licence Agreement for the customer which contains the contractual obligations of the customer and SCC, as well as rules and guidelines for the publication of the customer's accreditation status. Upon signature, the customer will be provided with, if they so choose, the SCC accreditation symbol applicable to their accreditation program, which the customer can use in its publicity. The guidelines and restrictions of use of this symbol are outlined in this agreement. Finally, the agreement also contains the Fee Schedule applicable to the customer in their chosen accreditation program. Payment of all fees in a timely

manner (as per the schedule) is a condition of accreditation; failure to do so may result in suspension and/or withdrawal of accreditation.

SCC will also prepare for the customer an official SCC Certificate of Accreditation. It will be signed by the Vice President, Accreditation Services, and affixed with the SCC seal. The customer will be presented the original signed certificate, suitable for framing. Many customers choose to mount their certificates in the main lobby or reception area of their facilities.

SCC will also post a notice of each customer's accreditation on SCC's website, and customers are invited to submit testimonials of its service for posting as well. Also, customers are encouraged to contact SCC if they have any comments, questions, concerns or praise about its service, and its staff.

Within the week following the publication of the accreditation, the customer will be sent by email a link to complete an online satisfaction survey concerning the completed assessment activity. Although completion of this survey is not mandatory, SCC encourages customers to provide their experience and honest opinions about the activity. These surveys are reviewed upon receipt so that SCC can assess its personnel, operations and processes, with the objective of continuously improving its service to customers.

Publicity Guidelines

A significant benefit of SCC accreditation is that an accredited customer may publicize its competence based on a nationally and internationally recognized accreditation program. SCC encourages such activities; however, restrictions apply to prevent misunderstanding about the significance of accreditation.

An accredited customer shall, when requested, make available to SCC staff and assessors, any advertising or promotional material making reference to its accreditation in communication media such as the internet, documents, brochures, etc.

The following are the publicity guidelines. An accredited customer shall:

(a) Only use the SCC accreditation symbol provided to them for premises of the customers that are specifically included in the scope of the accreditation;
(b) Only make claims of accreditation in respect of activities for which it has been granted accreditation;
(c) Not use its accreditation in a manner as to bring SCC into disrepute;
(d) Not make any statement regarding accreditation that SCC may consider misleading and unauthorized;
(e) Not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by SCC;
(f) Ensure that no report or certificate nor any part thereof is used in a misleading manner.

As SCC is a signatory to the IAF MLA, accredited customers for QMS, EMS, or Product, Process or Service certification may use the IAF MLA Mark in accordance with the defined principles which can be found in IAF ML 2:2016 General Principles on the use of the IAF MLA Mark. Prior to using the IAF MLA Mark, the customer is required to sign an IAF MLA Licensing Agreement, which is available upon request from SCC.

As SCC is a signatory to the ILAC MRA, accredited testing, calibration, and medical laboratories may use the ILAC MRA Mark in accordance with the defined principles which can be found in ILAC R7:05/2015 Rules for the Use of the ILAC MRA Mark, as well as ILAC P8:12/2012 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies. Prior to using the ILAC MRA Mark, the customer is required to sign an ILAC MRA Licensing Agreement, which is available upon request from SCC.

Verification of a customer's publicizing of its accreditation is a regular part of each assessment activity performed by SCC. If it is found that the customer has made incorrect references to their accreditation status, or has used the SCC accreditation symbol, IAF MLA Mark, or ILAC MRA Mark in a misleading way, SCC will require the customer to take appropriate actions to remedy the situation. These actions range from a request for corrective action, to, if warranted, the initiation of suspension of accreditation, publication of a correction or possibly legal action.

Accreditation Certificates

The customer may use their Certificate of Accreditation issued by SCC in any reasonable manner while the recipient's accreditation is valid. 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.

However, the customer may not use the Certificate in advertising without the prior consent of SCC. As well, the customer may not authorize a third party to use the Certificate.

Maintaining Accreditation

Once the customer has been granted accreditation, the accreditation cycle will commence, and there will be activities at regular intervals. These activities can include reassessment visits, surveillance visits, and witness audits. As well, SCC will also assess each applicable Fixed Office Location identified on the customer's Scope of Accreditation at least once per accreditation cycle, as indicated in the Accreditation Cycle Plan. Finally, the customer could choose to either expand or reduce the scope of their accreditation.

At regular intervals within the accreditation cycle the customer will be subject to a reassessment visit. The process for this visit is similar to the initial assessment process, as outlined in this document. SCC staff will contact the customer approximately three months before the scheduled reassessment. In that communication, the customer will be advised of what documentation they are required to submit, and the timelines for doing so. All other steps in the process remain the same.

Over the course of the customer's accreditation cycle, as a result of any nonconformity raised during the assessment activities, it may be necessary to schedule extraordinary assessments. If this is the case, SCC will notify the customer in advance, and the assessment process for this activity will be identical to the regular assessment process outlined in this document.

Scope Extensions and Reductions

It is possible that, at some point, the customer will decide that they need to either expand or reduce the scope of accreditation.

If the customer decides to expand their scope of accreditation, the customer will submit a request for scope modification, along with the necessary documents relevant to the areas they wish to add to their scope. From there, they will follow the same process as outlined in this document. SCC assessment staff will review the request, and determine the appropriate course of action. If the requested additions to the scope are deemed to be significantly different from the customer's existing scope of accreditation, an additional on-site assessment activity may be required, at a cost to the customer. If the request is not significantly different, the request may be assessed and completed without any additional on-site activities. Please note that there are costs to a scope extension, and these are outlined in the Fee Schedules accompanying each respective program's Accreditation Licence Agreement.

If for whatever reason, the customer wishes to reduce their scope of accreditation, the process is simple. The customer must make the request in writing, and once reviewed and approved, SCC staff will make the necessary changes to their scope of accreditation. The customer's scope reduction may entitle them to a partial refund of some annual fees; the parameters of this are outlined in the Fee Schedules accompanying each respective program's Accreditation Licence Agreement.

Circumstances may arise where the customer's accreditation must be either suspended or withdrawn. The suspension or withdrawal process may be voluntary, on the part of the customer, or imposed by SCC. The policies and procedures for both suspension and withdrawals are outlined in detail in the Suspensions and Withdrawals section of this document.

For any questions about SCC's accreditation programs, please visit www.scc.ca or contact SCC staff at accreditation@scc.ca.

Transfer of Accreditation

If an organization wishes to achieve SCC accreditation, and is already accredited by another Accreditation Body, it may be possible to transfer its accreditation. A transfer of accreditation is essentially a shortened application process that may not require an initial on-site assessment activity. SCC will only consider a transfer of accreditation if the organization is currently accredited by an accreditation body that is a signatory to ILAC, IAF, or a regional body member of either of those organizations. As well, if the applicant is from an economy outside of Canada, SCC's policies for cross-frontier accreditation will apply.

In order to determine whether a transfer of accreditation is feasible, SCC staff will request certain information from the applicant organization, including a copy of its last assessment report from the existing accreditation body. This will also help determine the timeline for the on-site assessment activity once accreditation has been granted by SCC.

Complaints

A complaint is an expression of dissatisfaction, other than an appeal, by any person or organization, against SCC, an SCC Service Delivery Partner or an accredited or applicant organization, where a response is expected, or an instance where a difference of opinion or interpretation on a program requirement justifies a formal documentation of the proceedings. Complaints must be submitted in writing, although verbal or other forms of communication may be made initially to advise SCC that a formal written complaint may be expected. The onus is on the complainant to articulate the nature of the complaint, and to provide the evidence and justification for the complaint. SCC will not take any direct action until the complaint is received in writing and supporting evidence has been provided.

If a complaint is centered on dissatisfaction with the accredited organization, its customers or competitors, it must initially be addressed directly to the most relevant body (e.g., the accredited customer). SCC will become involved in complaints only when discussions with such relevant bodies have been undertaken and unsatisfactorily resolved.

If a complaint is in regard to a specific finding raised during an assessment activity, the customer is required to submit the complaint in writing to the Account Manager, within ten (10) business days of the issuance of the finding. The customer is required to provide justification that the finding be withdrawn. These complaints will be assigned for review by an independent party with expertise related to the assessment, whose recommendation leads to a final decision

by SCC on the validity of the finding. A complaint on a finding will not normally alter the deadline for submission of evidence. The intention is that a complaint about a finding will not affect the overall timelines established for its resolution.

SCC will acknowledge, document and follow-up on all complaints and will assign a person for handling of the complaint giving respect to matters of confidentiality, conflict of interest and impartiality. SCC staff will validate the complaint, seek additional information where necessary, investigate and reply to the complainant in a timely manner. If the complaint cannot be validated the complainant will be informed.

SCC may involve other parties in the investigation and share the information received from the complainant.

Suspensions and Withdrawals

Suspension, withdrawal and scope reduction procedures may vary under certain regulatory schemes. If the customer is accredited under a regulatory scheme, SCC staff should be contacted to confirm any scheme deviations to the policies and procedures contained in this document.

Suspensions are intended to be temporary. Suspensions shall be processed as withdrawals if re-accreditation is not completed within a twelve month period.

While suspended (in full or in part), the accredited organization loses the privileges of delivering the accredited activities for the portion of the scope suspended. The letter of suspension details the restrictions imposed on the customer as a result of the suspension action.

While under suspension or upon withdrawal, the customer, and any affiliated parties, shall comply with the relevant and applicable provisions of this document. The customer shall immediately cease making reference to its SCC-accredited status for the suspended or withdrawn activities to any third parties, in any promotional materials, or letterhead, in test reports (for laboratories) or in any other documents or media (including the internet). The customer shall also cease displaying its Certificate of Accreditation on its premises and cease any use of the SCC accreditation symbol when full accreditation has been suspended or withdrawn. As well, the customer must cease using all other marks or symbols licensed through SCC related to their accreditation such as, but not limited to, the marks of IAF and ILAC.

Details describing the terms and conditions of work while suspended shall be provided in the Notice of Suspension. Generally, while suspended and under the terms described in the Notice of Suspension, a customer may continue to conduct work that is necessary to support existing certificates in the marketplace, for example factory surveillance work conducted by product

certification bodies or annual surveillance work by system certification bodies. Although work leading to the issuance of new certificates or re-certifications may be carried out, the certificates cannot be represented as being accredited. Similarly, any laboratory testing for suspended test methods and inspection of goods under ISO/IEC 17020 programs cannot be represented as being accredited. Where applicable, the customer, upon withdrawal, is required to provide its customers with information on the withdrawal of its accreditation and on its associated consequences.

Should SCC become aware of confirmed evidence of fraudulent behaviour, or of a customer intentionally providing false information, or a customer deliberately violating accreditation rules, SCC shall initiate its process for withdrawal of accreditation. As well, if a customer is discovered to be providing certification services to any standard used as a basis for accrediting organizations (e.g. ISO/IEC 17025 or ISO 15189), SCC shall initiate its process for suspension of accreditation.

Voluntary Suspensions or Withdrawals

An SCC-accredited organization may voluntarily suspend or withdraw all or part of its accreditation at any time by providing written notice to SCC. Requests must clearly state the elements of the customer's scope of accreditation that are to be suspended or withdrawn and should indicate the reasons for the decision. Requests will be processed within ten (10) business days, or as indicated by SCC upon receipt of request. Any unpaid and accrued fees shall be paid to SCC at the time the request for suspension or withdrawal is made.

SCC-Initiated Suspensions or Withdrawals

SCC may initiate suspension or withdrawal of an accreditation of a customer. This might occur when SCC determines that the customer has failed to comply with relevant terms and conditions of accreditation, including payment of applicable fees. The customer will be notified of such a decision in writing by SCC staff responsible for the file. The notification letter will state what is intended for suspension or withdrawal, the reasons for proceeding, and additional actions required to initiate the suspension or withdrawal.

The customer will be given no longer than thirty (30) calendar days to respond before the suspension is implemented. The customer may:

- provide appropriate corrective action that is acceptable to SCC, or
- accept the suspension or withdrawal, or
- submit a formal complaint to SCC with regards to the suspension warning (refer to the Complaints section of this document).

Once the suspension decision has been made, and the suspension is in effect, the customer may also appeal the decision (refer to the Appeals section of this document).

If a customer chooses to appeal a suspension decision made by SCC and the decision is upheld, the customer will be given thirty (30) calendar days after receiving the decision of the appeal to provide appropriate corrective action that is acceptable to SCC. Failure to implement the corrective action within the thirty (30) calendar days may, at SCC's sole discretion, result in withdrawal of the accreditation.

When a decision on suspension has been made, such suspension shall be implemented and remain in effect until the Appeal process is completed and a decision has been rendered.

