Standards Council of Canada
Conseil canadien des normes

REGISTRATION BODIES BULLETIN

Introduction

Over the past few months, the SCC's Conformity Assessment Staff, particularly those in the Registration Bodies Accreditation Program Division, have recognized there is a growing list of items of interest to our clients and potential clients. In addition, a need has been identified for a formal mechanism with which we can notify SCC accredited registration bodies of important program related items such as IAF ballot results, new program criteria, and interpretations.

Anticipating there will be an ongoing need to share important information, the Division Staff has decided to gather the information together into a Bulletin format. It is intended to serial number the Bulletins by calendar year and to publish them in the Canadian Conformity Assessment Conference / Registration Bodies (CCAC/RB) SiteScape Forum approximately once per quarter. In addition, the Bulletins will be available by email to those interested parties who are not members of the CCAC/RB Forum.

Suggestions for improvement to the Bulletin are to be sent to Sylvia Bienvenu (sbienvenu@scc.ca)

D.W. Wilson,
Director, Conformity Assessment

1. Administrative Items

1.1 New Staff

Over the past few months the QMS and EMS Accreditation Programs have undergone some staffing changes. As you may recall Naomi Pedneault replaced Pietiernella Chabot who joined the PALCAN Division last January. Naomi has recently left to return to school.

We would like to take this opportunity to introduce our three new staff members:

1- Sylvia Bienvenu
Administrative Officer
sbienvenu@scc.ca
tel : 613-238-3222 ext. 429

Sylvia's main responsibilities include resolving invoicing issues, tracking and reporting. She tracks audit activities, invoicing, expense reports etc. and liases with the finance department.

2- Nadine Hubert
Administrative Assistant
nhubert@scc.ca
tel: 613-238-3222 ext. 466

Nadine's main responsbility is in the processing, maintenance, typing and filing of documentation. For example she will send out your audit notification letters etc.

3- Sohini Famili
Program Officer
sfamili@scc.ca
tel : 613-238-3222 ext. 424

Sohini is responsible for scheduling and coordinating audit activities. She will also be handling any inquiries.

We hope this information will be useful to you and that you will join us in welcoming them to our team. Please feel free to contact them or the Senior Program Officers Hollie Last (hlast@scc.ca) and Stefan Janhager (sjanhager@scc.ca) at anytime.

1.2 National Standards System Conference

The Standards Council of Canada has announced it will convene an NSS Conference at Mont Ste. Anne, Quebec March 26th and 27th, 2002. This will be a Council-wide event with all branches, divisions and NSS stakeholders involved in the initiative. The conference will consist of plenary sessions, training workshops, break-out sessions, committee meetings and scheduled social activities. The SCC is planning some pre- and post-conference workshops, Advisory Committee meetings etc. to coordinate efforts and decrease travel costs.

SCC clients, volunteers to the SCC programs, government representatives, representatives of consumers and industry will be welcome at this major event designed to put forward ideas and gather in feedback and new ideas from attendees. For additional information, visit the SCC website at: http://www.scc.ca

1.3 Proposed New Fee Structure for RB's

For several months, the SCC Staff has been reviewing the Conformity Assessment Branch Fee Structures in the light of increasing costs, and growing programs, along with the funding needed to build new programs or activities within existing programs.

As an example, the RB Accreditation – QMS Staff have been working very hard to implement the new Canadian Medical Conformity Assessment System (CMDCAS) in partnership with Health Canada's Medical Devices Bureau. The added effort has taxed a small but efficient group itself going through a number of personnel changes (see the separate article). Such program development work must obtain its funding from the SCC client base; this is but one example where added effort is reflected in the SCC assessment and annual fees charged.

The current focus in the Fee Structure for RB's and the current target is to have a proposal to share with all accredited and applicant RB's by mid-November. It is anticipated that any changes to the current Fee Structure will be implemented April 1st, 2002.

