SCC

ACCREDITATION SERVICES

Accreditation Program Overview

2023-03-10

Standards Council of Canada

Open a world of possibilities.

Canada

Standards Council of Canada
55 Metcalfe Street, Suite 600
Ottawa, ON K1P 6L5

Telephone: + 1 613 238 3222
Fax: + 1 613 569 7808
accreditation@scc.ca
www.scc.ca

Permission to Reproduce

Aussi offert en français sous le titre *Aperçu des programmes d'accréditation.*

Table of Contents

Standards Council of Canada (SCC)

The Standards Council of Canada (SCC) is a federal Crown corporation established by the Standards Council of Canada Act (“the Act”) of the Parliament in 1970 to foster and promote efficient and effective voluntary standardization in Canada.

SCC carries out its mandate by:

- Accrediting, in accordance with criteria and procedures adopted by the Council, organizations in Canada or in a designated country that are engaged in conformity assessment, and maintaining a record of those accredited organizations and of their marks of conformity;
- Accrediting, in accordance with criteria and procedures adopted by the Council, organizations in Canada that are engaged in standards development, and maintaining a record of those accredited organizations and of their marks that relate to standardization

Accreditation

SCC, as an accreditation body, uses a formal process to independently assess the capabilities of conformity assessment bodies.

SCC develops and delivers accreditation services in accordance with ISO/IEC 17011, mandatory requirements from international arrangements, regulatory needs, the SCC Quality Manual, and the delegated authority from the Act.

ISO/IEC 17000's definition of accreditation: "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 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. As well, the OECD performs a Mutual Joint Visit of SCC's GLP program every ten years.

Benefits of Accreditation

There are many reasons why an organization may consider accreditation. Although all accreditation programs are 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. In summary the benefits are:

- Improving product or system quality and safety
- Demonstrating your market accountability
- Bringing you global recognition
- Reducing costs and increase efficiency
- Reducing your risk
- Offering you a competitive advantage

Benefits of SCC Accreditation

The Standards Council of Canada (SCC), internationally recognized by the IAF and ILAC, is:

- Well respected in Canada and around the world and consistently delivers high-quality and rigorous accreditation services
- Renowned for the thoroughness and value of its accreditation programs
- Known for their SCC staff being friendly, knowledgeable, and professional
- Offering full services in both English and French

SCC's Customers

The SCC delivers accreditation services primarily to Canadian customers working in Canada and abroad and international customers doing business in Canada.

SCC's Commitment to the Official Languages Act (OLA)

As a federal Crown corporation subject to the OLA, SCC is required to provide services in both official languages – English and French. These are the only official languages in which SCC's Accreditation Services operate. SCC offers full services in both English and French and provides some services in other languages, when possible.

SCC Accreditation Fees

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.

Accreditation 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 11 accreditation programs:

1. Management Systems Certification Body Accreditation
2. Product, Process, and Service Certification Body Accreditation
3. Certification Body Operating in Certification of Persons Accreditation
4. Greenhouse Gas Validation and Verification Body Accreditation
5. Inspection Body Accreditation
6. Testing and Calibration Laboratory Accreditation
7. Medical Laboratory Accreditation
8. Proficiency Testing Provider Accreditation
9. Good Laboratory Practice Recognition
10. Standards Development Organization Accreditation
11. Reference Material Producers Accreditation

SCC's website also contains information of various sub-programs, program specialty areas, and schemes that are available within these 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 programs mentioned above, each program has its own unique differences, such as their accreditation cycles. This information is detailed in individual appendices at the end of this document.

Accreditation Applications

Once an organization is ready to apply, they may request an application package through SCC's website. The application package will request key information about the organization's operations.

Once the applicant has submitted a completed application package to SCC, an initial application review will be performed. Applicants will be contacted for additional information if the submission package is incomplete. SCC does not guarantee that the application will go forward because of an organization applying for accreditation. 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].

An evaluation will be conducted which includes consideration of risk factors such as past enforced suspensions and withdrawals, fraudulent behaviour, disreputable conduct, regulatory infractions or any accreditation agreement violations with SCC or other Accreditation Bodies (ABs). An application may be rejected if one or more of these factors relate to the applicant or any legal or natural person or organization directly or indirectly controlling, or controlled by, or under direct, indirect, or common control with, the applicant, whether legal or natural.

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. The applicant decides which AB to engage for their accreditation.

Once successfully past the initial application review, payment of the applicable application fee is required for the application process to begin. The application fee is non-refundable.

[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.

Assessing Customer Readiness for Accreditation

Once the application package is complete, a Customer Services Team will be assigned, and an application document review will be scheduled and conducted. This document review will be performed to verify whether the applicant's management system, policies, and procedures meet the relevant requirements of the accreditation program applied for, and to determine the applicant's readiness for an initial assessment. If a nonconformity (NC) is raised from this review, the reviewer will contact the applicant and request the applicant to submit responses to the required actions. If the document review exceeds two (2) days of professional time, additional fees may apply.

Once SCC determines that the applicant is ready for an initial assessment, the applicant will be informed of the result of the documentation review. If the NCs are not addressed or if the applicant is not ready, the details will be communicated and the applicant will be provided the opportunity for a potential a pre-assessment meeting or, depending on the issues, to reapply later. The applicant can also request a pre-assessment visit.

Accreditation Assessments

When the NCs that arose from the document review have been resolved, the applicant will be contacted to set up the initial assessment. An initial assessment fee invoice must be paid before any scheduling begins. Depending on the accreditation program, the initial assessment may include a head office assessment, fixed office location assessment, witness audits, and/or other surveillance activities, as required. SCC staff will work with the applicant to find mutually agreeable dates for all applicable assessment 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 assignment 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/or observers, as required. 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 Account Manager (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.

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, 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. SCC utilizes information communication technology (ICT) such as laptops, mobile devices and various virtual resources that support the flow, storage, processing, and analysis of data to conduct assessments. All use of ICT conforms to SCC's IM/IT Security Policy.

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 is often useful to

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

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 assessment, the team will require access to information demonstrating conformity to the accreditation requirements. Where NCs are found, copies demonstrating evidence of the NCs 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 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 (including NCs) in 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 NCs uncovered during that day. This will give the customer the opportunity to provide any follow-up documentation that may resolve the NC 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 still conducting the office assessment. 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.

Remote Accreditation Assessments

The use of Remote Assessments is encouraged by SCC where possible. The decision to conduct Remote Assessments is the sole responsibility of SCC and is based on an evaluation of risk factors. SCC considers several factors when planning for remote assessments:

- Remote assessments should not cover the entirety of an accreditation cycle.
- Remote assessments are only possible where not prohibited by the accreditation criteria documents, scheme owner, or regulatory body.
- Remote assessments are intended to cover all the requirements that would normally be assessed during an equivalent assessment. However, where the remote assessment methodology cannot cover all requirements, SCC shall ensure appropriate follow-up with the conduct of an on-site visit.
- The Customer that is the subject of an assessment shall be responsible for providing the resources for a Remote Assessment.

Information and Communication Technology (ICT) for auditing or assessment purposes

Teleconferences, web meetings, interactive web-based communications, and remote electronic access to documentation are elements of Information and Communication Technology (ICT). CBs that audit or inspect their clients, subcontractors and suppliers remotely using ICT, may do so in part or in full, when permitted by the scheme or scheme owner. For the consistent use of ICT when auditing management systems, persons, or product, CBs must conform to IAF MD 4.