Immediate Suspension by SCC

An immediate suspension (partial or full) of a customer's accreditation scope may be imposed by SCC when SCC assessment teams have identified one, or a number of major nonconformities, or, if a customer has declined a surveillance activity by SCC, or, when a customer brings the accreditation body into disrepute, or, when a customer has been charged with a criminal offense. A customer may appeal the decision for an immediate suspension according to the Appeals section of this document.

Public Notification of Suspensions and Withdrawals

When a suspension or withdrawal of accreditation occurs, customers and the public are notified by the posting of a notice on SCC's website and the scope of the organization is amended to indicate the extent of the suspension or withdrawal. In addition, where other parties are involved, such as regulatory authorities, those parties shall also be notified by SCC of the changes in the accreditation status of the organization.

Reasons for the suspension or withdrawal are not communicated to the public. However, in each of the situations mentioned in the Suspensions and Withdrawals section of this document that lead to the SCC-initiated suspension or withdrawal of accreditation of a customer accredited under an IAF program (i.e. Management Systems Certification Bodies, or Product, Process, or Service Certification Bodies), SCC shall notify the IAF Secretariat of this decision and the reasons. The IAF Secretariat shall then communicate the decision and status to all IAF Member Accreditation Bodies in the following format:

> *"[Name of Accreditation Body] [state the action as 'withdrew' or 'suspended'] accreditation of [Name of CB] on [date] for [state the proven offence]"*[5]

[5] IAF Mandatory Document #7 (2010), *Harmonization of Sanctions to be Applied to Conformity Assessment Bodies*, Clause 5.1

Appeals

The Appeal Process

The appeal process is an independent review and evaluation of a decision made by SCC that directly relates to the accreditation status of the customer or applicant. An appeal typically relates to a decision made by SCC to deny, suspend or withdraw accreditation.

The complaint process should be used prior to an appeal and every attempt should be made to resolve the issues when a customer or applicant disagrees with a decision made by SCC.

When a decision on suspension has been made, that suspension shall be implemented and be in full force and remain in effect until the Appeal process is completed and a decision has been rendered.

Appeals shall be submitted to SCC in writing within thirty (30) business days of the relevant SCC decision. The request for Appeal or hearing places the onus on the appellant to submit a comprehensive package of evidence and justification for the appeal in writing, together with the request for appeal. The request will be reviewed to ensure it is complete. Appeals shall be addressed to the Chief Executive Officer (CEO) of SCC who will in turn bring it to the attention of the Governing Council, the appointed governing body of the Standards Council of Canada.

Following the outcome of an appeal and the announcement of the decision by the CEO, should the customer believe that the appeal has not been satisfactorily addressed, the organization has the option to file a complaint against SCC with IAF or ILAC, as appropriate.

Costs for Appeals and Hearings

The appellant has the option of requesting the appeal to be evaluated by either an Appeal Panel, or a person designated as the assigned action officer (AAO), an impartial person who is appointed by the CEO to conduct a review and evaluation of an appeal. When the appellant selects an Appeal Panel to review the appeal, the appellant may also request a hearing. Whichever appeal evaluation method is selected, an estimate of the expected costs will be provided in advance. The appellant will be required to provide a deposit of 35% of the expected costs at this time. The estimate may include costs, as applicable, for travel and accommodation of the Appeal Panel members to meet, SCC staff attendance at hearing, and costs of special meetings of the Council.

If the original decision is overturned, there will be no cost to the appellant for the process and the appellant will be promptly refunded any deposit. If the decision is upheld, the appellant will forfeit the deposit and be required to pay any amount over and above the initial deposit within thirty (30) calendar days following the date on which the decision is rendered.

Appointment of a Panel or an Assigned Action Officer (AAO)

When an Appeal Panel evaluation is selected by the appellant, the CEO will appoint an Appeal Panel within thirty (30) calendar days of receipt of a complete application for appeal or such other period of time as the CEO may require. The Appeal Panel shall consist of a minimum of 3 members, one of whom will be appointed as the Chair by the CEO.

When an evaluation by an AAO is selected by the appellant, the same procedures used to appoint an Appeal Panel shall apply, except the appointment is to take place within ten (10) working days of receipt of the appeal and supporting documents, or such other period of time as may be required.

Selection of an Appeal Panel or AAO

The person or persons appointed to adjudicate an appeal shall be selected giving consideration to their knowledge, training and experience to evaluate the subject matter of the appeal. They shall be independent of the issues and activities that led to the appeal, and shall have no conflicts of interest with the parties involved. The CEO will appoint a recording secretary to the Appeal Panel that shall be a member of SCC's staff.

Conducting an Appeal and Hearing

The AAO or Appeal Panel shall investigate the issue, to the extent necessary, to determine if the claim from the appellant is founded or not. A report containing the findings from the evaluation shall be prepared and submitted to the CEO for review and recommendation to the Council. The report should include at least the following:

- Original claim, evidence and justification provided by the Accredited organization or applicant
- Evidence gathered during the evaluation
- Summary of processes reviewed during the evaluation
- Minutes from the hearing (when and if hearing took place)
- Result of the vote (Appeal Panel only)
- Conclusion/recommendation

When the appellant has requested a hearing, the Appeal Panel will be responsible to make the necessary arrangements to conduct the hearing.

If it is determined by the Appeal Panel or the AAO that the claim by the appellant is well founded, the original SCC decision may be overturned, the AAO or Appeal Panel shall recommend a remedial action, if appropriate.

The Appeal Panel will aim to complete its function, including any hearing, within thirty (30) calendar days of its formation. The process using an AAO shall normally be completed within ten (10) business days from his/her appointment.

The final decision with respect to all matters on the appeal will be made by the Governing Council. The appellant will be informed of the decision and remedial action required, if any.

Reapplication

The termination of an accreditation, either by voluntary withdrawal or through the suspension and withdrawal process, will not preclude a customer from re-applying for accreditation at a future date. Such a reapplication will be evaluated under the same requirements and procedures applicable to new applications.

Annex A: Management Systems Certification Body Accreditation

A.1. Program Requirements

All Management Systems Certification Bodies (CBs):

- ISO/IEC 17021-1:2015 – Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements
- IAF MD4:2008 – IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems
- IAF MD 11:2013 – Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS) *(applies only to CBs certifying to multiple certification standards)*
- IAF MD 19:2016 - IAF Mandatory Document For The Audit and Certification of a Management System operated by a Multi-Site Organization (where application of site sampling is not appropriate)

CBs certifying either or both of QMS and EMS

- IAF MD1:2018 – IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling
- IAF MD2:2017 – IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
- IAF MD3:2008 – IAF Mandatory Document for Advanced Surveillance and Recertification Procedures
- IAF MD5:2015 – IAF Mandatory Document For Duration of QMS and EMS Audits

CBs certifying Quality Management Systems (QMS)

- ISO/IEC TS 17021-3:2017 - Competence requirements for auditing and certification of quality management systems

CBs certifying Environmental Management Systems (EMS)

- ISO/IEC TS 17021-2:2016 – Competence requirements for auditing and certification of environmental management systems

CBs certifying Food Safety Management Systems (FSMS)

- ISO 22000:2005 – Food safety management systems — Requirements for any organization in the food chain
- ISO/TS 22002-1:2009 – Prerequisite programmes on food safety -- Part 1: Food manufacturing
- ISO/TS 22003:2013 – Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems

CBs certifying Medical Devices Management Systems (MDMS)

- IAF MD 9:2017 – Application of ISO/IEC 17021 in Medical Device Quality Management Systems

CBs certifying Forestry

- SCC Requirements and Guidance for the Management Systems Accreditation Program: Sustainable Forest Management Sector Schemes

- ATFS-IMG-01:2015 – ATFS Independently Managed Group Certification Requirements
- SFI 2015-2019 – Requirements for the SFI Program: Standards, Rules for Label Use, Procedures and Guidance.
- CAN/CSA-Z804:2008 – Sustainable forest management for woodlots and other small area forests
- CAN/CSA-Z809-08 (R2013) – Sustainable forest management
- CAN/CSA-Z809:2016 – Sustainable forest management

CBs certifying Energy Management Systems (EnMS)
- ISO 50003:2014 – Energy management systems – Requirements for bodies providing audit and certification of energy management systems

CBs certifying Anti-bribery Management Systems
- ISO/IEC TS 17021-9:2016 – Competence requirements for auditing and certification of anti-bribery management systems

CBs certifying Occupational Health & Safety Management Systems (OH&SMS)
- ISO/IEC TS 17021-10:2018 – Competence requirements for auditing and certification of occupational health and safety management systems
- IAF MD 22:2018 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

A.2. Accreditation Cycle

The Management Systems accreditation program operates on a four year accreditation cycle that is structured with three years of surveillance activities followed by a reassessment activity every fourth year. Generally, the first surveillance activity will be conducted no later than twelve (12) months from the date of the assessment performed to support initial accreditation. Each surveillance activity thereafter will generally take place no more than twelve (12) months of the previous one. Each accreditation surveillance activity will be referenced by the designation S1, S2, S3 or RA depending on the stage of the CB in the accreditation cycle.

During the three (3) years between initial accreditation and reaccreditation and between each reaccreditation, annual surveillance will be conducted at the CB's head office and other fixed office locations to support continued accreditation.

In advance of each fiscal year, a four (4) year Accreditation Cycle Plan will be developed or updated and provided to the CB. The Accreditation Cycle Plan will identify the required assessment activity(ies) for each year of the accreditation cycle.

The Accreditation Cycle Plan will be based on information submitted by the CB in the most recent Fixed Office Location Survey, and will consider experience gained during previous assessment activities, the assessment team's recommendations, complaints received about accreditation, disclosed changes, publicly accessible information, adequacy of response to SCC-issued findings. If at any point a location is changed, added, or removed, the Fixed Office

Locations Survey is required to be submitted to SCC, within thirty (30) calendar days of the change.

As identified in the Accreditation Cycle Plan, surveillance activities for fixed office locations will be sampled over the Accreditation Cycle. A sampling methodology will be implemented for identification of surveillance activities for fixed office locations. Subcontracted entities, affiliates, partners, sister and/or parent organizations may be subject to assessment. If the objective evidence is found to be sufficient, SCC will perform surveillance activities at each fixed office location once over the four year accreditation cycle.

Witness audits are required for each program and/or standard for which the CB is issuing SCC accredited certificates. To determine the number of witness audits required to support continued accreditation, SCC will consider the volume of certifications issued under SCC accreditation, CB sector scheme qualification(s), complexity and number of the accredited scopes and economies within which the CB is operating as well as other additional factors per *IAF MD 17: Witnessing Activities for the Accreditation of Management Systems Certification Bodies.*

In the fourth (4) year of the Accreditation Cycle, SCC will conduct reaccreditation assessments. Reaccreditation assessments will be performed at the head office of the CB (or the SCC-accredited entity) and may be conducted at some other fixed office locations. The process for the determination of the required number and nature of witness audits for each normative standard for which the CB is issuing SCC accredited certificates, is the same as the process identified for initial accreditation and continued accreditation.

When requested, the CB shall promptly provide to SCC the complete and updated schedule of confirmed and planned audits (dates, location, audit team composition, audit type and scope, etc.), in order to allow the SCC to schedule or update the Accreditation Cycle Plan for the coverage of the scope of accreditation.

A CB may request that SCC conduct a joint assessment at a fixed office location with another accreditation body or that SCC consider another accreditation body's oversight results in lieu of performing an assessment activity identified in the Accreditation Cycle Plan. In such cases the CB must make the request in writing at least four months prior to the planned activity.

SCC will deploy an assessment team to sufficiently observe all audit activities. In some cases, this means there may be fewer SCC assessors than CB auditors at a given audit.

A.3. QMS and EMS IAF Code Recognition (Extension and Reduction)

The list of scopes of accreditation is based on the technical clusters and critical codes per *IAF MD 17: Witnessing Activities for the Accreditation of Management Systems Certification Bodies*.

Each accredited CB may have a number of QMS and EMS IAF Codes recognized once they have provided evidence of possessing the competence required. Code recognition may be extended upon submission of a scope extension request and may also be reduced pending the circumstances.

Applicants and accredited CBs seeking extension of the scope accreditation are required to submit one application for each QMS/EMS IAF code. Following receipt of the application information, a review of the information will be performed and witness audit activity may be recommended based on the general rules applicable to QMS and EMS schemes outlined in *IAF MD 17: Witnessing Activities for the Accreditation of Management Systems Certification Bodies*

When applying for accreditation, the CB must specify a minimum of one QMS and/or EMS IAF code for recognition for accreditation programs which are quality based.

Once the CB is accredited, the CB may apply for scope extension to add one or more QMS and/or EMS IAF codes to their scope of accreditation.

During annual surveillance activities, the assessment team will review the competence of auditors for recognized QMS/EMS IAF codes, and review the technical expertise for recognized codes at the reviewer and policy levels. The assessors will provide information in the accreditation report confirming the scope of accreditation or a recommendation related to the scope.