1.4 TG-QMSRO membership change and new Chair

2001-08-15/16, the TG-QMSRO met to discuss several program-related issues, and for a workshop on the IAF Guidance on the application of ISO/IEC Guide 62. At that meeting, Mr. Jock Sherry announced that he would be stepping down as Chair of the TG-QMSRO after several years of service. Mr. Sherry will continue to provide valuable program input and perform audit activities as a member of the TG-QMSRO. In addition, members at that meeting approved the inclusion of a representative on the committee from our CMDCAS partners Health Canada and Mr. Egan Cobbold was subsequently nominated for membership. Since that time, we are pleased to announce that TG-QMSRO member Richard Lesieur has been nominated and approved as Chair of the TG-QMSRO, and the Advisory Committee on Conformity Assessment (ACCA) has approved Mr. Egan Cobbold as a TG-QMSRO member.

1.5 SCC participation in IAAR

Recently, the SCC was invited to participate in the IAAR. It is anticipated that Don Wilson, Director, Conformity Assessment will be representing the SCC at future IAAR meetings.

2. Program Operational Items

2.1 Expansion of Registration Bodies – QMS Accreditation Program area of operations

Progressively over a period of several years, the SCC's sphere of operation has expanded to suit our client base. First we expanded into the U.S. with the signing of the Free Trade Agreement, then beyond with NAFTA and into Europe with the Canada-European Union Mutual Recognition Agreement. More recently, the SCC has had the countries and economies of the Americas and the Asia Pacific added to the SCC's geographic mandate. At a recent meeting, the SCC's Council (Board of Directors) agreed that all accreditation programs could accept applications from countries/economies designated in the SCC Act by Order-in-Council.

It should be noted that the SCC strongly supports the use of Mutual Recognition Arrangements such as the International Accreditation Forum (IAF)'s Multi-Lateral recognition Arrangement (MLA) as a means of obtaining reciprocal recognition of Canadian RB's. Nonetheless, there can be program reasons why foreign-based RB's may wish (or need) to seek SCC recognition. An example where there is a need for offshore RB's to seek SCC accreditation is where that body wishes to be qualified to operate in the CMDCAS program.

As many of our clients are aware, the SCC-ANSI/RAB bilateral MRA has given clients accredited by one accreditation body or both, the opportunity to make use of the results of the other accreditation to minimize the cost of becoming accredited by the SCC or maintaining

SCC accreditation. In the case of initial accreditation, while the SCC does perform audit activities, we are able to use the audit results of RAB to determine the scope of the audit activities, develop an audit plan, and as preliminary evidence that the applicant has met the program requirements. To maintain accreditation, SCC and RAB have begun performing joint audit activities and accepting the other AB audit results on a rotating basis in lieu of audit activity. We have found that a benefit to the utilization of this MRA is a decrease in costs for the registration body, specifically the principal ongoing savings are where surveillance audits are either joint or alternated.

The SCC supports an eventual regime that will allow for broader mutual recognition, and it is felt that the SCC-ANSI/RAB experience has moved both AB's down a road to full mutual recognition. Nevertheless, it will be a while before the rest of the IAF MLA signatories will be operating as do we with our ANSI/RAB MRA partner.

2.2 New Program Development

There are a number of SCC RB – QMS clients who have expressed an interest in having the SCC expand its QMS program to offer new accreditation services to these clients. These include:

- Aerospace Quality
- Hazard Analysis Critical Control Point (HACCP)
- Occupational Health and Safety

The SCC Staff is participating in the Aerospace group meetings and we are moving toward finding an Aerospace auditor for the TG-QMSRO and offering that service to RB's in the near future. The HACCP service is part of a much larger discussion that is ongoing with government officials looking for answers in terms of On Farm Food Safety, while the OH & S discussions are beginning to form around several standards that are available.

It is expected that more serious work will begin on these ventures in January, following the re-evaluation of the SCC's RB-QMS program in December.

In parallel, but for the longer term, the SCC is participating in discussions on the subject of Climate Change and E-Commerce. Both these subjects stand the chance of becoming a significant part of the SCC programs in the future.

Another venture on which some preliminary work has been done relates to the SCC's Program for the certification of personnel- an update of the existing Auditor Certifiers Accreditation Program. The up-dated program will expand beyond the accreditation of auditor certifiers to a much broader field of certification bodies and subject areas. The criteria document to be adopted by the SCC next year as the core document for this program will be ISO/IEC 17024, *General requirements for bodies operating certification systems of persons*, a new standard under development by ISO/CASCO. This program will be completely overhauled so that it can be streamlined and cost-effective both for our clients and ourselves.