Before using ICT, CBs must obtain agreement of mutually acceptable information security and confidentiality measures with the other party that satisfy data protection measures and regulations. A documented risk assessment must precede the use of each instance of ICT to determine the impact on the effectiveness of the audit, or part of the audit when conducted remotely. Prior notification to those involved and competence of operators shall be ensured by the CB. Audit or inspection reports shall indicate the proportion of the audit or inspection conducted via ICT and the effectiveness of the ICT in meeting the audit objectives. SCC will verify conformity through on-going assessments and verification to ensure CBs comply with the criteria set out in IAF MD 4.

IAF MD 4 is a mandatory requirement for certification bodies in the management systems, certification of persons, and product, process, and service certification programs. The requirements can also be applied to other accreditation programs that use remote audit or assessment practices where permitted.

Addressing Assessment Nonconformities

At the conclusion of the closing meeting, or shortly thereafter, the applicant will be provided with an electronic copy of the Findings Report which is the report of all nonconformities (NCs), observations, and commendations. 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 NCs 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 3-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 a disagreement between the organization and the assessment team on a particular finding at any point in the process, and the applicant wishes to formally challenge them, the organization may do so. 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.

Accreditation Decisions

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

Once the Lead Assessor completes the Accreditation Review Package (which includes the Accreditation Report among other documents), SCC will then engage the Accreditation Review Team (ART) to review the report and other supporting documentation. The objective of this review is to ensure that SCC's accreditation procedures have been met throughout the assessment, and that the resolution of NCs has met all requirements for accreditation. The ART review 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 review 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 assessment evidence is not sufficient, they may request further information and may request additional assessment activities.

The result of the ART review is part of the decision made by the Vice-President, Accreditation Services, as to whether the applicant has met the requirements for accreditation. The Vice-President or their delegate reviews the output of the ART, along with the Accreditation Report and other supporting documentation, to complete 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 Status

Once the final SCC accreditation decision has been made:

- SCC will prepare an Accreditation Licence Agreement. This agreement 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 requested, the SCC accreditation symbol applicable to their accreditation program. The customer can use this symbol publicly. The guidelines and restrictions of use of this symbol are outlined in this agreement.
    - Finally, the agreement also contains the Fee Schedule for the applicable 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 or withdrawal of accreditation.
- SCC will verify that the customer has fully paid all invoices issued.
    - Due payments and a signed accreditation agreement must be completed before granting accreditation (sharing the accreditation certificate, publishing the SCC scope of accreditation, posting a notice of accreditation).
- Once the accreditation agreement is signed and the customer has paid all due invoices:
    - SCC will post the scope of accreditation and a notice of accreditation on the SCC website.
    - SCC will prepare 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 send an Accreditation Cycle Plan (as applicable) to the accredited organization. This plan outlines all of the required accreditation activities that the customer needs to meet to maintain their accreditation status. This is required by SCC to continue to comply with ISO/IEC 17011.

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 or manipulated if 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. Moreover, the customer may not authorize a third party to use the Certificate.

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 referring 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 certification bodies for the below may use the IAF MLA Mark in accordance with defined principles of:

- Product, Process or Service certification
- Quality Management Systems (QMS) (ISO 9001)
- Environmental Management Systems (EMS) (ISO 14001)
- Energy Management Systems (EnMS) (ISO 50003)
- Food Safety Management Systems (FSMS) (ISO 22000)
- Medical Devices Management Systems (MDMS) (ISO 13485)
- Anti-bribery Management Systems (ISO 37001)
- Occupational Health & Safety Management Systems (OH&SMS) (ISO 45001)

Information Security Management Systems (ISMS) (ISO/IEC 27001)
The defined principles for the use of the IAF MLA Mark are found in IAF ML 2 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 laboratories below may use the ILAC MRA Mark in accordance with the defined principles:

- Testing laboratories
- Calibration laboratories
- Medical laboratories

The defined principles for the use of the ILAC MRA Mark are found in:

- ILAC R7 Rules for the Use of the ILAC MRA Mark
- ILAC P8 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 making SCC accreditation public 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.

Transfer of Accreditation

SCC will only consider a transfer of accreditation if the organization is currently accredited by an Accreditation Body (AB) 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.

To determine whether a transfer of accreditation is feasible, SCC will request the below:

1. The date of the last assessment with the existing AB.
2. A copy of the last accreditation report, including evidence that all findings have been satisfactorily resolved and approved by the existing AB.
3. The current scope of accreditation with the existing AB.
4. Proposed Scope of Accreditation being requested.
5. Confirmation from the existing AB that the applicant is in good standing, including evidence that no outstanding fees remain unpaid to its existing AB.
6. Records of any recent results of applicable proficiency testing programs, including any required follow-up activities (where required by the Accreditation program).
7. Any other relevant information that may be pertinent.

A document review of the above, will help determine any additional SCC accreditation requirements to be met and the timeline for the next reassessment activity.

If SCC determines that it cannot approve the accreditation without its own assessment activity beforehand, the applicant shall proceed through the normal Accreditation process.

Consistent with all accreditation decisions, a transfer of accreditation decision includes an ART review and an accreditation decision by the Vice-President or their delegate.

Once SCC approves the transfer of accreditation, the date of the first assessment activity to be performed by SCC shall be determined using the below:

Visit Schedule for Non-SCC accredited organization being transferred		
Date of last assessment visit by existing AB	*Next SCC Visit*	*Type of SCC Visit*
Within 6 months of request	Within 18 months	Reassessment
More than 6 months but less than 12 months of request	Within 12 months	Reassessment
More than 12 months but less than 18 months of request	Within 6 months	Reassessment
More than 18 months but less than 24 months of request	Within 3 months	Reassessment
Over 24 months before request	Within 3 months	Full assessment before granting accreditation

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 reaccreditation, surveillance, and/or witness assessments. 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 reassessed. The process for this assessment is like the initial assessment, 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 the documentation they are required to submit, and the timelines for doing so. All other steps in the process remain the same.

If an NC is raised over the course of the customer's accreditation cycle or 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.

Suspensions and Withdrawals

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.

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 because 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 referring 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 several major NCs, 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, *Harmonization of Sanctions to be Applied to Conformity Assessment Bodies*

Scope Modifications

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

If the customer decides to either expand or reduce 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 or remove from their scope. From there, they will follow the same assessment process as outlined in this document. SCC assessment staff will review the request and determine the appropriate course of action.

For scope extensions, if the requested additions to the scope are deemed to be significantly different from the customer's existing scope of accreditation, an additional 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 activities.

For scope reductions, the justification and rationale need to include whether the reduction has an impact on the organization's ability to perform competently for the remainder of the scope.

A scope modification fee is applicable, and this is outlined in the Fee Schedule of the signed accreditation agreement.

Relocations and Renovations

According to the SCC Accreditation/Recognition Agreement the customer must advise SCC of any changes that could affect their accreditation/recognition status. This would include, but is not limited to, significant changes to the premises (which includes personnel, equipment, facilities, working environment or other resources). It is understood that in the context of this section, changes to premises includes relocation and renovation of facilities.

Planning and performing a relocation (or renovation) can be difficult with unexpected delays and thus can have many uncertainties. It is however the customer's responsibility to keep SCC informed of the progress.

Changes in premises will have varied impact on the customer's operation depending on the accreditation or recognition program.