A.4. Classification of nonconformities

Within the Management Systems Accreditation Program, nonconformities are classified into two categories, Major and Minor. A major nonconformity is the absence of, or the failure to implement and maintain, one or more quality management system requirements of the reference standard, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the credibility of the certificates issued by the applicant or accredited body; or, a number of minor nonconformities against one or more requirements, which when combined, can represent a breakdown of the CB’s system; or, a minor nonconformity that was previously issued and not addressed effectively by the CB. A minor nonconformity may be a single observed lapse in the CB’s system.

While minor nonconformities must be addressed as per the timelines addressed in the main body of this document, for major nonconformities, the CB will have only sixty (60) calendar days from the date of issuance of the nonconformity to provide evidence of resolution and corrective action.

A.5. Advanced Surveillance and Recertification Procedures (ASRP)

Certification Bodies operating in Quality Management System (QMS) and Environmental Managements System (EMS) certification have the option of utilizing the Advanced Surveillance and Recertification Procedures (ASRP) program when assessing and certifying their clients. This program relies heavily, but not fully, on an organization's internal audits, management review processes, surveillance activities, and other methods. IAF MD3:2008 specifies the minimum requirements that certification bodies need to implement when conducting services.

A CB wishing to include the ASRP program to its accredited activities is required to submit an application to SCC and demonstrate, through an assessment, conformity to all requirements specified in IAF MD3:2008. Upon approval, the Accreditation Body will include the ASRP program for QMS and/or EMS, as deemed appropriate, in the CB's scope of accreditation.

A.6. Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management System

Certification Bodies operating in Management Systems have the ability to utilize the Computer Assisted Auditing Techniques (CAAT) program when auditing and certifying their clients. This program includes audits that utilize teleconferences, web meetings, interactive web-based communications, and remote electronic access to the management system documentation and/or management system process. IAF MD4:2008 specifies the minimum requirements, in addition to those stated in ISO/IEC 17021-1, that certification bodies need to implement when conducting CAAT services, and how to maintain compliance with their accreditation. Certification bodies must agree on mutually acceptable information security measures with their clients before using CAAT. If it represents more than 30% of the planned on-site activity time, the certification body shall justify the plan and request approval from SCC. Once a CB is able to demonstrate a robust process for managing and utilizing the CAAT system, SCC as the Accreditation Body can grant a "blanket approval" for the remote assessment activities to go over the 30% of allocated time planned for on-site activities, however it shall not replace a full on-site activity. SCC will verify compliance through on-going assessments and verification to ensure CBs comply with all criteria set out in IAF MD4:2008.

Annex B: Product, Process, and Service Certification Body Accreditation

B.1. Program Requirements

All Product, Process, and Service Certification Bodies (CBs):

- ISO/IEC 17065:2012 - Conformity assessment — Requirements for bodies certifying products, processes and services
- SCC Requirements and Guidance - Product, Process and Service Certification Body Accreditation Program

CBs operation in the elevator scheme:

- General Requirements for Accredited Elevator/Escalator Certification Organizations (AECO)
- ASME A17.7.1/CSA B44.7.1 General Requirements for Accredited Elevator/Escalator Certification Organizations

CBs operating in Safe Quality Food Initiative scheme

- Criteria for SQF Certification Bodies - SQF Requirements on the Application of ISO/IEC 17065:2012

CBs operating in the CanadaGAP scheme

- CanadaGAP Program Management Manual

CBs operating in the forestry scheme:

- PEFC ST 2002:2013 Requirements for Certification Bodies operating Certification against the PEFC International Chain of Custody Standard
- SFI 2015-2019 Section 4 Chain of Custody Standard
- SFI 2015-2019 Section 9 Audit Procedures and Auditor Qualifications and Accreditation

B.2. Accreditation Cycle

CBs are accredited for a four-year accreditation cycle. During the three years between initial accreditation and reassessment and between each reassessment, annual oversight activities will be conducted on a sampling basis across the CB head office and fixed office locations to confirm continued conformance with accreditation requirements. Generally, the first surveillance assessment will take place one-year following the initial assessment. Each surveillance activity thereafter will generally take place at twelve-month intervals.

Each annual oversight activity following accreditation or reassessment will be referenced sequentially by the designation S1, S2 or S3. Annual surveillance assessments may be shorter duration and focus on a portion of the accreditation requirements.

In the fourth year of the accreditation cycle, SCC will conduct a reassessment of the Head Office and selected fixed office locations. Reassessment will consider all elements of the accreditation requirements. Witness audits will also be conducted.

Surveillance and reassessment oversight activities at fixed office locations may comprise of an on-site surveillance, the acceptance of an evaluation report from an accreditation body, or the conduct of a witness audit. The focus of reassessments and annual surveillance activities will be influenced by experience gained during previous accreditation activities.

Each year SCC will provide the CB with an updated planned Accreditation Cycle Plan containing the outline of activities for the next 4 years, the specific locations to be assessed and assessment teams (if known) for the upcoming year, and will be developed from the most recent information collected from the CB with respect to fixed office locations and corporate changes. The Accreditation Cycle Plan will identify all of the required assessment activities that SCC plans to perform to satisfy continued accreditation.

Upon receipt of the Accreditation Cycle Plan, the CB shall review it and notify SCC of any concerns with the planned assessment activities. Annual assessment activities use sampling of the fixed office locations so that each location is assessed at least once during the accreditation cycle following the initial assessment. Sampling may increase if the CB performance raises doubt as to the credibility of the certificates issued by the CB.

SCC will assess each fixed office location at least once during the four year accreditation cycle. A fixed office location is defined as being where the CB conducts one or more the following activities:

- policy formulation and approval;
- process and/or procedure development and approval;
- initial assessment of competence, and approval of technical personnel and subcontractors;
- control of the monitoring process of competence of personnel and subcontractors and its outcomes;
- contract review including technical review of applications and determining the technical requirements for certification activity in new technical areas or areas of limited sporadic activity;
- decision on certification including technical review of evaluation tasks

Unlike the initial assessment where technical experts are assigned to the assessment team to cover all the technical areas being requested, technical experts will be rotated on the teams in the S1, S2, S3 and reassessment years so that all technical areas outlined on the scope of accreditation are reviewed at least once over the four-year accreditation cycle.

A CB may request that SCC conduct a joint assessment at a fixed office location with another accreditation body or that SCC consider another accreditation body’s oversight results in lieu of

performing an assessment activity identified in the Accreditation Cycle Plan. In such cases the CB must make the request in writing at least four months prior to the planned activity.

B.3. Witness Audit Requirements

Witness audits are conducted by SCC as a means of verifying that the CB is satisfactorily implementing its procedures. Witness audits are required for initial accreditation, and normally at the second annual surveillance activity (S2) and at the reassessment (RA) which normally occurs in the fourth year following the assessment. SCC may also require witness audits for scope extensions and for CBs with many fixed office locations. This will be determined on a case-by-case basis.

Initial accreditation or scope extensions can be conditional upon the successful scheduling of one witness audit within 6 months from the date of the granting of accreditation. If the witness audit is not scheduled within the 6 months' timeframe then the accreditation or scope extension will be withdrawn.

B.4. Scope Management

The SCC accredited scopes[6] for CBs are published using the International Classification for Standards (ICS) codes[7] for each of the different product certification schemes. All accredited CBs shall have a current list of standards to which they offer certification under SCC accreditation, and these standards shall be grouped into customer defined technical categories (e.g. 'plumbing', 'hazardous locations', 'photovoltaic', etc.). This list must be in MS Excel or a tab delimited format. CBs must have a documented process in place to update their list of standards.

If an ICS code is defined in the standard itself, that ICS code must be used. If there is no ICS code listed on the standard itself, CBs are expected to use their best professional judgement in determining the ICS code, and document the technical rationale for the decision. Note that these records may be assessed by SCC at any time.

If a CB wishes to provide SCC accredited certifications using a standard that falls under an ICS code that is already on its published SCC scope of accreditation and in the same technical area, the CB may certify to that standard under its SCC accreditation without submitting a scope modification application.

If a CB wishes to provide SCC accredited certifications using a standard that falls under an ICS code that is not on its published SCC scope of accreditation, the CB must submit a scope modification application.

If a CB requires a confirmation from SCC that a standard falls under an ICS code on the scope of accreditation (e.g. a letter for a regulator), a scope modification application is required, for which fees are applicable.

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[6] Including any means by which a CB indicates its certifications are covered by the scope of SCC accreditation.

[7] International Classification for Standards (ICS) codes available as a downloaded PDF https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/international_classification_for_standards.pdf or online browseable catalogue https://www.iso.org/search/x/query/list%2520of%2520ics%2520codes

Annex C: Certification Body Operating in Certification of Persons Accreditation

C.1. Program Requirements

- ISO/IEC 17024:2012 Conformity assessment — General requirements for bodies operating certification of persons

C.2. Accreditation Cycle

The program for the accreditation of certification bodies certifying persons operates on a four year accreditation cycle that is structured with three years of surveillance activities followed by a reassessment activity every fourth year.
In advance of each fiscal year, a four year accreditation cycle plan will be developed or updated and provided to the CB. The accreditation program will identify the required assessment activities for each year of the accreditation cycle.

The accreditation cycle plan will be based on information submitted by the CB in the most recent Fixed Office Location Survey, and will consider experience gained during previous assessment activities, the assessment team's recommendations, complaints received about accreditation, disclosed changes, publicly accessible information, and adequacy of response to SCC-issued findings. If at any point a location is changed, added, or removed, the Fixed Office Locations Survey is required to be completed and submitted to SCC within thirty calendar days of the change.

As identified in the accreditation cycle plan, surveillance activities for fixed office locations other than the head office will be sampled over the four year accreditation cycle. A sampling methodology will be implemented for identification of surveillance activities for fixed office locations.

Subcontracted entities, affiliates, partners, sister and parent organizations may be subject to assessment. If the objective evidence is found to be sufficient, SCC will perform surveillance activities at each fixed office location other than the head office, once over the four year accreditation cycle.

During the three years between initial accreditation and reaccreditation and between each reaccreditation, annual surveillance activities will be conducted at the CB head office and other fixed office locations to support continued accreditation.

The first surveillance activity will be conducted no later than twelve months from the date of the assessment performed to support initial accreditation. Each surveillance activity thereafter will take place no more than twelve months of the previous one. Each accreditation surveillance

activity will be referenced by the designation S1, S2, S3 or RA depending on the stage of the CB in the accreditation cycle.

In the fourth year of the Accreditation Cycle, SCC will conduct reaccreditation assessments. Reaccreditation assessments will be performed at the head office of the CB (or the SCC accredited entity) and may be conducted at other fixed office locations. Witness audits will also be conducted for each normative standard for which the CB is issuing SCC accredited certificates. The process for the determination of the number and nature of witness audits is the same as the process identified for initial accreditation and continued accreditation.

C.3. Witness Exam Requirements

As part of the accreditation process, SCC is required to witness the certification process. Witness activities could be of the organization's certification/examination process or by each certification/licensing scheme. Witness activities may also be conducted to review the implementation of other parts of the CB's quality system. Examples of such witness audits include but are not limited to re-certification process, certification and/or examination, criteria development, committee meetings. This activity is part of the CB demonstrating conformance with the accreditation requirements.

SCC's policy is to conduct one witness exam activity during the initial assessment period, followed by two witness exams over the four year accreditation cycle. These witness exams will generally occur in the second surveillance year, and in the reaccreditation year.

Initial accreditation or scope extensions can be conditional upon the successful scheduling of one witness audit within 6 months from the date of the granting of accreditation. If the witness audit is not scheduled within the 6 months' timeframe then the accreditation or scope extension will be withdrawn.

Annex D: Greenhouse Gas Validation and Verification Body Accreditation

D.1. Program Requirements

- ISO 14065:2013 Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition
- ISO 14066:2011 Greenhouse gases — Competence requirements for greenhouse gas validation teams and verification teams
- IAF MD6:2014 Application of ISO 14065:2013

Validation and Verification Bodies working under the Verified Carbon Standard (VCS) in accordance with the VCS Rules, as defined by VCS document *Program Definitions*.

D.2. Accreditation Cycle

The initial accreditation (IA) for Greenhouse Gas Validation and Verification Bodies (VVBs) requires the VVB to demonstrate access to sufficient technical expertise in the relevant sectors for which accreditation is sought and shall be evaluated by the SCC assessment team during the office assessment for competence for all sectors for which they seek accreditation. Witness audits (WA) are required for the different organization-level verification, project-level validation, and project-level verification dependent upon what levels the VVB seeks accreditation for.

Initial accreditation or scope extensions can be conditional upon the successful scheduling of witness audit(s) within 6 months from the date of the granting of accreditation. If the witness audit is not scheduled within the 6 months' timeframe then the accreditation or scope extension will be withdrawn.