Other possibilities exist and as they become more definite, details will be shared with our clients.

2.3 Modification of Audit reports and use of CAR's

Earlier this fiscal year, both the QMS and EMS programs began the use of Corrective Action Request forms to cite non-conformities and to record their acceptance by Registration Bodies during audit activities. In September 2001, audit teams also began using a new audit report format that incorporates ISO 10011 criteria and provides further feedback to our clients. It is our hope that registration bodies find the detail of these audit reports useful and an added value to their annual audit activity. Please feel free to provide any comments regarding the format of the audit reports to the Senior Program Officer, EMS, Stefan Janhager (sjanhager@scc.ca).

2.4 Customer Feedback Forms

As part of on on-going monitoring process of TG-QMSRO auditor performance, the QMS and EMS programs will shortly begin use of a customer feedback form. The customer feedback form will request information on:

1. the adequacy of the auditors knowledge of program criteria;
2. clarity of information/answers provided;
3. professionalism;
4. preparedness for assessment activity;
5. management of the audit team (lead); and,
6. presentation of the opening/closing meeting.

The form will also include an area for written comments related to the assessor such as their significant strengths and weaknesses and other comments. The SCC will provide customer feedback forms with the audit notification documents or with the witness audit organizational profile form in the case of witness audits. Electronic versions of the Customer Feedback form will be sent electronically to all registration bodies when the form has been finalized and implemented. Once the audit activity is complete, we ask that you complete the form and return it to the Program Officer. Your comments will be collected and analyzed as part of our program maintenance. Please be assured that any comments will remain confidential and will be used to enhance and ameliorate our programs.

2.1 Accreditation and Trademark Agreements and Accreditation Certificates

As several accreditation bodies are in the process of reaccreditation, and in light of program updating, it is expected that all accreditation and trademark agreements will be reissued, and accreditation certificates will require updating and re-issuance for all SCC accredited registration bodies.

The current template for accreditation and trademark agreements will be sent to SCC legal counsel for review and any necessary modification, at which time the SCC will be issuing or re-issuing accreditation and trademark agreements to SCC accredited registration bodies for signature and return to SCC for file. Please note that Registration bodies are not permitted to use the SCC logo without a current, signed trademark agreement. In addition, the SCC will shortly begin implementation of the use of a new logo for the accreditation programs that will reflect our signatory status in the IAF and PAC MLA. Other changes will address revisions to the IAF Guidance on the application of ISO/IEC Guide 61.

Our timeline for this project to be completed is 2001-12-31. In anticipation of this deadline, we would request that each registration bodies provide confirmation of the legal name of the SCC accredited legal entity to the Program Officer, Sohini Famili (sfamili@scc.ca) before 2001-11-31.

2.2 TG-QMSRO audit activities and monitoring plan for ISO 9001:2000 transition period

At the 2001-08-15/16 meeting, TG-QMSRO members approved a plan for TG-QMSRO audit activities and monitoring to determine the effective implementation of ISO 9001:2000 by registration bodies. It should be noted that registration bodies have previously been notified that 2001-2002 audit activities will be addressing the effective implementation of the IAF Guidance in transitioning to ISO 9001:2000, and that an ISO 9001:2000 initial registration or upgrade would be witnessed by the TG-QMSRO.

In addition to these activities and until the 3-year transition period is over, TG-QMSRO auditors during annual audit activities will also:

1. Verify that the Registration Body has an ISO 9001:2000 transition plan in place;
2. Verify that the Registration Body has implemented that plan;
3. Ensure that documents supporting the registration (ie. Procedures, checklists) have been updated to reflect ISO 9001:2000;
4. Sample auditor files to ensure that auditors have received ISO 9001:2000 training;
5. Sample ISO 9001:2000 audit files during file review activities to review "Statements of Effectiveness" and ensure auditor is qualified to perform ISO 9001:2000 audits;
6. Ensure that a plan is in place to monitor auditors performance, understanding and transition to the new standard,
7. Examine ISO 9001:2000 registration certificates to ensure exclusions have been identified.