For the Laboratory (Testing, Calibration or Medical) and Proficiency Testing Provider programs:

When advising SCC of the changes, the customer shall provide SCC with (this is not meant to be an exhaustive list):

1. The extent of the change (changes to the scope of accreditation).
2. The plan for the implementation of the change (similar to a transition plan it would show the sequence of events/steps taken by the lab to ensure the quality of the data throughout the work. The plan should include:
    a. The methods that are affected.
    b. Where possible, a floor plan showing when equipment is moved, any temporary locations and the date and location of the destination.
    c. Any calibration, verification, or revalidation procedure in place for the equipment after the move.
    d. If there are any acclimation procedures in place (typically for toxicology methods).
    e. What measures are being put in to place to safeguard the quality of work.
    f. If any work is being subcontracted.
3. Baseline data obtained for the methods prior to the change.
4. Any changes to the organization's legal or commercial ownership.
5. Any changes in personnel (technical or managerial).
6. Any training or retraining activities planned.
7. Any changes in current policies or procedures (related to SCC's scope of accreditation).
8. Any changes to the equipment used to perform accredited work.

SCC may request data obtained after the change to provide evidence that the methods continue to provide quality data, e.g.

- Results of PT done at the new location.
- Evidence of effective environmental controls within the organization (e.g. work area environmental charts, water testing results)

Upon receipt of the notification, SCC will evaluate the impact on accreditation. Possible actions include:

1. Making a note of the changes for the next regularly scheduled assessment.
2. Performing a desk review of the documentation received.
3. Scheduling an extraordinary assessment to determine the action taken as a result of the change. This is typically targeted to occur within 3 months of the change.
4. Revising the timelines of the next regularly scheduled assessment.
5. Adjusting the scope of accreditation.
6. Temporarily suspending the scope of accreditation (full or in part) until an evaluation can be conducted.

If SCC is not advised of the changes in advance the scope of accreditation may be suspended (full or in part) until an assessment can be performed to show that the premises are fit for purpose.

For the Inspection Body program:

If inspections are performed on the premises or inspection equipment is stored at the premises:

When advising SCC of the changes, the customer shall provide SCC with (this is not meant to be an exhaustive list):

1. The extent of the change (changes to the scope of accreditation).
2. The plan for the implementation of the change (similar to a transition plan it would show the sequence of events/steps taken by the organization to ensure that the quality of the work is not jeopardized).
3. Any changes to the organization's legal or commercial ownership.
4. Any changes in personnel (technical/management).
5. Any changes in current policies and/or procedures (related to SCC's scope of accreditation).
6. Any calibration/verification/revalidation procedures in place for the equipment after the move (if applicable).
7. Evidence of proper environmental controls within the organization.

Upon receipt of the notification SCC shall evaluate the impact on accreditation. Possible actions include:

1. Make note of the changes within the SCC system and provide this information to the next regularly scheduled onsite assessment team.
2. Perform a desk review of the documentation received.
3. Schedule an extraordinary assessment to assess the impact of the change. This is typically targeted to occur within 3 months of the change.
4. Revise the timelines of the next regularly scheduled assessment.
5. Revise the scope of accreditation.
6. Temporarily suspend the scope of accreditation (full or in part) until an evaluation can be completed.

If SCC is not advised of the changes in advance, the scope of accreditation may be suspended (full or in part) until an assessment can be performed to verify that the premises are fit for purpose.

For the Good Laboratory Practice program:

A change in location, under most circumstances will require, at a minimum a facility-based inspection. The inspection should occur within a few months of the move.

SCC should be advised of renovations of areas where raw data is generated (or in close proximity to areas where GLP activities are occurring and could be affected). SCC should be provided with the plan for the work that details the scope of the work, floor plans (if applicable), any data gathered to show that the area is fit for use in cases where there are any QA based activities associated with the work, and if the work has already been done. SCC will determine the course of action to be taken based on the records provided. Renovations may require a facility-based inspection.

For Certification Bodies of Management Systems, Product, Process and Service Certification, Certification of Persons, Greenhouse Gas Validation and Verification and Standards Development Organizations:

A change in premises will not normally result in any extra assessment activity but will be noted for the next regularly scheduled assessment.

SCC’s Commitment to Quality and Improvement

Customers are encouraged to contact SCC if they have any comments, questions, concerns, or compliments. SCC is committed to its quality policy, its quality management system, and ongoing improvements.

The customer will be invited to complete an online satisfaction survey concerning their 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 processes, with the objective of continuously improving its accreditation services.

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.

SCC processes three types of complaints:

1) **Against SCC or SCC Service Delivery Partner**
2) **Against an organization accredited by SCC or an SCC applicant**
   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 the complaint has been addressed through the complaint process of such relevant bodies and thought to be unsatisfactorily resolved.
3) **Against an SCC-issued NC**
   If a complaint is regarding a specific finding raised during an assessment activity, the customer is required to submit the complaint in writing to the Account Manager, ideally 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 an independent reviewer for handling of the complaint giving respect to matters of confidentiality, conflict of interest and impartiality. SCC shall be responsible for gathering and verifying all necessary information to validate a complaint related to accreditation. SCC staff will validate the complaint, seek additional information where necessary, review 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 review and share the information received from the complainant.

Please follow the steps outlined on https://www.scc.ca/en/complaints to submit a complaint.

Important points to consider while submitting a complaint in addition to https://www.scc.ca/en/complaints:

1. 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 proceed until the complaint is received in writing and supporting evidence has been provided.
2. SCC accredits Standard Development Organizations (SDO). SCC itself does not develop standards.
3. SCC is not a regulator and cannot enforce specific standards to be used for specific markets nor can enforce market needs. SCC does not take an industry or market position on any standard or market need.
4. SCC can bring stakeholders (such as regulators, scheme owners, clients of certification bodies, researchers, etc.) together to develop standards because of a market demand.
5. SCC's role is to ensure conformity to standards through conformity assessments, as part of the accreditation process.
6. If an accredited organization is the subject of the complaint, SCC will not process a complaint before that organization has had the opportunity to process the complaint through its complaint process.
7. Complaints received about an SCC accredited organization shall:
   - Be validated for being within the scope of accreditation (complaints that relate to activities beyond those accredited may be rejected or referred to another authority).
   - Be referred to that organization for resolution through their complaint process before SCC takes any action, and
   - Contain sufficient, factual evidence to support the complaint.
8. Complaints shall not be accepted if the sole intent is determined to be to discredit SCC or an accredited organization.
9. Complaints shall not be accepted if the same circumstance has been previously investigated and resolved without additional relevant evidence that warrants the issue being opened again.
10. Complaints about an accredited organization shall not be accepted if the complainant is not prepared to disclose their identity. However, the details may be provided to the next assessment team for consideration.
11. Complaints shall be addressed in an effective manner and as soon as circumstances reasonably permit.
12. People investigating complaints shall be qualified, but SCC shall be responsible for decisions at all levels of the handling process for complaints.
13. Formal notice of the conclusion of the complaint process shall be communicated to the complainant and be provided by a member of SCC staff not involved in the subject of the complaint.
14. SCC shall not take any discriminatory action against the complainant because of the investigation or decision of a complaint.

Appeals

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.

Customers shall have the right to appeal any decision made by SCC that affects the accreditation status of the Customer.

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.