Once accredited, VVBs are accredited for a four-year accreditation cycle. Each year SCC will provide the VVB with an updated Accreditation Cycle Plan. This document contains the overall activities for the next 4 years, and the specific locations to be assessed and assessment teams (if known) for the upcoming year, and will be developed from the most recent information collected from the VVB with respect to fixed office locations and corporate changes.
The Accreditation Cycle Plan will identify all of the required assessment activities that SCC plans to perform to satisfy continued accreditation.

Upon receipt of the Accreditation Cycle Plan, the VVB shall review it and notify SCC of any concerns with the planned assessment activities. SCC will request that the VVB complete a Witness Audit Selection Form to assist SCC with the planning of the actual witness audits. Annual assessment activities use sampling of fixed office locations so that each location is assessed at least once during the accreditation cycle following the initial assessment. Sampling

may increase if the VVB performance raises doubt as to the credibility of the validation/verification statements issued by the VVB.

A head office (HO) or other fixed office location assessment is required each surveillance year for the three years between IA and reassessment (RA). The HO annual oversight activities will be conducted on a sampling basis across the VVB head office and other fixed office locations to confirm continued conformance with accreditation requirements. Generally, the first surveillance assessment will take place one-year following the date the initial assessment took place and not the date of when the accreditation certificate is granted. Each surveillance activity thereafter will generally take place at twelve-month intervals from the initial assessment date. Where necessary, a Technical Expert is assigned to the IA assessment team and any WA assessment teams related to the Technical Sectors being requested and/or witnessed.

Each annual oversight activity following accreditation or reassessment will be referenced sequentially by the designation S1, S2 or S3. Annual surveillance assessments are of shorter duration and focus on a portion of the accreditation requirements with a focus being given to any issues, such as NCRs, and corrective actions from the previous assessment(s).
In the fourth year of the accreditation cycle, SCC will conduct a reassessment of the HO. Reassessment will consider all elements of the accreditation requirements. Any fixed office location and witness audit requirements that were not completed in the surveillance years will be conducted in the RA year. The focus of annual surveillance activities and reassessments will be influenced by experience gained during previous activities.

A VVB may request that SCC conduct a joint assessment at a fixed office location with another accreditation body or that SCC consider another accreditation body's oversight results in lieu of performing an assessment activity identified in the Accreditation Cycle Plan. In such cases the VVB must make the request in writing at least 4 months prior to the planned activity.

D.3. GHGAP Witness Audits Requirements

D.3.1 Initial Accreditation:

a. The VVB shall demonstrate access to sufficient technical expertise in the relevant sectors for which accreditation is sought. The VVB shall be evaluated by the SCC assessment team during the office assessment for competence for all sectors for which they seek accreditation.
b. Witness audits are required for both project level validation/verification and organization-level verification, if the VVB seeks accreditation for both levels.
c. **Organization Level – Verification**:
    i. Accreditation for organizational level verification requires at least one witness audit.
    ii. A level 3 witness audit shall satisfy a level 1 or a level 2 category;
    iii. A level 2 witness audit shall satisfy the level 2 and the level 1 category;

iv. A witness audit in Sector 3.2 and Sector 9 are mandatory if the VVB seeks accreditation in these sectors. The maximum number of witness audits required for a VVB applying for all organization-level sectors shall be five.
v. To achieve accreditation in more than one main sector of the same level, a minimum of one witness audit per main sector is required.
vi. To achieve accreditation in three or more level 3 sectors, three witness audits shall be conducted.

d. **Project Level – Validation/Verification**
   i. Witnessing of validation activities within a given sector shall count towards recommendation on accreditation for project verification for the same sector.
   ii. Accreditation for project validation requires witnessing of project validation activities. Witnessing of verification activities shall not be extended to the recommendation on accreditation for validation.
   iii. Witness audit requirements are identified in Table 2 below.
   iv. In addition to completion of the required witness audit for Sector A accreditation, demonstration of competence for the Sector A sub-sectors is required for accreditation of those requested sub-sectors.
   v. A VVB must undergo four project-level witness audits to be considered for accreditation for all of the group sectors.

D.3.2 Annual Surveillance

a. VVBs shall undergo witness audits over the accreditation cycle.
b. VVBs accredited for up to two sectors shall undergo a witness audit in each sector over the accreditation cycle.
c. Where a VVB is accredited for three or more sectors, a risk based approach shall be taken in the selection process.
d. Selection process may consider elements such as total emissions per facility, type of emissions, combustion versus process or non-CO_2, and single or multi-sites to determine levels of risk
e. Preference may also be given to witnessing sectors:
   vi. where required by regulation or sector programs,
   vii. where previous witness audits have yielded nonconformities;
   viii. to observe personnel that have not yet been witnessed;
   ix. that have not previously been witnessed;
   x. where total emissions per facility exceed 25 kilo tonnes.

Table 1 - GHG Technical Sectors for Scoping Accreditation – Organization Level

ORGANIZATION LEVEL			
Group 1	**Verification**		**Witness Audit Requirement**
Sector 1	**General**		
	1.1 Service	Examples: Public, administration, education, storage & communications, IT, government.	Level 1 or above
	1.2 Aviation Road Transportation, Railways & Shipping	Examples: Transportation	Level 1 or above
Sector 2	**General Manufacturing**		
	Examples: Food products, household goods, textiles, wood products, pulp & paper, basic metals and fabricated metal products, electrical equipment, machinery & equipment, medical devices, rubber and plastic products. Note: Includes civil engineering		Level 2 or above
Sector 3	**Power Generation and Electric Power Transactions**		
	3.1 Power Generation	Examples: Combustion of natural gas or coal; transmission and distribution.	Level 2
	3.2 Electric Power Transactions	Examples: Purchase transactions, resale transactions, wheeling transactions.	Mandatory
Sector 4	**Mining & Mineral Production**		
	Examples: Cement production, lime production, glass production, coal and other process uses of carbonates.		Level 3
Sector 5	**Metals Production**		
	Examples: Aluminum, ferroalloy, iron, steel, lead, magnesium and zinc		Level 3
Sector 6	**Chemical Production**		
	Examples: Ammonia production, nitric acid production, adipic acid production, urea production, carbide production, caprolactam production, glyoxal and		Level 3

	glyoxylic acid production, titanium dioxide production, soda ash production, and fluorochemical production.		
Sector 7	**Oil & Gas extraction, Production & Refining including Petrochemicals**		
	Examples: Oil & natural gas production, pipelines & specialty organic chemical production, and refining processes.		Level 3
Sector 8	**Waste Handling & Disposal**		
	Examples: Water & wastewater treatment, landfills, manure management systems, composting facilities		Level 3
Sector 9	**Agriculture, Forestry & Other Land Use (AFOLU)**		
	Removal of CO_2 from the atmosphere by forests and other land use. Emissions resulting from actions such as decomposition, harvest, conversion or development, fire and species choice.	Examples: Forests and rangelands	Mandatory

Table 2 - GHG Technical Sectors for Scoping Accreditation – Project Level

PROJECT LEVEL			
Group 2	**Validation**		**Witness Audit Requirements**
Group 3	**Verification**		
Sector A	**GHG Emission reductions from fuel combustion**		
	A.1 Renewable energy production	Examples: Hydro power generation, biomass energy, biomass fuels, geothermal power, fuel cells, solar power, wind energy.	Sector and sub-sector competence demonstration is required. A witness audit of a Group 3 Sector A or Sector B activity is required.
	A.2 Energy efficiency improvements	Examples: Fuel switching and waste heat recovery	
	A.3 Transportation		
Sector B	**GHG emission reductions from industrial processes (non-combustion, chemical reaction, chemical fugitive emissions, flare & venting from oil, and other)**		

	Destruction of ozone depleting substances	Examples: SF6 replacement, SF6 emission avoidance, HFC destruction and decomposition, PFC anode effect mitigation, production of nitric acid and adipic acid, reduction emissions from destruction of N_2O in manufacturing	Mandatory. A witness audit of a Sector B activity is required.
Sector C	**GHG Emission Reductions & Removals from Agriculture, Forestry & Other Land Use (AFOLU)**		
	Carbon sequestration due to afforestation, avoided deforestation, sustainable forest management, and re-vegetation. Soil carbon sequestration due to improved agricultural land management (no-till, grass cover)		Mandatory
Sector D	**Carbon Capture and Storage**		
	Carbon Sequestration in Geological Formations Examples: injection into underground geological formations such as abandoned oil and gas reservoirs, saline aquifiers or unminable coal seams		Mandatory
Sector E	**GHG Emissions from Livestock**		
	Animal waste management – CH_4, N_2O Examples: Methane collection and destruction, livestock and other anaerobic digester operations, agriculture methane emission reductions, agricultural carbon emission reductions.		Demonstrated sector competence is required. A witness audit of either a Sector E or Sector F activity is required.
Sector F	**Decomposition of Waste Material, Handling and Disposal**		
	Landfill use, waste handling and disposal, and coal mine methane.	Examples: • Capture and destruction of landfill gas • Capture and use of landfill gas such as with biodigestion, aerobic treatment • Methane recovery in wastewater treatment • Avoidance of methane production in wastewater treatment.	Demonstrated sector competence is required. Activities selected from either Sector E or Sector F is required.

D.4 Verified Carbon Standard (VCS) Program

For information on the VCS Program and the VCS Rules, please refer to the most recent versions of the VCS program documents available on the VCS website (www.v-c-s.org).

The following is the listing of the SCC GHG Technical Sectors and the correlated VCS Technical Sectors. To be accredited in a VCS Technical Sector, the VVB must be accredited by SCC in the corresponding SCC GHG Technical Sector.

Table 3 - GHG Technical Sectors for Scoping Accreditation – SCC and VCS Program

SCC GHG Technical Sectors	VCS Technical Sectors
G2 SA.1 and/or G3 SA.1 GHG Emission Reductions from fuel combustion: Renewable energy production	1. Energy Industries (renewable/non-renewable sources) 2. Energy distribution
G2 SA.2 and/or G3 SA.2 GHG Emission Reductions from fuel combustion: Energy efficiency improvements	3. Energy demand
G2 SA.3 and/or G3 SA.3 GHG Emission Reductions from fuel combustion: Transportation	7. Transport
G2 SB and/or G3 SB GHG Emission Reductions from industrial processes (non-combustion, chemical reaction, chemical fugitive emissions, flare & venting from oil, and other)	4. Manufacturing industries 5. Chemical industry 8. Mining/mineral production 6. Construction 9. Metal production 10. Fugitive emissions from fuels 11. Fugitive emissions from industrial gases 12. Solvents use
G2 SC and/or G3 SC GHG Emission Reductions & Removals from Agriculture, Forestry & Other Land Use (AFOLU)	14. Agriculture, Forestry, Land Use
G2 SD and/or G3 SD Carbon Capture and Storage	N/A
G2 SE and/or G3 SE GHG Emissions from Livestock	15. Livestock and manure management
G2 SF and/or G3 SF Decomposition of Waste Material, Handling and Disposal	13. Waste handling and disposal

Annex E: Inspection Body Accreditation

E.1. Program Requirements

- Inspection Body ISO/IEC 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection
- SCC Requirements and Guidance - Inspection Body Accreditation Program
- ILAC P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies

IBs inspecting Electrical Equipment:
- CSA Model Code SPE-1000
- Canadian Electrical Code
- The applicable product standards

IBs inspecting Medical Electrical Equipment
- CSA Model Code SPE-3000
- Canadian Electrical Code
- The applicable product standards

IBs inspecting Medical Gas Piping Systems:
- CAN/CSA Z305.1-92 Non-Flammable Medical Gas Piping Systems: Part III Certification and Part V Testing, Piping and Terminal Units.
- CAN/CSA Z305.6 Medical Oxygen Concentrator Central Supply System For use with Non-Flammable Gas Piping Systems, Part 16 Certification.
- CSA Z7396.1-06 Medical gas pipeline systems — Part 1: Pipelines for medical gases and vacuum.

IBs inspecting Commercial and Industrial Gas-fired Appliances and Equipment:
- CAN/CSA-B149.1 Natural gas and propane installation code
- CAN/CSA-B149.2 Propane storage and handling code
- CAN/CSA-B149.3 Code for the field approval of fuel-related components on appliances and equipment
- CSA C22.1 Canadian Electrical Code, Part I; Safety Standard for Electrical Installations
- CAN/BNQ 1784-000 Canadian Hydrogen Installation Code
- CSA B51 Boiler, pressure vessel and pressure piping code
- Variances or provincial deviations (such as VAR-GAS-05-05 [rev 2] Gas Safety Variance on the application of CAN/CSA-B149-3.05, Alberta Municipal Affairs, Safety Codes Council) as may be issued from time to time by the Provincial or Territorial Regulatory Authority
- Relevant requirements of the National Building Code of Canada and the National Fire Code of Canada.