In a related item, the TG-QMSRO provided guidance to the Registration Bodies that statements of effectiveness in audit reports should reflect an examination of the following items during audit activities:

1. The commitment and involvement of management in effective implementation as demonstrated by the management reviews and the observation auditors;
2. The degree of reliance that can be placed on internal audit activity;
3. The effective implementation of Corrective and Preventive Action Systems;
4. The effectiveness of documentation and records reviewed by the audit sample;
5. The implementation of the Quality Management Program as reviewed by the audit sample; and,
6. The effective implementation of a continual improvement program.

TG-QMSRO auditors will begin implementation of the above guidance and items in audit plans immediately.

2.7 SCC accreditation: Policy Clarification related to Scope of Accreditation

Several Registration Bodies have recently requested clarification regarding the scope of their accreditation by the SCC. Subsequent to discussion and a policy decision by the TG-QMSRO, program staff can confirm that registration bodies are accredited by the SCC to register organizations to Quality Systems which is not exclusive to the ISO 9000 series of Quality Management Systems standards. Registration Bodies can issue registration to a specific quality based standard (ie. ISO 13485/88) under their SCC accreditation if recognized to the relevant scope or qualified to the relevant sector.

Specifically, Registration Bodies are requested to note that registration certificates can be issued to ISO 13485/88 prior to CMDCAS qualification if the registration body has been recognized for the applicable scope under their SCC accreditation (ie. Electrical and optical equipment). In addition, Registration Bodies who do not wish to pursue CMDCAS qualification can issue registration certificates to ISO 13485/88 if recognized for the applicable scope. References to CMDCAS can only be made if the Registration Body has been qualified to that sector.

Further clarifications can be provided on a case by case basis by contacting the Senior Program Officer, QMS, Hollie Last (hlast@scc.ca).

2.8 CAN-P-1517A Implementation

Since it was originally approved in August 1997, CAN-P-1517 *Conditions and Procedures for the Accreditation of Organizations Registering Quality Systems* has not been revised. Subsequent to a review of internal SCC procedures, and pursuant to modifications to SCC procedures to address changing program requirements, the CAN-P-1517 has been updated and revised as CAN-P-1517A.

The attached CAN-P-1517A has been reviewed and approved by the TG-QMSRO and ACCA, and will be going forward to SCC Council shortly for final approval mid-November. No further changes are expected to the attached document.

Once approved, the final version will be forwarded electronically to all Registration Bodies. No major changes have been made from the previous version of CAN-P-1517 to areas that are addressed by TG-QMSRO auditors during audit activity (ie. Use of SCC logo) and therefore, TG-QMSRO will immediately incorporate CAN-P-1517A in audit planning and during annual audit activities.

2.9 Coordination of Witness Audit Activity and Use of Witness audit Organizational Profile form

With the recent staffing changes, program staff would like to provide the following clarification regarding the procedure for the coordination of witness audit activity:

1. At the beginning of the fiscal year, the Program Officer will forward a form indicating required audit activities for that year, and requesting indication of further anticipated witness audit activities and related information.

2. When the requested audit activity is approximately 2 months away, the Program Officer will request a list of scheduled audit activities related to the scope of the audit to be witnessed and an audit will be selected for witnessing.

3. The selected audit will be confirmed with the Registration Body and the TG-QMSRO audit team selected and assigned.

4. The Registration Body will be notified of the audit team and requested to complete a witness audit organizational profile form.

5. The completed Witness Audit Organizational Profile form and supporting attachments are requested to be submitted in one package to the SCC for forwarding to the audit team at least 3 weeks prior to the scheduled witness audit activity.

6. Once the witness audit activity has been completed, a de-briefing will occur between the TG-QMSRO audit team and Registration Body audit team being witnessed.

7. The SCC will issue a Witness Audit Report and the Registration Body will be requested to provide responses to non-conformities or clarifications if applicable until all issues have been resolved to the satisfaction of the audit team.