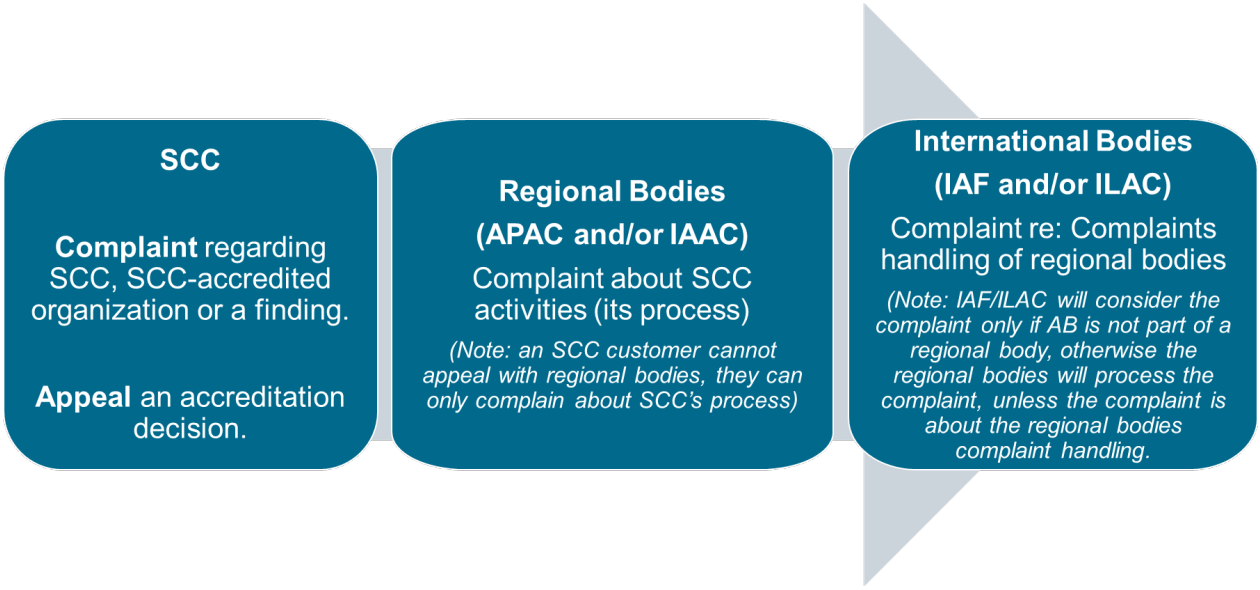
When a decision on suspension has been made, that suspension shall be implemented and be in full force and remain in effect until the Appeal process is completed and a decision has been rendered.

Appeals shall be submitted to SCC in writing within thirty (30) business days of the relevant SCC decision. The request for an Appeal 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, if the appellant believes that the appeal has not been satisfactorily addressed, they are encouraged to file a complaint about SCC with the regional body representing IAF or ILAC (APAC and IAAC), as applicable. If the regional body determines that SCC is nonconforming, SCC will implement corrections and corrective actions as needed to close the nonconformity.

- SCC shall be responsible for all decisions at all levels of the handling process for appeals.
- SCC shall not take any discriminatory action against the appellant as a result of the investigation or decision of an appeal.

The summary of the process is presented below:



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 the appeal in isolation. When the appellant selects an Appeal Panel to review the appeal, the appellant may also request a hearing before the panel makes its recommendation in isolation. Whichever appeal evaluation method is selected, an estimate of the expected costs is provided in advance. The appellant is 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 appeal is upheld, there will be no cost to the appellant for the process and the appellant will be promptly refunded any deposit. If the appeal is overruled, 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 appeal 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 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 length 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 considering 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 review 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:

i. Original claim, evidence and justification provided by the Accredited organization or applicant
ii. Evidence gathered during the evaluation
iii. Summary of processes reviewed during the evaluation
iv. Minutes from the hearing (when and if hearing took place)
v. Result of the vote (Appeal Panel only)
vi. 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.

Accreditation 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 MD 1:2018 – IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling
- IAF MD 2:2017 – IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
- IAF MD 4:2022 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 11:2013 – Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (applies only to CBs certifying to multiple certification standards)
- IAF MD 23:2018 – Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies

CBs certifying Quality Management Systems (QMS) (ISO 9001)

- ISO/IEC 17021-3:2017 – Competence requirements for auditing and certification of quality management systems
- IAF MD 5:2019 – IAF Mandatory Document for the Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

CBs certifying Environmental Management Systems (EMS) (ISO 14001)

- ISO/IEC 17021-2:2016 – Competence requirements for auditing and certification of environmental management systems
- IAF MD 5:2019 – IAF Mandatory Document for the Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

CBs certifying Food Safety Management Systems (FSMS) (ISO 22000)

- ISO/TS 22003:2013 – Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems
- ISO 22000:2018 – 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
- FSSC 22000 scheme version 5 – Food Safety System Certification
- IAF MD 16:2015 – Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

CBs certifying Medical Devices Management Systems (MDMS) (ISO 13485)

- IAF MD 9:2022 – Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

CBs certifying Forestry

- SCC Requirements and Guidance for the Management Systems Accreditation Program: Sustainable Forest Management Sector Schemes
- ATFS-IMG-01:2021 – ATFS Independently Managed Group Certification Requirements
- SFI 2022 – Requirements for the SFI Program: Standards, Rules for Label Use, Procedures and Guidance.
- CAN/CSA-Z809:2016 – Sustainable forest management

CBs certifying Energy Management Systems (EnMS) (ISO 50003)

- ISO 50003:2021 – Energy management systems – Requirements for bodies providing audit and certification of energy management systems

CBs certifying Anti-bribery Management Systems (ISO 37001)

- 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 45001)

- ISO/IEC TS 17021-10:2018 – Competence requirements for auditing and certification of occupational health and safety management systems
- IAF MD 5:2019 IAF Mandatory Document for the Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
- IAF MD 22:2019 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

CBs certifying the CyberSecure Canada program:

- Please refer to the SCC website as the general information listed below does not necessarily apply.
- RG-CyberSecure-Canada-AP – Requirements and Guidance for the Accreditation of CyberSecure Canada Certification Bodies

CBs certifying Information Security Management Systems (ISMS) (ISO/IEC 27001) or Privacy Information Management Systems (PIMS) (ISO/IEC 27701):

- ISO/IEC 27006:2015/Amd 1:2020 – Information technology — Security techniques — Requirements for bodies providing audit and certification of information security management systems (with Amendment 1)

PIMS has the additional requirement that accreditation for ISMS certification is a prerequisite

Nuclear Scheme (CSA N299):

- CSA N299 Ensuring Nuclear Safety with High Quality

CBs certifying to the Aerospace Standards AS9100, AS9110, AS9120:

- AS9101 Rev. F – Quality Management Systems - Audit Requirements for Aviation, Space and Defense Organizations
- AS9104/1A – Requirements for Certification of Aviation, Space, and Defense Quality Management Systems
- ISO/IEC 17021-3:2017 – Competence requirements for auditing and certification of quality management systems
- IAF ID 3 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations Informative
- IAF MD 5:2019 – IAF Mandatory Document for the Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
- IAF MD 12:2016 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries
- IAF ML 4:2016 Policies and Procedures for a MLA on the Level of Single Accreditation Bodies and on the Level of Regional Accreditation Groups
- IAQG Certification Oversight Team (ICOT) ICOP Certification Scheme Resolutions Log, as applicable
- IAQG ICOT Supplemental Rules, as applicable
- ICOP resolutions published in the OASIS database (see IAQG ICOP Resolutions Log)

CBs certifying Business Continuity Management Systems (BCMS) (ISO 22301):

- ISO/IEC TS 17021-6:2014 Conformity Assessment – Requirements for bodies providing audit and certification of management systems, Part6: Competence requirements for auditing and certification of business continuity management systems

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 (except for the CyberSecure Canada scheme that operates a two-year accreditation cycle). 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 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, 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 (except for the CyberSecure Canada scheme where witnessing of certification activities is dependent on the type of auditing conducted by the CB). 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.*

For initial accreditation of each scheme, SCC will witness both stage 1 and stage 2 audits, for at least one of the CB's clients. Prior to witnessing the stage 2 of the same audit, the applicant CB shall submit the completed report and conclusions from the stage 1 audit to SCC. If the CB does not have any new clients, it is possible to witness one renewal or two surveillances which cover the key processes.