E.2. Accreditation Cycle

The inspection body accreditation program operates on a four year accreditation cycle that is structured with three years of surveillance activities followed by a reassessment activity every fourth year.

SCC conducts annual assessments and witness audits of each Inspection Body (IB) to ensure continued conformance with accreditation criteria. The first annual assessment usually takes place approximately one year following the date of accreditation. Annual assessments will be rotated among IB sites where equipment and inspection personnel are located[8]. As well, there shall be a full reassessment conducted every four years at the head office locations.

The assessment team will witness at least one inspection carried out by the IB at the time of the annual assessment activity. See the table in section E.4 for the minimum requirements.

E.3. Witness Audits

Because the most significant element of inspection activities is the competence of the inspectors, the assessment activities will include the witnessing of inspectors. The number of witnessed inspections will be based on:

- the fields and types of inspection to be covered by the scope of accreditation;
- the IB's procedures for selecting, training, qualifying and monitoring inspectors in a given field;
- internal auditing practices of the IB;
- the geographical location of the premises from which the inspectors operate;
- any regulatory requirements;
- the extent to which inspectors exercise professional judgment; and,

When deciding on the types of inspection activity to be witnessed, the following factors will be considered:

- The variety of products covered by the inspection activity.
- The level of hazard inherent in those products.
- Qualification, experience and skills needed by the inspectors.
- Any regulatory requirements.

The examination of equipment and documentation used by the witnessed inspectors will form part of the witness activity.

The SCC team will seek to confirm that:

- the inspector has the competence for the task being performed;
- the inspector's competence is consistent with the records;
- the inspector is using the correct up-to-date documents and equipment fit for the purpose;
- the proper application of the method by the inspector; and,
- record keeping and reporting conforms to the inspection method and the IB's procedural requirements.

[8] Note that for customers inspecting Medical Gas Piping Systems, on-site assessments will generally only occur during the initial assessment, and during the reassessment years. Additional assessments may occur when required by SCC (e.g. in response to complaints).

E.4. Witness Audit Frequency

The minimum witness audit frequency requirement is based on the type of inspection program that is accredited by SCC. If an IB is accredited for more than one inspection program, then the requirements shall still be met within each program.

Type of Product Inspected	Minimum number of witness audits to be conducted each year[9]
Electrical Products	Two
Medical Electrical Equipment	Two
Medical Gas Piping Systems	One
Commercial and Industrial Gas-fired Appliances and Equipment	One

Initial accreditation or scope extensions can be conditional upon the successful scheduling of one witness audit within 6 months from the date of the granting of accreditation. If the witness audit is not scheduled within the 6 months' timeframe then the accreditation or scope extension will be withdrawn.

[9] Each year in this context refers to SCC's fiscal calendar, April 1 to March 31.

Annex F: Testing and Calibration Laboratory Accreditation

F.1. Program Requirements

All Laboratories

- ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories
- SCC Requirements & Guidance – Proficiency Testing for Testing and Medical Laboratories
- SCC Requirements and Guidance for Calibration and Measurement Traceability in Testing Laboratories
- SCC Requirements & Guidance on the Use of Information Technology in Accredited Laboratories
- SCC Requirements and Guidance for Method Validation in Testing Laboratories
- SCC Requirements and Guidance for the Accreditation of Testing Laboratories
- SCC Requirements and Guidance for the Accreditation Of Testing and Calibration Laboratories Performing On-Site Testing and Calibrations
- ILAC P8:12/2012 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
- ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10:01/2013 ILAC Policy on Traceability of Measurement Results
- ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration

Laboratories performing forensic testing

- SCC Requirements and Guidance for the Accreditation for Forensic Testing Laboratories

Laboratories performing Information technology security evaluation & testing

- SCC Requirements and Guidance for the Accreditation of Information Technology Security Evaluation and Testing Facilities including Cryptographic Module and Algorithm Testing Facilities

Laboratories performing mineral analysis testing

- SCC Requirements and Guidance for the Accreditation of Mineral Analysis Testing Laboratories

Laboratories performing Test Method Development & Evaluation and Non-Routine Testing

- SCC Requirements and Guidance for Accreditation of Laboratories Engaged in Test Method Development and Non-Routine Testing

F.2. Accreditation Cycle

Upon initial accreditation, each accredited laboratory will be subject to regular reassessment activities. The due date for the first reassessment is twelve months after the laboratory is

granted accreditation, or two years after the assessment visit, whichever comes first. After the first reassessment, the reassessments will then occur every two years.

In the years between reassessment years, 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, and to submit a summary of its participation in proficiency testing activities. The Surveillance Questionnaire is then reviewed by SCC staff who will confirm if the information provided is acceptable. If deficiencies are identified, SCC staff will follow-up with the laboratory.

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

1. Initial Assessment Visit	May 26, 2019
2. Accreditation granted	March 07, 2021
3. First Reassessment Visit	May 26, 2021
4. Surveillance Questionnaire	May 26, 2022
5. Next Reassessment Visit	May 26, 2023
6. Surveillance Questionnaire	May 26, 2024

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 organization's staff. The visits should take place within 3 months of the due date.

The Surveillance Questionnaires will be sent 1 to 3 months before the due date. Responses are to be received at SCC on or before the due date.

Changing the Scheduled Due Dates

The organization will be notified of the initially scheduled due date at the same time as they are notified that accreditation is granted. Organizations 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 the organization has been granted accreditation. However, some restrictions apply:

- Advancing Due Dates: Due dates may be advanced (where the revised 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.

- Delaying Due Dates: Due dates may be delayed (where the revised due date is later) by up to three (3) months only once within a 5 year period. Five (5) years from the new due date, the organization may request a further delay.

F.3. Serious and Critical Nonconformities

Occasionally, within the course of an assessment activity the assessment team will discover serious or critical nonconformities which must be addressed with more urgency. A serious nonconformity is one or a series of nonconformities for which documentation alone cannot provide confidence in the effectiveness of their resolution. A critical nonconformity is one or a series of nonconformities that affect test/calibration results or that render the management system ineffective.

In these instances and when serious or critical nonconformities have been identified, the assessment team will consider if:

- accreditation can be granted or maintained, and/or;
- there is a need for more extensive surveillance of the laboratory, and;
- shorter timeframes are required for the laboratory to submit the plan of corrective action and evidence of its implementation.

If a serious or critical nonconformity is discovered, the assessment team will consider the following when applicable:

a) For applicant laboratories, the team will consider recommending a reduction of the proposed scope in the case where only certain portions of the scope are affected by the critical nonconformity;
b) For accredited laboratories, the team will consider recommending immediate full or partial suspension of the scope of accreditation or the formulation of a request from the laboratory to voluntarily suspend or withdraw affected tests/calibrations from the scope of accreditation;
c) In the situation when an accredited laboratory has requested a scope extension, and the problem is generalized, the team will consider not recommending any requested scope extension. When the problem is localized, the team will consider not recommending scope extensions in the affected area;
d) The team will recommend an extraordinary on-site assessment when the review of the supporting documentation alone may not definitely provide the confidence that the corrective measures are effective.
e) The team will consider recommending an extraordinary on-site assessment to assess the continued effective implementation of the QMS or when there are concerns that a laboratory will be capable to effectively maintain the corrective action assessed at a previous extraordinary on-site assessment
f) The possibility of conducting the next reassessment in advance of the scheduled date may also be considered. Specific conditions related to the areas affected by the critical nonconformities require consideration for this recommendation.
g) Extraordinary activities can be compounded when different aspects of the laboratory technical and management system have identified critical nonconformities.

An additional or early on-site assessment will be deemed necessary when the team judges that the situation is such that:

- fully mastering the newly implemented process will take time; or
- the team is concerned about recurrence due to the magnitude of the change or due to a lack of sufficient evidence to determine that the problem will not reoccur.

Recommendations following the discovery of critical nonconformities will be made by the lead assessor to SCC for decision and the decision will be communicated to the laboratory.

F.4. Partner Organizations

Certain portions of SCC's Laboratory Accreditation Program are provided in partnership with other organizations that are qualified and monitored on a regular basis by 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 SCC. SCC retains the authority and right for the approval and granting of accreditation. Applications and fees for accreditation through a partner are processed directly by the Partner and not by SCC.

Complaints, appeals and suspensions related to accreditation are processed exclusively through SCC and the requirements of this document. The mandatory withdrawal or suspension of a laboratory's accreditation (full or partial scope) may only be authorized by SCC.

The Calibration Laboratory Assessment Service (CLAS) of the National Research Council of Canada (NRC) is the Partner Organization for calibration laboratories. In addition to accreditation by SCC, CLAS certifies specific measurement capabilities of calibration laboratories of successful applicants in support of the Canadian National Measurement System and allows the use of the CLAS logo. For more information about this program see the NRC CLAS information via www.nrc-cnrc.gc.ca

Bureau de normalisation du Québec - Évaluation des laboratoires (BNQ-EL) is the Partner Organization for those organizations located in Québec who may wish to obtain SCC laboratory accreditation through BNQ-EL. Consult the BNQ-EL website for details: www.bnq.qc.ca

F.5. Group Accreditation

SCC is able to grant group accreditation to laboratories operating from more than one location. To facilitate customer management, group accreditation will consist of at least two locations operating under the same legal entity. Accredited laboratories seeking group accreditation must make the request to do so to their respective Account Manager. First time applicants must request group accreditation when applying.

In general, organizations best suited for group accreditation carry out the same or similar testing and/or calibration activities at all locations.

F.5.1 Prerequisites

Organizations must:

a) demonstrate that all locations within or seeking group accreditation ("the Group") are part of the same legal entity;
b) demonstrate that all these locations operate under the same management system (as defined in ISO/IEC 17025) with a central office;
c) The following needs to be identified to SCC:
    i. a contact person for the Group having defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; and
    ii. a central contact person for the Group for the purpose of billing by SCC;
d) document fully the relationships between all locations which are part of the Group and the extent of interaction (e.g. allocation of testing and/or calibration work, transfer of samples between locations, movement of technical staff and/or equipment and centralized or otherwise rationalised arrangements for reporting of results);
e) if applicable, have mechanisms in place to track progress of work throughout the locations of the Group, regardless of any transfer of work between locations;
f) ensure that customers are aware and agree with any transfer of work between locations; and
g) clearly identify the tests and/or calibrations to be included on the scope of accreditation which can be carried out at each location for which accreditation is to be maintained or sought.

A location may not hold more than one SCC laboratory accreditation. SCC may terminate a laboratory's individual accreditation if and when the same laboratory is brought into a group accreditation.

F.5.2 Scopes and certificates of group accreditation

Individual scopes of accreditation and certificates are issued by SCC to each location within the Group, each location having a unique identification number (accreditation file number). The scope of accreditation of each location will contain references to the location being part of a group accreditation and will list all the other locations being part of the group.

F.5.3 Assessment and accreditation processes

All SCC accreditation processes for laboratory accreditation apply to group accreditation. Before a new location (which does not hold accreditation from SCC) can be brought into an existing group accreditation, SCC must conduct a full assessment of the new location entering the Group. If applicable, all required actions must be resolved and closed as per program description prior to the new location joining the Group. In addition, there shall be no outstanding required actions from previous assessments of the other locations in the Group.

As a general rule, on-site assessment of each location involved in the Group are scheduled and conducted as per program description.

All locations will cooperate so that on-site assessments can be conducted within approximately the same time period; ideally within 6 months of each other. To facilitate this coordination, reassessment dates of all locations within the Group will be aligned. As much as possible, the same Lead Assessor will be assigned the assessment of each location within the Group. The same assessors and/or technical experts may be used at the different locations when the same or similar type of testing and/or calibration activity is performed.

For reassessment visits, the entire management system will be reassessed over the Group. Some locations may have an abbreviated reassessment provided that: 1) the entire scope of tests and/or calibrations is reassessed at each location; 2) the reassessment is thorough enough to allow a reliable determination of the collective conformity of the management system throughout the Group; 3) the reassessment plan takes into account such factors as past performance and complexity of tests or calibrations; and 4) the activities sampled for reassessment vary between locations and from one visit to the next.

Organizational structures and inter-relations can differ considerably between organizations. Assessments and reassessments will take these into consideration while ensuring that the principles outlined in this document are respected.

A findings report will be prepared by the assessment teams for each individual location within the Group. The individual reports will identify clearly the findings applicable to specific locations. A corporate report will also be prepared where findings that are common to all locations will be summarized (e.g.: finding pertaining to the Quality Manual). The assessment teams will present each location with their respective findings. The corporate report will be presented at the last scheduled visit for the Group.

Recommendations for accreditation and continued accreditation may be presented to SCC by the assessment team in a single aggregate report covering the visits to all locations in the Group, provided that these reports describe the scope of assessment activities carried out at each location and provided that they identify the location(s) to which each requirement applies.

F.5.4 Suspension, reduction and withdrawal of accreditation

Suspensions, reductions, and withdrawals in scope at one location will automatically involve consideration by SCC of the implications for the Group. Where associated activities at other locations are affected or where distinction between affected and unaffected activities at different locations is not feasible, the suspension, reduction, or withdrawal of scope would apply across the Group. The Group may request suspension or withdrawal of specific locations from the group accreditation.

In the event of withdrawal or resignation of the group accreditation, any location included in the Group that wishes to remain accredited will need to apply for individual accreditation, and to pay an application fee. SCC will apply its full accreditation processes to such applications.

F.6. Scope Retention for Routine Tests Conducted Infrequently

Definition for Routine Tests Conducted Infrequently: The analytical requirement has been encountered before, however, the testing is not in regular use or has low or very occasional sample requests, e.g. seasonal. A suitable, validated, accredited test method for solving the issue exists; however, specific quality assurance and quality control measures are required prior to the commencement (reuse) of the testing on customer samples and need to be defined by the laboratory in a documented procedure.

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

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

Qualified Staff: Have qualified testing staff (not including trainees) that can perform all the tests listed in the accredited scope. The training records shall 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: Provide and have available the latest test report(s) or representative test report(s) for the all the tests listed in its accredited scope.

Note: The testing laboratory must keep itself informed of changes to industry requirements, regulations, and improvements to technology used in the test. The laboratory may need to revalidate a non–standard test procedure when changes occur.

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.

The testing laboratory shall participate in external proficiency testing, or inter-laboratory comparison, or external quality assessment where it is available and have appropriate quality control procedures to assure the quality of the test results (refer to SCC Requirements & Guidance - Proficiency Testing for Testing and Medical Laboratories).

Annex G: Medical Laboratory Accreditation

G.1. Program Requirements

- ISO 15189:2012 Medical laboratories — Requirements for quality and competence
- ISO 22870:2016 - Point-of-care testing (POCT) — Requirements for quality and competence
- ISO 15190:2003 - Medical laboratories — Requirements for Safety
- CAN/CSA-Z902-15 Blood and blood components
- SCC Requirements & Guidance – Proficiency Testing for Testing and Medical Laboratories

G.2. Accreditation Cycle

SCC or the applicable Partner ensures continued compliance with accreditation requirements by conducting on-site assessments of each accredited medical laboratory. Interim to the on-site assessments, medical laboratories are required to complete and respond to a surveillance questionnaire.

In order to obtain accreditation, the laboratory shall undergo an initial on-site assessment. Subsequently, the laboratory will undergo an on-site assessment one year after being granted accreditation (first reassessment). Starting with the first reassessment, the laboratory will undergo an on-site reassessment every two years. For years where no on-site reassessments are scheduled, the laboratory will be requested to complete a surveillance questionnaire.

A reassessment is similar to an initial assessment. The reassessment is a comprehensive on-site evaluation to confirm full conformance with all the clauses of the applicable standard and with specific applicable program requirements, conducted to confirm maintenance of accreditation. During the on-site reassessment, the entire scope of accreditation is reassessed. Each discipline for which the laboratory is accredited is reviewed. The reassessment team is composed of a Lead Assessor, and additional assessors competent to perform the technical assessment of the laboratory.

In the years between on-site reassessments, 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 and to submit a summary of its participation in proficiency testing activities. Completing the Surveillance Questionnaire in a timely manner is essential to maintaining the conditions of accreditation. The Surveillance Questionnaire is then reviewed by appropriate SCC staff or Partner equivalent who will confirm if the information provided is acceptable. If deficiencies are identified, appropriate SCC staff or Partner equivalent will follow-up with the laboratory.

G.3. Partner Organizations

For organizations located in the province of Quebec, SCC's Medical Laboratory Accreditation Program is provided in partnership with the Bureau de normalisation du Québec - Évaluation des laboratoires (BNQ-EL) that is qualified and monitored on a regular basis by SCC. In these cases, BNQ-EL receives the application and conducts the assessment of the applicant as well as the maintenance and surveillance activities. BNQ-EL forwards a recommendation for accreditation to SCC which retains the authority and right for the approval and granting of accreditation. Applications and fees for accreditation through BNQ-EL are processed directly through BNQ-EL and not through SCC.

Complaints, appeals and suspensions related to accreditation are processed exclusively through SCC and the requirements of this document. Mandatory withdrawal of a medical laboratory's accreditation may only be authorized by SCC.

Those organizations located in Quebec who may wish to obtain SCC medical laboratory accreditation through BNQ-EL are advised to the BNQ-EL website for further details: www.bnq.qc.ca.

G.4. Group Accreditation

SCC is able to grant group accreditation to laboratories operating from more than one location. To facilitate customer management, group accreditation will consist of at least two locations operating under the same legal entity. Accredited laboratories seeking group accreditation must make the request to do so to their respective Account Manager. First time applicants must request group accreditation when applying.

In general, organizations best suited for group accreditation carry out the same or similar testing and/or calibration activities at all locations.

G.4.1 Prerequisites

Organizations must:

a) demonstrate that all locations within or seeking group accreditation ("the Group") are part of the same legal entity;
b) demonstrate that all these locations operate under the same management system (as defined in ISO 15189) with a central office;
c) The following needs to be identified to SCC:
    i. a contact person for the Group having defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; and
    ii. a central contact person for the Group for the purpose of billing by SCC;
d) document fully the relationships between all locations which are part of the Group and the extent of interaction (e.g. allocation of testing and/or calibration work, transfer of

samples between locations, movement of technical staff and/or equipment and centralized or otherwise rationalized arrangements for reporting of results);

e) if applicable, have mechanisms in place to track progress of work throughout the locations of the Group, regardless of any transfer of work between locations;
f) ensure that customers are aware and agree with any transfer of work between locations; and
g) clearly identify the tests and/or calibrations to be included on the scope of accreditation which can be carried out at each location for which accreditation is to be maintained or sought.

A location may not hold more than one SCC laboratory accreditation; SCC may terminate a laboratory's individual accreditation if and when the same laboratory is brought into a group accreditation.

G.4.2 Scopes and certificates of group accreditation

Individual scopes of accreditation and certificates are issued by SCC to each location within the Group, each location having a unique identification number. The scope of accreditation of each location will contain references to the location being part of a group accreditation and will list all the other locations being part of the group.

G.4.3 Assessment and accreditation processes

All SCC accreditation processes for laboratory accreditation apply to group accreditation. Before a new location can be brought into an existing group accreditation, SCC must conduct a full assessment of the new location entering the Group. If applicable, all required actions must be resolved and closed as per program description prior to the new location joining the Group. In addition, there shall be no outstanding required actions from previous assessments of the other locations in the Group.

As a general rule, on-site assessment of each location involved in the Group are scheduled and conducted as per program description.

All locations will cooperate so that on-site assessments can be conducted within approximately the same time period; ideally within 6 months of each other. To facilitate this coordination, reassessment dates of all locations within the Group will be aligned to coincide.

The same Lead Assessor will be assigned the assessment of each location within the Group. The same assessors and/or technical experts may be used at the different locations when the same or similar type of testing and/or calibration activity is performed.

For reassessment visits, the entire management system will be reassessed over the Group. Some locations may have an abbreviated reassessment provided that: 1) the entire scope of tests and/or calibrations is reassessed at each location; 2) the reassessment is thorough

enough to allow a reliable determination of the collective conformity of the management system throughout the Group; 3) the reassessment plan takes into account such factors as past performance and complexity of tests or calibrations; and 4) the activities sampled for reassessment vary between locations and from one visit to the next.

Organizational structures and inter-relations can differ considerably between organizations. Assessments and reassessments will take these into consideration while ensuring that the principles outlined in this document are respected.

A report will be prepared by the assessment teams for each individual location within the Group. The individual reports will identify clearly the findings applicable to specific locations. A corporate report will also be prepared where findings which are common to all locations will be summarized (e.g.: finding pertaining to the Quality Manual). The assessment teams will present each location with their respective findings. The corporate report will be presented at the last scheduled visit for the Group.

Recommendations for accreditation and continued accreditation may be presented to SCC by the assessment team in a single aggregate report covering the visits to all locations in the Group, provided that these reports describe the scope of assessment activities carried out at each location and provided that they identify the location(s) to which each requirement applies.

G.4.4 Suspension, reduction and withdrawal of accreditation

Suspensions, reductions, and withdrawals in scope at one location will automatically involve consideration by SCC of the implications for the Group. Where associated activities at other locations are affected or where distinction between affected and unaffected activities at different locations is not feasible, the suspension, reduction, or withdrawal in scope would apply across the Group. The Group may request suspension or withdrawal of specific locations from the group accreditation.

In the event of withdrawal or resignation of the group accreditation, any location included in the Group that wishes to remain accredited will need to apply for individual accreditation, and to pay an application fee. SCC will apply its full accreditation processes to such applications.

G.5. Scope Retention for Routine Tests Conducted Infrequently

Definition for Routine Tests Conducted Infrequently: The analytical requirement has been encountered before; however, the testing is not in regular use or has low or very occasional sample requests, e.g. seasonal. A suitable, validated, accredited test method for solving the issue exists; however, specific quality assurance and quality control measures are required prior to the commencement (reuse) of the testing on customer samples and need to be defined by the laboratory in a documented procedure.

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

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

Qualified Staff: Have qualified testing staff (not including trainees) that can perform all the tests listed in the accredited scope. The training records shall 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: Provide and have available the latest test report(s) or representative test report(s) for the all the tests listed in its accredited scope.

Note: *The medical laboratory must keep itself informed of changes to industry requirements, regulations, and improvements to technology used in the test. The laboratory may need to revalidate a non–standard test procedure when changes occur.*

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.

The medical laboratory shall participate in external proficiency testing, or inter-laboratory comparison, or external quality assessment where it is available and have appropriate quality control procedures to assure the quality of the test results.

G.6. Guidelines for the Presentation of Medical Laboratory Testing Scopes

G.6.1 Introduction

This Annex provides guidance in the preparation of the Scope of Accreditation to be presented for submission to the Standards Council of Canada (SCC) Medical Laboratory Accreditation Program with an application for accreditation. This Annex will help organizations to prepare their proposed testing scope in application for accreditation and avoid delays caused by revisions to the proposed scope during the accreditation process. The criteria in this Annex also apply to maintaining accredited scopes.

The Scope becomes an Accreditation Document and is intended to formally and precisely state the activities for which the laboratory is accredited. Accreditation is site specific and even when

part of a larger organization the accredited site must be identified on the Scope (the scope is site specific).
For medical laboratories, the scope may be defined as a fixed scope or a flexible scope. An organization may choose, in agreement with the accreditation body, a fixed or a flexible scope.

When SCC accredits an organization, the Scope becomes the Scope of Accreditation.
The laboratory initially drafts the Scope for which accreditation is sought. Scopes for medical laboratories being serviced by SCC or by partner will be finalized after review and discussions between appropriate parties and the laboratory.

SCC recognizes that it may be impractical, in some cases, to specify precise details for every test for which accreditation is sought. Therefore applicant and accredited laboratories are allowed to opt for a flexible scope.

The guiding principle is that the Scope of Accreditation must state capabilities as clearly and unambiguously as possible in order not to be misleading in any way about the accredited capabilities.

The scope may be revised following an assessment or reassessment visit. This can consist of either a suitable reduction or could, when acceptable to both parties, result in added capabilities. The revision can also be editorial to ensure the criteria in this Annex are met.

G.6.2 Definitions

Fixed Scope: The Scope may contain a single test or many test methods in a range of disciplines. It is a combination of information concerning the field of activity (e.g. testing), the product/object tested and the methods and procedures used.

The fixed scope lists the field of testing, the tests or types of tests performed, and material or matrices tested, and, where appropriate the methods used.

Flexible Scope: A flexible scope lists the disciplines for which the laboratory is accredited to perform tests, the sub discipline as well as the technology, methodology or analytical principle used. In addition to the flexible scope, the laboratory must maintain a current list of methods (with matrices) covered by the accreditation including newly modified, introduced or developed methods. This list shall be a controlled document and shall be part of the management system documentation/records. This list shall be readily and publicly available. The flexible scope shall make reference to this list or shall give information on how to obtain the list. Accredited laboratories having a flexible scope are allowed to modify their own laboratory-developed methods, to use updated versions of the standard methods for which they are accredited, to introduce similar new methods, or to use/modify a method that they are accredited for, without having to report to the Accreditation Body in advance, provided that these modifications and updated versions or new methods do not incorporate new measurement principles that are not

covered by the original description of the scope. The laboratory must have a procedure to manage the flexible scope.