For initial accreditation of AQMS scheme, SCC shall perform at least one Stage 2 WA for each additional AQMS standard for which an AQMS accreditation is being sought.

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.

During each accreditation cycle, SCC should conduct at least one witness audit for a recertification or initial (stage 1 and 2) certification, for each normative standard for which the CB is issuing SCC-accredited certificates.

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 SCC to schedule or update the Accreditation Cycle Plan for the coverage of the scope of accreditation.

A CB may request that SCC conducts a joint assessment at a fixed office location with another accreditation body or that SCC considers 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, EMS and OH&SMS IAF Code Recognition (Extension and Reduction)

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

The list of scopes of accreditation for OH&SMS is based on the technical clusters and critical codes per Appendix E of IAF MD 22: Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS). The specific approach for sampling of OH&SMS scopes is consistent with section 4 of IAF MD 17.

Each accredited CB may have several QMS, EMS and OH&SMS 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/OH&SMS 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* and those applicable to OH&SMS scheme outlined in IAF MD 22: *Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)*.

When applying for accreditation, the CB must specify a minimum of one QMS, EMS or OH&SMS 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, EMS and/or OH&SMS IAF codes to their scope of accreditation.

During annual surveillance activities, the assessment team will review the competence of auditors for recognized QMS/EMS/OH&SMS 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. EnMS Technical Areas Recognition

The EnMS scope of accreditation is based on the technical areas listed in ISO 50003: Energy management systems – Requirements for bodies providing audit and certification of energy management systems

Each accredited CB may have up to eight technical areas recognized, once they have provided evidence of possessing the competence required and satisfied the witness audit requirements, as applicable.

These technical areas are:

1. Industry – light to medium
2. Industry – heavy
3. Buildings
4. Building complexes
5. Transport
6. Mining
7. Agriculture
8. Energy supply

When applying for accreditation, the CB must specify a minimum of one technical area for recognition for EnMS accreditation program.

During initial accreditation cycle, the CB will be subject to an office assessment and at least one EnMS witness audit activity, depending on the technical areas involved.

During the initial office assessment, the assessment team will verify implementation of CB processes and demonstration of CB personnel competence for all the desired EnMS technical areas.

Witness audit activities required during initial accreditation will be determined on a case-by-case basis, depending on the outcome of the office assessment, and based on a risk approach.

Initial accreditation may be granted for one or more technical areas based on the results of the office assessment and one or more witnessed audit(s)witness.

For example: if the CB is applying for technical areas related to light/medium industry and heavy industry, a witness audit related to just heavy industry may satisfy the initial accreditation requirements for both technical areas.

Selection of witness audits during surveillance/reaccreditation will be determined based on the technical areas listed in CB scope of accreditation, with the goal of covering of applicable technical areas during 2 accreditation cycles.

Once accredited, the CB may apply for a scope extension to add one or more EnMS technical areas to their scope of accreditation.

Technical area recognition may be extended upon submission of a scope extension request and may also be reduced pending the circumstances.

Accredited CBs seeking extension of the scope accreditation are required to apply outlining the technical areas subject to extension request. Following receipt of the application information, a review of the information will be performed, and a witness audit activity may be required prior to granting the scope extension.

A.5. Classification of NCs

Within the Management Systems Accreditation Program, NCs are classified into two categories, Major and Minor. A major NC 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 NCs against one or more requirements, which when combined, can represent a breakdown of the CB's system; or, a minor NC that was previously issued and not addressed effectively by the CB. A minor NC may be a single observed lapse in the CB's system.

While minor NCs must be addressed as per the timelines addressed in the main body of this document, for major NCs, the CB will have ninety (90) calendar days from the date of issuance of the NC to provide evidence of resolution and corrective action.

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
- IAF MD 4:2022 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

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 2002:2020 Chain of Custody of Forest and Tree Based Products – Requirements
- PEFC ST 2003:2020 Requirements for Certification Bodies operating Certification against the PEFC International Chain of Custody Standard
- PEFC (Annex 6) – Certification and Accreditation Procedures
- SFI 2022 Section 4 Chain of Custody Standard
- SFI 2022 Section 9 Audit Procedures and Auditor Qualifications and Accreditation

CBs operating in the Transport Canada Electronic Logging Devices (TC ELD) scheme

- Section 79 of the Commercial Vehicle Drivers Hours of Service Regulations (the Regulations)
- Technical Standard for Electronic Logging Devices
- ELD Technical Requirements Test Specifications

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 office surveillance activity, 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 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.

Note: for the TC ELD scheme, every location performing TC ELD testing or certification activities must be visited by an SCC technical expert at least once during the four-year accreditation cycle.

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.

Due to the requirements of the TC ELD scheme, the SCC technical expert will observe a sample of tests during the assessment of fixed office locations.

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’). This list must be in 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 confirmation from SCC that a standard corresponds to 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.

[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 browsable 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
- IAF MD 4:2022 – IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

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: Validation and Verification Body Accreditation

D.1. Program Requirements

- ISO/IEC 17029:2019 - Conformity assessment — General principles and requirements for validation and verification bodies
- ISO 14064-3:2006 - Greenhouse gases —Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions
- ISO 14064-3:2019 - Greenhouse gases – Part 3: Specification with guidance for the verification and validation of greenhouse gas statements
- ISO 14065:2013 Greenhouse gases — Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition
- ISO 14065:2020 Greenhouse gases — General principles and requirements for bodies validating and verifying environmental information
- ISO 14066:2011 Greenhouse gases — Competence requirements for greenhouse gas validation teams and verification teams
- IAF MD 6:2014 Application of ISO 14065:2013

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 experts in the relevant sectors for which accreditation is sought and shall be evaluated by SCC during the assessment for competence for all sectors for which they seek accreditation.

Office and witnessing activities may be conducted in part or whole in a remote capacity based on past performance and other considerations.

Initial accreditation or scope extensions can be granted upon the successful completion of witness assessments within 6 months of the date of granting accreditation. If the required witness assessments are not completed within the 6-months' timeframe, then the accreditation or scope extension may be withdrawn. SCC may conduct a scope extension remotely and may forego the onsite witness assessment requirement following the completion of the document review process.

Once accredited, the program operates on a four-year accreditation cycle, structured with three years of surveillance activities followed by a reassessment activity every fourth year. Each surveillance activity thereafter will generally take place no more than twelve (12) months of the previous activity. Each surveillance activity is referenced by the designation S1, S2, S3 or RA depending on the stage of the accreditation cycle.