Flexible scope allows for flexibility such as:

- flexibility concerning parameters/analytes which allows for changes with respect to parameters that are analyzed using a method;
- flexibility concerning the performance of the method which allows for changes in the performance of the method for a given specimen type and a given parameter (e.g. modification of measuring range and uncertainty for a specific parameter);
- flexibility concerning the method which allows adoption of methods that are equivalent to methods already covered by accreditation.

A flexible scope does not allow the laboratory to make the following changes without informing the accreditation body (see request for scope extension):

- introduce a new matrix/sample or modify a matrix/sample for an accredited method or analysis
- introduce a new method or a new equipment using an analytical principle or technology different than the ones already evaluated during an on-site visit;
- to change the principle or technology of an existing accredited method for a method that has been evaluated during an on-site visit.

Analytical principle: General principle that describes the method performed by the laboratory to detect, identify, characterize and/or determine the concentration of an analyte (parameter), including, if necessary, the pre-treatment or the detection method. In the analytical principle, the technology is described when necessary.

Technology: Specific technique used in a method to realize the analytic principle.

Non-routine Analysis: Refers to ad-hoc or one-of-a-kind work that is carried out for a specific purpose and may reflect a degree of innovation and limited notice. Typically it is used in the context of work on out of the ordinary samples where established methods of analysis are unsuitable. These analyses required either significant adaptation of established methods, new method development or the establishment of innovative approaches. Non-routine analysis and routine analysis conducted infrequently may be included in the scope of accreditation.

G.6.3 Content of a Scope

Only those tests for which a laboratory can demonstrate competence in compliance with the SCC requirements, those of the test method and the requirements of ISO 15189 will be listed in the Scope of Accreditation.

Accreditation means recognition of the competence of a laboratory to carry out and report tests in accordance with specified requirements in the methods. In general, SCC does not accredit activities of a subjective or interpretative nature.

SCC grants accreditation to a laboratory for those activities that the laboratory itself is competent to carry out. Laboratories are required to be capable of demonstrating that they themselves perform the test or measurement for which accreditation is sought or granted.

Accreditation can only be granted for tests or measurements that a laboratory can demonstrate, by objective evidence, that they have conducted themselves.

In the case of a fixed scope, the scope of accreditation must be as detailed as possible and give the specific identification of all testing methods to be accredited. The scope must list the disciplines, the sub disciplines, the methodology, the matrix, the parameters and analytes and the reference to a standardized method, if applicable.

G.6.4 Medical Disciplines

There are 13 Principle Disciplines for medical laboratory accreditation:

1) Anatomical Pathology
2) Biochemistry
3) Cytology
4) Genetics / Cytogenetics
5) Hematology
6) Immunology
7) Maternal Serum Screening
8) Microbiology
9) Molecular Biology
10) Mycology
11) Parasitology
12) Transfusion medicine
13) Virology

Point of Care Testing (POCT) may be included in the scope of accreditation, however an accreditation cannot be granted for an organization that is asking for POCT accreditation only. A laboratory choosing to obtain POCT accreditation according to ISO 22870 must list point of care testing on the scope of accreditation in the annexes to the scope created for this purpose. Under the discipline to which the POCT belong, an indication is included to link the discipline to the corresponding POCT.
The Appendix A of the scope of accreditation lists the sites within the same establishment of the accredited laboratory where POCT are performed.
The Appendix B of the scope of accreditation lists the sites outside the accredited laboratory where POCT are performed.

Each Principal Discipline may be divided into sub-categories that are more specific. These are named Sub-disciplines. As a general rule, tests are listed under the appropriate Principal Disciplines. A Sub-discipline must be listed with its corresponding Principal Discipline.

Each of the Principal Disciplines or Sub-disciplines may have an optional description added immediately below. This is a free form text that the laboratory may use to characterize or describe that discipline. The only restriction is that it cannot be misleading with regards to the actual testing capabilities associated with the discipline nor constitute publicity in any manner. SCC reserves the right to edit these descriptions as deemed appropriate.

A test may not be listed more than once even if it applies to multiple disciplines. For these cases the test is to be listed under the first listed applicable Principle Discipline. Additional listings are referenced to the first Principal Discipline where the test is listed.

When an organization operates a flexible scope, the additional requirements outlined in ILAC G18:04/2010 *"Guideline for the Formulation of Scopes of Accreditation for Laboratories"* shall be met.

G.7. Policy for the Selection of Sample Collection Facilities and of Establishements where POCT are offered to be Evaluated On-Site

G.7.1 Introduction

This document is intended for the assessment of medical laboratories which have multiple sample collection facilities and/or establishments where POCT are performed/offered (sites) to ensure that the evaluation provides adequate confidence in the conformity of the management system to the relevant standard across all facilities (sites) and that the evaluation is both practical and feasible in economic and operative terms.
Normally initial assessments and subsequent reassessments should take place at every site of the organization that is to be covered by the accreditation. However, where an organization's activity is carried out in a similar manner at different sites, all under the organization's authority and control, the accreditation body may put into operation appropriate procedures for sampling the sites at the initial assessment and subsequent reassessments. This document addresses the calculation of sample size.

G.7.2 Requirements for the organization

The organization's management system shall be under a centrally controlled and administered plan and be subject to central management review. All the relevant sites (including the central administration function) shall be subject to the internal audit program of the organization and all shall have been audited in accordance with that program prior to the accreditation body starting its evaluation.

It shall be demonstrated that the central laboratory of the organization has established a management system in accordance with the relevant management system standard and that the whole organization meets the requirements of the standard.

G.7.3 Sampling

Methodology

The sample should be selected based on the factors set out below and should result in a representative range of different sites being selected, without excluding the random element of sampling within a certain geographical region.

The sample should be selected so that the differences among the sites selected over the period of validity of the certificate are as large as possible.

The site selection may include, among others, the following aspects:

- results of internal site audits and management reviews or previous accreditation assessments;
- records of complaints and other relevant aspects of corrective and preventive action;
- significant variations in the size of the sites;
- variations in shift patterns and work procedures;
- complexity of the management system and processes conducted at the sites;
- maturity of the management system and knowledge of the organization; and
- geographical dispersion.

This selection is to be done at the start of the assessment process. The laboratory shall be informed of the sites to be included in the sample. This can be on relatively short notice, but should allow adequate time for preparation for the assessment activity.

Size of Sample

The following calculation should be applied:

Guiding the number of sites to be visited is as follows:
Initial assessment and subsequent reassessments: the size of the sample should be the square root of the number of remote sample collection sites, rounded up to the next whole number.

The main sample collection site (usually the one attached to the laboratory) shall be assessed during every initial accreditation and subsequent reaccreditations.

The size or frequency of the sample should be increased where the accreditation body's risk analysis of the activity covered by the management system subject to accreditation indicates special circumstances in respect of factors such as:

- Variations in working practices (e.g. shift working);
- Variations in activities undertaken;
- Records of complaints and other relevant aspects of corrective and preventive action;
- Results of internal audits and management review; and
- Results of the accreditation body's previous assessment activities.

Example:
One laboratory with one central sample collection site and 27 sample collection sites

Initial assessment: central sample collection site and 6 (sq. root of 27 rounded up to the next whole number) sample collection sites are visited (total of 7).

Reassessment: central sample collection site and 6 (sq. root of 27 rounded up to the next whole number) sample collection sites are visited.

Additional Sites

On the application of a new group of sites to join an already accredited laboratory, the new group of sites is considered as an independent set for the determination of the sample set for the scheduled reassessment. After the inclusion of the new group, the new sites will be added to the existing ones for determining the sample size for future reassessment visits.

Example:
For the previous example, the laboratory decides to include new 5 sites.
For the reassessment, central sample collection site, 6 (sq. root of 27 rounded up to the next whole number) sample collection sites among the ones previously accredited and 3 sites among the new ones (sq. root of 5 rounded up to the next whole number) are visited, total visited sites being 9.
For the future reassessments, 7 (sq. root of 32 rounded up to the next whole number) sites are visited.

G.7.4 Outcome of the assessment of sample collection facilities and of the establishments where POCT are offered/performed

In order for an organization to obtain and maintain accreditation, all the visited sites shall meet the appropriate requirements of the standard.

Annex H: Proficiency Testing Provider Accreditation

H.1. Program Requirements

- ISO/IEC 17043:2010 - Conformity assessment — General requirements for proficiency testing

H.2. Accreditation Cycle

Upon initial accreditation, each accredited laboratory will be subject to regular reassessment activities. The due date for the first reassessment is twelve months after the laboratory is granted accreditation, or two years after the assessment visit, whichever comes first. Reassessments will then occur every two years after that date.

In the year between reassessment years, 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, but not limited to these. The Surveillance Questionnaire is then reviewed by SCC staff who will confirm if the information provided is acceptable. If deficiencies are identified, SCC staff will follow-up with the laboratory.

H.3. Partners

Certain portions of SCC's Proficiency Testing Provider Accreditation Program are provided in partnership with other organizations that are qualified and monitored on a regular basis by SCC. In these cases, the Partner Organization receives the application and conducts the assessment of the applicant as well as the maintenance and surveillance activities. The Partner Organization forwards a recommendation for accreditation to SCC. SCC retains the authority and right for the approval and granting of accreditation. Applications and fees for accreditation through a Partner are processed directly through the Partner Organization and not through SCC.

Complaints, appeals and suspensions related to accreditation are processed exclusively through SCC and the requirements of this document. Mandatory withdrawal of a proficiency testing provider's accreditation may only be authorized by SCC.

Bureau de normalisation du Québec - Évaluation des laboratoires (BNQ-EL) is the Partner organization for those organizations located in Québec who may wish to obtain SCC proficiency testing provider accreditation through BNQ-EL. Consult the BNQ-EL website for details: www.bnq.qc.ca

Annex I: Good Laboratory Practice Recognition

I.1. Program Requirements

- No.1, OECD Principles on Good Laboratory Practice (1998)
- No.2, Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995)
- No.3, Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (1995)
- No.4, Quality Assurance and GLP (1999)
- No.5, Compliance of Laboratory Suppliers with GLP Principles (2000)
- No.6, The Application of the GLP Principles to Field Studies (1999)
- No.7, The Application of the GLP Principles to short-term Studies (1999)
- No.8, The Role and Responsibilities of the Study Director in GLP Studies (1999)
- No.9, Guidance for the Preparation of GLP Inspection Reports (1995)
- No.11, The Role and Responsibility of the Sponsor in the Application of the Principles of GLP (1998)
- No.12, Requesting and Carrying out Inspections and Study Audits in another country (2002)
- No.13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies (2002)
- No.14, The Application of the Principles of GLP to in vitro Studies (2004)
- No.15, Establishment and Control of Archives that Operate in Compliance with the Principles of GLP (2007)
- No.16, Guidance on the GLP Requirements for Peer Review of Histopathology (2014)
- No. 17, Application of GLP Principles to Computerised Systems (2016)

I.2. Program Scope

The Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) is a managerial concept covering the organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Non-clinical health and environmental safety studies covered by the principles of GLP include work conducted in the laboratory, in greenhouses and in the field. A 1989 OECD Council Decision-Recommendation [C(89)87(Final)] established that OECD Member countries, in which testing of chemicals for purposes of assessment related to the protection of human health and the environment being conducted pursuant to the principles of GLP, shall establish procedures for monitoring compliance with GLP based upon facility inspections and study audits. To this end, in 1995, the Standards Council of Canada (SCC) was established as a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD and functioning in accordance with the OECD document Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice. Health Canada's Pest Management Regulatory Agency (PMRA) in its role as the regulatory authority for pesticide registration in Canada, and Health Canada's Health Products and Food Branch of Health Canada (HPFB) have recognized SCC as the GLP MA of facilities submitting human health and environmental safety studies. The HPFB GLP policy directive applies to sponsors submitting non-clinical data in Clinical Trial Applications, New Drug Submissions or

Drug Identification Number applications relating to pharmaceuticals, radiopharmaceuticals or biologic drugs for human use. Non-clinical studies include all in vitro and in vivo testing, not involving human subjects, performed to determine the safety of human drugs. A comprehensive list of studies requiring compliance to the Principles of GLP is available from the respective receiving authorities. A 1981 OECD council decision [C(81)30(Final)] decided that data generated in an OECD Member country in accordance with the OECD Principles of GLP shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of human health and the environment; that is, the Mutual Acceptance of Data (MAD). SCC GLP MA in-compliance recognition of domestic test facilities and test sites (including field sites) involved in pre-market non-clinical human health and environmental safety studies on pesticides, industrial chemicals, and pharmaceuticals meets the requirements of the OECD Decision on MAD, and facilitates acceptance of Canadian pesticide, industrial chemical, and pharmaceutical GLP studies submitted to receiving authorities in other OECD Member countries.

This document describes SCC's policies and procedures in its role as the GLP MA with respect to granting GLP recognition. The GLP MA activities focus primarily on inspections and study audits of domestic facilities completing non-clinical studies for submission to HC-PMRA (pesticides), HC-HPFB (Health Products and Food Branch) and also to Environment Canada for the New Substances Program (Industrial Chemical). Facilities conducting other non-regulated GLP studies can, however, apply for GLP compliance recognition and be inspected by SCC. SCC functions in accordance with the Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (2) and on a full cost recovery basis according to the Council's current published fee structure.

I.3. Personnel and Training

SCC maintains a roster of qualified GLP inspectors with practical experience as required by the scope of the areas of expertise included in each receiving authority's GLP program.

Inspectors are obtained primarily from government Departments or Agencies. If qualified inspectors are not available from these sources, individuals are contracted from the private sector. However, in all instances, SCC has in place conflict of interest protocols that will ensure the independence of the inspectors from the GLP facility, audited studies and corresponding study sponsors.

SCC inspectors have no powers of access to facilities or study data; however, once on site inspectors are tasked with conducting inspections, study audits, interviewing staff, and taking samples or documents as evidence of non-compliance. Any facility that refused such access or does not permit copying of evidence will be declared Not-in-Compliance and will be removed from the program.

I.4. Inspection Cycle

Facilities are subject to a routine full inspection on a 2-year cycle with biennial inspections due on the anniversary date of the facility's first inspection date.

For organizations with multiple field sites in different geographical locations, initial GLP recognition is based on inspection of the headquarters site and typically at least one remote site provided that all such sites are functioning under the same management and operational procedures. Subsequent routine inspections are conducted in a manner that would permit a rotation through those sites yet to be inspected and in a manner whereby all the field test sites are seen over a four year period.

Field sites will be inspected during the months which permit the inspection of all aspects of the field site. This includes the inspection of the actual field(s) where the crop will be planted and the inspection of field site equipment such as that used for the application of pesticides in the field. In the Canadian climate, this will typically mean that field site inspections cannot occur during the winter months or when weather is such that would not allow the inspection of all aspects related to a field site.

I.5. Monitoring Authority Operation

Generally, the GLP program operates according to the same process as outlined in the main body of this Program Overview document. However, due to the nature of the OECD GLP program and the differences between it and standard ISO conformity assessment programs, certain deviations do occur. In order to properly adhere to OECD requirements, the recognition process is detailed below.

The GLP MA operation is consistent with the *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (No.2)* with the recognition of GLP compliance based upon facility inspections and study audits conducted as per the *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (No.3)*.

I.5.1 Application

I.5.1.1 A facility applies to the GLP MA (SCC) for recognition by submitting the following:

a) a completed application form;
b) facility information as described in the application form; and
c) the appropriate non-refundable application fee according to the current published SCC fee structure.

I.5.1.2 An SCC Account Manager is assigned to the file and acknowledges receipt of the application.

I.5.2 Pre-inspection Activities

I.5.2.1 The application and supporting documentation are reviewed by a qualified Program Manager and additional information is requested, if required. For a GLP-compliant facility undergoing a routine full re-inspection, any new information will be reviewed prior to the visit.
I.5.2.2 When the submitted documentation is deemed complete, a team of inspectors is assembled and a mutually acceptable date is arranged for an inspection. The facility may veto the selection of the inspector(s) but must provide written rationale for such action.

I.5.2.3 A facility is given appropriate advance notice of any impending inspection or specific study audit.

I.5.3 Facility Inspections and Study Audits

I.5.3.1 Inspections to assess GLP compliance fall into the following categories:

a) an initial complete full inspection, including a facility inspection and study audit(s) for facilities which have previously conducted GLP studies;
b) a facility-only inspection for facilities which have not conducted GLP studies. In this case, a pre-inspection is performed to determine that the necessary infrastructure is in place (facilities, equipment, staff, SOPs, archives, etc.) to permit the facility to successfully conduct GLP compliant studies. Once a complete study is available, it is subsequently audited on-site to fully complete the recognition process;
c) an extraordinary inspection to verify that identified GLP non-compliances from a previous inspection have been suitably addressed;
d) a regularly scheduled biennial full inspection completed within 3-months of the anniversary date of compliance recognition; or
e) specific study audits requested by national or international receiving authorities.

I.5.3.2 Inspection costs are borne by the recipient facility. Costs associated with I.5.3.1 (e) are covered internally by the GLP MA.

I.5.3.3 Inspection findings (including those of section I.5.3.1 (b) are discussed with facility representatives during a Closing Meeting in accordance with the *Revised Guidance for the Conduct of Test Facility Inspections and Study Audits (3)*. During this meeting, a written findings report outlining all non-compliances (where applicable) is presented to the facility representatives. The report is then signed and dated by the inspector(s) and facility management.

I.5.3.4 Following inspection and within ten (10) days, the facility may appeal any findings in the inspectors' report with which it disagrees.

I.5.3.5 In response to a request for a specific study audit, as per I.5.3.1 (e), SCC and the facility schedule a time agreeable to both parties to conduct the study audit. SCC provides the

requesting authority with a detailed report which provides a summary of the activity and an outline of findings if applicable.

I.5.4 Post-inspection Activities

I.5.4.1 Upon completion of all required actions, the inspectors review the facility's response and provided evidence of compliance to the GLP inspection findings. Depending upon the nature of the GLP non-compliances, a re-inspection might be needed to verify that actions have been implemented as per clause I.5.3.1 (c). The inspectors review and approve the facility responses, but do not grant GLP compliance.

I.5.4.2 The Lead Inspector provides a recommendation; the file is then assigned to an independent, qualified reviewer. If the independent reviewer cannot make a positive recommendation, the facility will be advised of further actions required for compliance. The facility may then either take appropriate action, terminate its application or appeal the GLP MA's decision.

I.5.5 Granting or Continuing Recognition of GLP Compliance

I.5.5.1 Continued recognition is based upon the results of regularly scheduled biennial full routine inspections (or as stated above for field sites).

I.5.5.2 SCC's Vice President of Accreditation Services or their delegate grants a facility Recognition of GLP Compliance or continued in-compliance status.

I.5.5.3 If compliance is not granted the facility is advised of the reasons and may appeal the decision, following the procedures established by SCC for this purpose. Following a final decision for not granting or continuing recognition of GLP compliance, the facility may reapply at a later date.

I.5.5.4 GLP compliance is recognized by issuing formal documentation to compliant facilities: a certificate and formal letter granting recognition or continued recognition of GLP compliance. Applicant Facilities inspected for facility-only are issued a letter acknowledging that the necessary infrastructure is in place (facilities, equipment, staff, SOPs, archives, etc.) to permit the facility to successfully conduct GLP compliant studies.
Additionally, a list of GLP compliant facilities, their dates of compliance and their areas of expertise is maintained on the SCC website.

I.5.5.5 A recognized GLP facility must continue to comply with the requirements and conditions of the OECD Principles of GLP and to cooperate with SCC in its performance as a GLP MA verifying such compliance. Specifically, the facility shall:

a) allow SCC to carry out routine inspections, typically conducted at approximately two-year intervals, to support continued compliance;

b) allow SCC to carry out specific study audits at the request of national or international receiving authorities; and
c) report immediately, to SCC, any change that could affect its GLP compliant status. This includes, but is not limited to, changes in the area of studies conducted, personnel (particularly management, QA and Study Directors) or facility infrastructure.

I.5.6 Actions Resulting from GLP Non-compliance

I.5.6.1 Where only minor non-compliances have been found, such that the integrity of studies will not be compromised, SCC may grant or continue to grant GLP compliance (as per clause I.5.7.2) or, as appropriate, provide the Receiving Authority (RA) which requested a specific study audit with a detailed report of the findings.

I.5.6.2 Where major non-compliances are found, the action taken by the GLP MA is dependent upon the particular circumstances of each case. Actions may include:
a) issuing a recommendation to the RA that a study be rejected;
b) issuing a statement to the facility and the receiving authority of the inadequacies or faults found which might affect the validity of studies conducted in the facility; or
c) refusing to grant or continue to grant recognition of GLP compliance.

Such an action may include the removal of the facility from the program, a corresponding notation in the GLP MA list of inspected facilities described in clause I.5.8, notification to the applicable receiving authorities, and to the OECD.

I.5.7 Facility GLP Compliance Status

I.5.7.1 OECD GLP MAs must report facility compliance to each other and do so as: In-compliance; Pending; or Not-in-compliance. However, being declared **“Not-in-compliance”** can have consequences to a facility as it could mean a world-wide receiving authority rejection of study submissions. SCC will use the category Not-in-compliance where required.

I.5.7.2 If a facility inspection or study audit identifies GLP non-compliances which will not significantly compromise the integrity of studies, and the facility proposes to address them within the prescribed 90 days, an In-compliance status may be granted to the facility.

I.5.7.3 If the facility cannot complete the required actions within three months, it shall be subject to a Not-in-Compliance status. For a recognized facility the In-compliance status will be changed to **“Pending”** (with qualification) and can lead to a **“Not-in-compliance”** (withdrawn) status.

I.5.7.4 A facility that does not adhere to the requirements of clause I.5.5.7 shall be subject to a Not-in-compliance status, and shall be withdrawn from the program.

I.5.8 Reporting Facility GLP Compliance

SCC, as the GLP MA maintains a list of inspected facilities in Canada including the identification of the facility, dates of inspection and decisions, nature of the inspection, fields of compliance, area(s) of expertise and compliance status. The list which also identifies facilities recognized in accordance with clause I.5.5.2 (b) as having the necessary infrastructure in place to perform GLP compliant studies is annually reported to all OECD member counties and observers, the European Commission, the OECD secretariat and applicable domestic receiving authorities. The GLP MA immediately informs all parties of all changes to a facility's GLP compliance status.

I.6. GLP Recognition Publicity Guidelines

The following statement is recommended for use as a publicity statement by a recognised GLP facility:

"GLP compliance has been recognized by formal documentation issued on Yr/Mo/Day by the Standards Council of Canada, GLP Monitoring Authority based upon an inspection and study audits conducted Yr/Mo/Day - Yr/Mo/Day in the area(s) of [type of study(ies)] of [Chemical Type]."

Should a facility request to be removed from the SCC GLP program, or should a facility be withdrawn by SCC from the SCC GLP program, the facility must immediately cease issuing all reference to its former GLP compliant status. Upon reinstatement a facility may resume such publicity.

Annex J: Standards Development Organization Accreditation

J.1. Program Requirements

- Requirements & Guidance – Accreditation of Standards Development Organizations
- Requirements & Guidance – National Adoptions of International/Regional Standards and Other Deliverables

J.2. Accreditation Cycle

In advance of each fiscal year, a three year accreditation cycle plan will be developed or updated and provided to the Standards Development organization (SDO).The accreditation program will identify the required assessment activity(ies) for each year of the accreditation cycle.

During the three (3) years between initial accreditation and reaccreditation and between each reaccreditation, annual surveillance activities will be conducted at the SDO's head office. The first surveillance assessment activity will be conducted no later than twelve (12) months from the date of the assessment performed to support initial accreditation. Each surveillance assessment thereafter will take place no more than twelve (12) months of the previous assessment. Each accreditation activity will be referenced by the designation S1, S2, and RA.

The following clauses of the requirements will be reviewed during the surveillance assessment activity(ies);

- Canadian Relevance (5.1)
- Separation of Management Activities (5.3)
- Continuity of Operations (5.4)
- Identification of Canadian Interest & Need (4.2)
- Avoiding Duplication (4.3)
- Equal access and Effective Canadian Participation to the Standards development process by Concerned Interests (6.3)
- Work Program (4.4)
- Notice of Intent (6.6.1)

In the third (3) year of the Accreditation Cycle, SCC will conduct reaccreditation assessments. Reaccreditation assessments will be performed at the head office of the SDO. All clauses of the requirements will be reviewed and verified during the reaccreditation assessment (RA) activity.

J.3. Self Declaration

Requests for self-declaration of compliance with SCC's Requirements & Guidance for SDOs are processed through the SCC Account Manager assigned to the SDO.

The operational criteria for SDO's to self-declare are as follows;

- Completion by the SDO of Part 1 of the Request for Self-Declaration Status form
- SCC's accreditation of the SDO is in good standing.
- Document review by Accreditation Services Branch (ASB) to confirm SDO's policies and procedures are aligned with the 2017 Requirements & Guidance for SDOs.
- Evidence that SDO staff have been trained on the policies and procedures submitted to ASB.
- Five (5) successful National Standards of Canada (NSC) approvals to the current R&Gs by the Standards and International Relations Branch (SIRB).

Once the decision is made, the self-declaration status will be posted to the SCC website.

J.4. ISO/IEC Information Centre

Upon accreditation of the SDO, SCC shall notify the ISO/IEC Information Centre of the SDO's acceptance of the WTO/TBT Annex 3 code, and publicize the accreditation.