During the three (3) years between initial accreditation and reaccreditation and between each reaccreditation, annual surveillance will be conducted at the VVB's head office and other fixed office locations to support continued accreditation. Each year, SCC will provide the VVB with an updated Accreditation Cycle Plan. This outlines the 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.

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.

Where necessary, a Technical Expert is assigned to the assessment (head office or witness activities) with expertise related to the technical sectors being assessed.

VVB shall review the Accreditation Cycle Plan upon receipt and notify SCC of any concerns with the planned assessment activities. When required, SCC will request that the VVB complete a Witness Assessment Selection Form to assist with the planning of the witness assessments. 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 or verification statements issued by the VVB.

Annual surveillance assessments are of shorter duration than accreditation or reaccreditation assessments and focus on a portion of the requirements with a focus being given to any issues such as NCs from the previous assessments.

In the fourth year of the accreditation cycle as part of the reaccreditation, SCC conducts a reassessment of the head office. Reaccreditation will consider all elements of the requirements. Any fixed office location and witness assessment requirements that were not completed in the surveillance years will be conducted in the RA year. The focus of annual surveillance activities and reassessments may 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 6 months prior to the planned activity.

D.3. Witness Audit Requirements

SCC witnesses VVB activities over the accreditation cycle.

Following the granting of initial accreditation, accreditation will be granted conditionally for technical sectors that are yet to be assessed. This is with the objective of performing a successful witness audit for each of the critical technical sectors (Mandatory, Required, Level 3). Non-critical technical sectors (Level 1, Level 2) and critical technical sectors not covered in a witness audit, will be assessed using file reviews during office assessments throughout the accreditation cycle.

If a technical sector (critical or non-critical) is not assessed before the end of the accreditation cycle, then this sector will be removed from the scope of accreditation. Additionally, a technical sector will be removed if during the surveillance periods it becomes evident that the VVB cannot demonstrate competence for this sector.

SCC applies a risk-based approach when completing witness audit activities for organization and project level sectors. This approach is outlined in the next section.

a. **Organization Level – Verification Witness Assessment Requirements**

To maintain accreditation, a minimum of one witness assessment per main sector in Group 1 (organization verification) is required.

The maximum number of witness audits for a VVB accredited for all organization-level sectors shall be five.

Witness audits shall be prioritized based on the following risk-based criteria:

i. Level 3 sectors shall be prioritized over level 2 and level 1 sectors
ii. Level 2 sectors shall be prioritized over level 1 sectors
iii. Sectors 3.2 and 9 must be witnessed

Table 1 - Technical Sectors for Scoping Accreditation – Organizational Level

		Risk Level of Witness Activity
Group 1	**Verification**	
Sector 1	G1 S1.1 General: Service	Level 1 or above
	G1 S1.2 General: Aviation Road Transportation, Railways & Shipping	Level 1 or above
Sector 2	G1 S2 General Manufacturing	Level 2 or above
Sector 3	G1 S3.1 Power Generation	Level 2
	G1 S3.2 Electric Power Transactions	Mandatory
Sector 4	G1 S4 Mining & Mineral Production	Level 3
Sector 5	G1 S5 Metals Production	Level 3
Sector 6	G1 S6 Chemical Production	Level 3
Sector 7	G1 S7 Oil & Gas extraction, Production & Refining including Petrochemicals	Level 3
Sector 8	G1 S8 Waste Handling & Disposal	Level 3
Sector 9	G1 S9 Agriculture, Forestry & Other Land Use (AFOLU)	Mandatory

b. Project Level – Validation/Verification Witness Assessment Requirements

i. Witnessing of validation activities within a given sector shall count towards recommendation on maintaining accreditation for project verification for the same sector.
ii. Maintaining accreditation for project validation requires witnessing of project validation activities. Witnessing of verification activities shall not be extended to the recommendation on maintaining accreditation for validation.
iii. In addition to completion of the required witness assessment for Sector A, demonstration of competence for the Sector A sub-sectors is required for maintaining accreditation of those requested sub-sectors.
iv. A VVB must undergo four project-level witness assessments to maintain accreditation for all of the group sectors.

Additional factors during the planning and 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-site to determine levels of risk. Preference may be given to witnessing sectors and/or activities:

a) Where required by regulation or sector programs,
b) Where previous witness audits have yielded NCs;
c) To observe personnel that have not yet been witnessed;
d) That have not previously been witnessed;
e) Where total emissions per facility exceed 25 kilo tonnes.

During years when a witness assessment is not conducted, SCC will perform a document review of a sample of completed verifications. These reviews shall be documented in the office assessment report.

Table 2 - Technical Sectors for Scoping Accreditation – Project Level

		Risk Level of Witness Activity	
		Group 2	**Group 3**
		Validation	**Verification**
Sector A	**GHG Emission reductions from fuel combustion**		
	G2 and/or G3 A.1 Renewable energy production	Required	Required, unless covered by G3 SB
	G2 and/or G3 A.2 Energy efficiency improvements		
	G2 and/or G3 A.3 Transportation		
Sector B	**GHG emission reductions from industrial processes (non-combustion, chemical reaction, chemical fugitive emissions, flare & venting from oil, and other)**		
	G2 and/or G3 SB Destruction of ozone depleting substances	Mandatory	
Sector C	**GHG Emission Reductions & Removals from Agriculture, Forestry & Other Land Use (AFOLU)**		
	G2 and/or G3 SC 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**		
	G2 and/or G3 SD Carbon Sequestration in Geological Formations	Mandatory	
Sector E	**GHG Emissions from Livestock**		
	G2 and/or G3 SE Animal waste management – CH4, N2O	Sector E or Sector F	
Sector F	**Decomposition of Waste Material, Handling and Disposal**		
	G2 and/or G3 SF Landfill use, waste handling and disposal, and coal mine methane.	Sector E or Sector F	

D.4. Verified Carbon Standard (VCS) Program Scheme

Scheme requirements for the Verified Carbon Standard (VCS) Program in accordance with the VCS Rules, is defined by VCS document Program Definitions. This includes:

- VCS Program Guide
- VCS Standard
- Agriculture, Forestry and Other Land Use (AFOLU) Requirements
- Jurisdictional and Nested REDD (JNR) Requirements
- Ozone Depleting Substances (ODS) Requirements

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 program website (verra.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 –Technical Sectors for Scoping Accreditation – VCS Program

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

D.5 ICAO Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA)

ICAO requirements are detailed in ICAO's Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA). CORSIA supports ICAO's goal to stabilize net carbon dioxide emissions from international aviation at 2020 levels, despite the projected increase in air traffic. Scheme requirements include:

- RG-GHG-ICAO CORSIA - SCC Requirements and Guidance for Accreditation of GHG Verifiers for ICAO-CORSIA Emissions and Emissions Unit Cancellation Reports
- ICAO CORSIA Documents
  - International Civil Aviation Organization, Standards and Recommended Practices – Annex 16 Volume IV
  - International Civil Aviation Organization, Environmental Technical Manual – Volume IV

The following are the scheme-specific accreditation and verification standards.

A witness audit will be required specific to the CORSIA scheme.

Accreditation standards	ISO 14065:2013 ISO 14066:2011 IAF MD 6:2014 International Civil Aviation Organization, Standards and Recommended Practices – Annex 16 Volume IV International Civil Aviation Organization, Environmental Technical Manual – Volume IV
Verification standards	ISO 14064-3:2006 International Civil Aviation Organization, Standards and Recommended Practices – Annex 16 Volume IV International Civil Aviation Organization, Environmental Technical Manual – Volume IV

D.6 Clean Fuel Regulation (CFR) Program Scheme

The CFR scheme requirements are detailed in ECCC's Clean Fuel Regulations which present regulatory requirements and guidance to ensure uniformity in the implementation. The CFR supports ECCC's goal to incentivize innovation and adoption of clean technologies and expand the use of low carbon intensity fuels throughout the economy.

Please refer to the below references for more information:

https://www.canada.ca/en/environment-climate-change/services/managing-pollution/energy-production/fuel-regulations/clean-fuel-regulations/compliance.html

https://laws-lois.justice.gc.ca/eng/regulations/SOR-2022-140/index.html

The following are the scheme-specific accreditation and verification standards:

Accreditation standards	ISO 17029:2019 ISO 14065:2020, ISO 14065:2013 ISO 14066:2011
Verification standards	ISO 14064-3:2019 Clean fuel regulations: methods for verification and certification.

The following is the listing of the SCC Technical Sectors.

A witness audit will be required specific to the CFR scheme. CFR sectors may overlap with organizational and/or project sectors.

Table 4 – Technical Sectors for Scoping Accreditation – CFR Program Scheme

	Sectors	Description
Sector 1	Fossil Fuels	Production, import, distribution, and delivery (including at fueling stations) of fossil fuels to end users and distribution companies.
Sector 2	Renewable/Bio/Low-carbon-intensity (CI) Fuels	Production, import, distribution, and delivery (including at fueling stations) of non-fossil, low-carbon-intensity (CI), renewable, and biofuels.
Sector 3	Electricity	Production, distribution of electricity, and transactions related to electricity (including at charging stations for EVs)
Sector 4	Green Hydrogen (from non-fossil fuels)	Production, import, distribution, and delivery of green hydrogen from renewable sources.

Annex E: Inspection Body Accreditation

E.1. Program Requirements

Conformity to the following is required by customers in the Inspection Body Accreditation program:

- Inspection Body ISO/IEC 17020:2012 Conformity assessment — Requirements for the operation of various types of bodies performing inspection
- ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- SCC Requirements and Guidance - Inspection Body Accreditation Program (except Rail-only IBAP)

E.1.1 Scheme requirements

Inspection Bodies can conduct inspections in one or more of the following sub-programs:

- Inspection of Electrical Equipment
- Inspection of Medical Electrical Equipment
- Inspection of Medical Gas Piping Systems
- Inspection of Commercial and Industrial fuel-burning Appliances and Equipment

Independent Safety Assessors can conduct assessments in the following sub-program:

- Independent Safety Assessor for Railway Systems

Independent Safety Assessors must also conform to:

- SCC Requirements and Guidance - Independent Safety Assessor for Railway Systems Accreditation Program

E.2. Accreditation Information

Requirements and information on the operation of the Inspection Body Accreditation Program are in the applicable Requirements and Guidance documents
These include information on:

- Program requirements
- Accreditation Cycle
- Witness Audit Requirements
- Witness Audit Frequency Requirements
- Witness Audit Complexity Requirements

E.3. Accreditation Cycle and Witness Audit Requirements

Please refer to SCC Requirements and Guidance - Inspection Body Accreditation Program

Annex F: Testing and Calibration Laboratory Accreditation

F.1. Program Requirements

All 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 Method Verification and Validation in Testing Laboratories
- SCC Requirements and Guidance for the Accreditation of Testing Laboratories
- SCC Requirements and Guidance for the Presentation of Laboratory Scope of Accreditation
- ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status
- ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10:07/2020 ILAC Policy on Traceability of Measurement Results
- ILAC P14:01/2020 ILAC Policy for Measurement Uncertainty in Calibration
- ILAC G18:04/2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories

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

Laboratories performing Analyses of Foods (United States Food and Drug Administration)

- Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF)

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 would confirm if the information provided is acceptable. If deficiencies are identified, SCC staff will follow-up with the laboratory.

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 NCs

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

In these instances, and when serious or critical NCs 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 NC 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 NC;
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 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 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 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 NCs require consideration for this recommendation.
g. Extraordinary activities can be compounded when different aspects of the laboratory technical and management system have identified critical NCs.

An additional or early 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 NCs 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 nrc.canada.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 can 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 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 rule, an assessment of each location involved in the Group are scheduled and conducted as per program description.

All locations will cooperate so that the assessments can be conducted within approximately the same time; 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 clearly identify 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., a 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 if 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).

F.7. Accreditation of offsite sample preparation location as part of the accreditation of a mineral analysis laboratory

Mineral analysis laboratories may wish to include in their scope of accreditation the sample preparation activities performed in locations away from the laboratory location. These offsite sample preparation locations shall be included in the scope of accreditation (hence the sample preparation shall be part of the accredited method) provided that the laboratory meets the specific criteria for offsite sample preparation location laid out in SCC Requirements and Guidance for the Accreditation of Mineral Analysis Testing Laboratories.

- Offsite sample preparation locations are under the operational control of the laboratory;
- The location that is accredited for the method is the location that performs the analytical portion of the method[8].

In general, the off-site sample preparation location is not assessed by visiting the location, as the assessment is included in the on-site assessment of the laboratory. However, the assessment team assessing the laboratory, or SCC may decide, based on the results of the assessment that a visit of the offsite sample preparation location is needed. In such a situation, SCC may schedule a visit of one or several offsite sample preparation locations. The scope listing indicates that the sample preparation is performed at a different location and lists all the offsite sample preparation locations under the control of the laboratory which are covered by the accreditation.

[8] The offsite sample preparation location cannot be accredited for the physical preparation alone. SCC does not accredit sample preparation as a standalone activity.

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 15190:2020 - Medical laboratories — Requirements for Safety
- ILAC G18:04/2010 Guideline for the Formulation of Scopes of Accreditation for Laboratories
- CAN/CSA-Z902-20 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 assessments of each accredited medical laboratory. Interim to the assessments, medical laboratories are required to complete and respond to a surveillance questionnaire.

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

A reassessment is like an initial assessment. The reassessment is a comprehensive 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 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 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 would 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

For accreditation programs where the accreditation is granted to a location, rather than to an organization (e.g., laboratory accreditation or medical laboratory accreditation), SCC may offer Customers with more than one accredited location a "group" accreditation.

SCC can grant group accreditation to laboratories operating from more than one location. Accredited laboratories seeking group accreditation must make the request 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.

SCC shall make every effort to schedule the assessment activities within a group accreditation for the same time period, and where possible and appropriate, using the same assessment team.

SCC shall, for reassessment visits, assess the entire management system over the entire group; however, SCC may reduce the assessment time needed at specific locations if it can be demonstrated that there is enough similarity between the scope of accreditation and operations of multiple locations.

SCC shall prepare a separate accreditation report for each location's assessment; however, these separate reports will be combined for the purpose of the final recommendation of accreditation to the VP, Accreditation Services.

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) Consist of at least two locations operating under the same legal entity.
c) Demonstrate that all these locations operate under the same management system (as defined in ISO 15189) with a central office;
d) 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 always followed; and
    ii. a central contact person for the Group for the purpose of billing by SCC;
e) 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);
f) 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;
g) Ensure that customers are aware and agree with any transfer of work between locations; and
h) 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 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.

Generally, an assessment of each location involved in the Group are scheduled and conducted as per program description.

All locations will cooperate so that reassessments can be conducted within approximately the same 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 clearly identify 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 if 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. Policy for the Selection of Sample Collection Facilities and of Establishments where POCT is offered to be Evaluated

G.6.1 Introduction

This document is intended for the assessment of medical laboratories which have multiple sample collection facilities and/or establishments where POCT is performed or offered (sites) to ensure that the evaluation provides adequate confidence in the conformity of the management system to the applicable 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 included in the scope of 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.6.2 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.6.3 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 is 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 (total of 7).

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 5 new 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 sites visited being 9.
For the future reassessments, 7 (sq. root of 32 rounded up to the next whole number) sites are visited.

G.6.4 Outcome of the assessment of sample collection facilities and of the establishments where POCT is offered or performed

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 would 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

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 its derivatives are used, it is understood that this includes GLP inspections.

I.1. Program Requirements

- No.1, OECD Principles on Good Laboratory Practice
- No.2, Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice
- No.3, Revised Guidance for the Conduct of Laboratory Inspections and Study Audits
- No.4, Quality Assurance and GLP
- No.5, Compliance of Laboratory Suppliers with GLP Principles
- No.6, The Application of the GLP Principles to Field Studies
- No.7, The Application of the GLP Principles to short-term Studies
- No.8, The Role and Responsibilities of the Study Director in GLP Studies
- No.9, Guidance for the Preparation of GLP Inspection Reports
- No.11, The Role and Responsibility of the Sponsor in the Application of the Principles of GLP
- No.12, Requesting and Carrying out Inspections and Study Audits in another country
- No.13, The Application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies
- No.14, The Application of the Principles of GLP to in vitro Studies
- No.15, Establishment and Control of Archives that Operate in Compliance with the Principles of GLP
- No.16, Guidance on the GLP Requirements for Peer Review of Histopathology
- No.17, Application of GLP Principles to Computerised Systems
- No.19, Management, Characterisation and Use of Test Items
- No.22, GLP Data Integrity
- No. 23, Advisory Document of the Working Party on Good Laboratory Practice on Quality Assurance and GLP

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)] was made 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 pesticide/biocide products, industrial chemicals, disinfectant efficacy studies, veterinary medical products, medical devices, tobacco products and pharmaceuticals meets the requirements of the OECD Decision on MAD, and facilitates acceptance of Canadian 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 but can extend to foreign markets provided that they are not OECD member countries or full adherents. Facilities conducting other non-regulated GLP studies can 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 (No.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.

Inspectors are obtained from government Departments/Agencies or from contractors from the private sector. 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 it 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. 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 inspector 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 object to the selection of the inspector(s) but must provide written rationale. SCC will review the rationale and determine if a change is required.

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, an 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 to fully complete the recognition process.
   A facility only inspection can also be performed for facilities that have already successfully completed a full inspection but have not performed a GLP study since the last inspection. Back-to-back facility only inspections are not permitted;
c) an extraordinary inspection to verify that identified GLP non-compliances from a previous inspection have been suitably addressed.
   An extraordinary inspection can also be performed when an organization moves, has significant renovations/changes to the facility or when a facility wishes to increase their areas of expertise;

d) a regularly scheduled biennial full inspection targeted to be 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 I 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 (No. 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 representative.

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.5.3.6 Onsite inspections are the preferred method of monitoring however remote inspections can be performed when deemed acceptable by SCC (for example, if it is not considered safe for the inspection team to travel to the facility).

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, an extraordinary inspection might be needed to verify that actions have been implemented as per clause I.5.3.1 (c).

If the inspector(s) cannot close the findings and does not believe that an extraordinary inspection will provide confidence in the data quality and integrity for the work that was done since the last inspection the facility may be deemed as not in compliance (not in compliance can be for the whole facility or limited to specific studies), may be suspended and/or may be removed from the monitoring program.

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, withdraw from the monitoring program 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 to the program later on.

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 on 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 studies conducted, personnel (particularly management, QA and Study Directors) or facility infrastructure.

I.5.6 Actions Resulting from GLP Noncompliance

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 circumstances of each case. Actions may include:

a) requesting an extraordinary inspection to follow up on issues identified;

b) requesting that the facility amend the study final report(s) to indicate that it was not run in compliance with the OECD Principles on GLP;
c) suspending, refusing to grant or continue to grant recognition of GLP compliance.

Such 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 an in-compliance status is generally provided. After the inspection the facility is given 90 days to resolve the findings. During this time and up until the final decision is made the facility is given a "Pending" status. Once a positive final decision is made the status is changed to "in compliance".

I.5.7.3 Each occasion where major deficiencies are noted are treated on a case-by-case approach. The criteria used to apply a not-in-compliance status:

- Major deviations from GLP requirements that have a negative impact on the quality or integrity of the raw data/report.
- Systemic non-compliances.
- Lack of appropriately trained, qualified and experienced personnel in critical positions.
- Continuing non-compliance seen on consecutive inspections.
- Facility's inability to provide adequate evidence of conformity to close inspection findings within the prescribed period.

I.5.7.4 A facility that does not adhere to the requirements of clause I.5.5.5 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, nature of the inspection, area(s) of expertise and compliance status. The list is reported annually to all OECD member counties and full adherents, 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)]."

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

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.

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 activities 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 activities:

- Identification of Canadian Interest & Need (4.2)
- Avoiding Duplication (4.3)
- Work Program (4.4)
- Canadian Relevance (5.1)
- Separation of Management Activities (5.3)
- Continuity of Operations (5.4)
- Staff Competence (5.5)
- Record Keeping (5.7)
- Equal access and Effective Canadian Participation to the Standards development process by Concerned Interests (6.3)
- Notice of Intent (6.6.1)
- Technical Committee Approval Process (6.7)
- Notification of Suits or Claims (6.15)
- Criteria for (continued) approval of SDO Self-Declaration Status (9.2)

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 SDOs to self-declare are as follows:

1. Completion by the SDO of Part 1 of the Request for Self-Declaration Status form
2. SCC has approved at least five distinct standards as NSCs.
3. The NSCs shall be representative of the SDOs scope of work.
4. The five distinct standards should be representative of the technical work areas where the SDO normally conducts its standards development.
5. No standard submitted by the SDO during the three-year period was denied the NSC designation by SCC, due to a failure to comply with the Requirements & Guidance for SDOs.
6. The SDO is not in arrears with respect to any accreditation fees invoiced.
7. The SDO does not have any open NCs from the last assessment activity.
8. The SDO does not have any open complaint (whether expressed as a complaint or appeal) about an NSC.

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 WTO Standards Information Gateway, WTO/TBT Annex 3 code and publicize the accreditation.

Annex K: Reference Material Producers Accreditation

K.1. Program Requirements

- ISO 17034:2016 - General requirements for the competence of reference material producers

K.2. Accreditation Cycle

Upon initial accreditation, each accredited organization will be subject to regular reassessment activities. The due date for the first reassessment is twelve months after the organization 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 Reference Material Producer 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 Reference Material Producer will be required to identify any significant changes that have been made to the quality management system, key staff, procedures, production process, facilities and equipment, suppliers / subcontractors but not limited to these. The Surveillance Questionnaire is then reviewed by SCC staff who would confirm if the information provided is acceptable. If deficiencies are identified, SCC staff will follow-up with the Reference Material Producer.