8. If the witness audit is applicable to a scope extension or sectoral qualification activity, relevant documentation will be balloted for approval. For witness audits related to accreditation, results will be incorporated into the relevant reaccreditation reports.

The Witness Audit Organizational Profile is a new form that has been in use for the past three months. This form requests information on the organization being witnessed, auditors, previous audit activity and logistics. Electronic copies of this form have been distributed to Registration Bodies and are available on the CCAC Sitescape area.

3. Sector Information

3.1 Sector Information

3.1.1 QS 9000

The current applicable criteria for the QS 9000 sector program is the IASG Sanctioned QS9000:1998, Third Edition. In August 2001, an interpretation was forwarded to Registration Bodies for implementation in their QS 9000 program. Information regarding QS 9000 and interpretations can be accessed at the following URL: http://qs9000.asq.org/sancl.html

3.1.2 AS 9000

In August, 2001, the SAE released AS9100A A Revision - Quality Systems - Aerospace - Model for Quality Assurance in Design, Development, Production, Installation and Servicing. Further information regarding AS 9000 can be found by accessing the SAE website at http://www.sae.org.

3.1.3 TL 9000

TL 9000 has issued a new version of the criteria handbook (Book 1, Release 3.0). This new and revised release of the TL 9000 Quality Management System Requirements Handbook incorporates the recently released ISO 9001:2000. Further information regarding the new handbook can be found by accessing the QuestForum website at the following URL: http://questforum.asq.org/public/purpose.shtml .

The QuestForum also met to discuss TL 9000 issues in July/August 2001. Results of that meeting have been posted for information to the following URL: http://questforum.asq.org/public/telecommunicator/QFTCJulAug01Berlin.pdf

3.1.4 CMDCAS

A detailed update regarding the status of the CMDCAS sectoral program has been provided as a separate item below. The SCC has recently uploaded an area on our website specifically dedicated to CMDCAS information. This area provides general CMDCAS information for Registration Bodies, medical device manufacturers, training information, criteria documents, listing of applicants and qualified registration bodies for CMDCAS etc. The URL for this area is: http://www.scc.ca/cmdcas/index_e.html

3.3 CMDCAS

3.3.1 Amendments to QS requirements of Medical Devices Regulations (MDR)

- Section 97(3) of the regulations has been amended to postpone the coming into force date of the QS requirements. The official text has been published in the Gazette of July 4, 2001.

- Amendments to sections 32 (change from attestation to certificate) and 43 (clarification of text - QS requirements to apply all Class II, III and IV manufacturers already holding device licences) are being processed.

3.3.2 Guidance documents

- The terms and conditions for the *Voluntary Implementation Phase of the Quality Management System Requirements under the Medical Devices Regulations* have been available since August 2001.

- The *DRAFT Guidance on the Content of ISO 13485 and ISO 13488 Quality System Certificates Issued by CMDCAS Recognized* is currently under revision. A new version will be available shortly. The following upcoming change is to be noted:

  For each medical device licence, the following has to be provided by medical device manufacturers to Health Canada as evidence of compliance to the QS provisions of the Medical Devices Regulations (MDR): a single QS certificate issued by a CMDCAS recognized registrar to the entity and address that are identified in HC's records as being the legal manufacturer with an attached list of addresses for the locations where regulated activities under the MDR are performed and are under the control of the manufacturer's quality system. Locations can be facilities, business units, sites, organizational units or others. This requirement applies during the *Voluntary Implementation Phase* ending January 1, 2003 and after the coming into force of the QS requirements at that date. Additional details will be provided in the guidance document.

- A draft *Guidance on the acceptance of QS certificates before and after January 1, 2003* will be posted for a 30-day consultation period within the end of October. Among others, it provides Health Canada's criteria for the acceptance of new ISO 13485/88 certificates, as well as the ones for existing ISO 13485/88 certificates, or upgraded certificates for ISO 9001/02, EN 46001/02.

- CMDCAS qualified registrars and those who have applied for that recognition are responsible for ensuring that requirements found in new and existing CMDCAS guidance documents are incorporated into their procedures.

3.3.3 CMDCAS training

- Requirements for the renewal and maintenance of the CMDCAS qualification are under development. Qualified trainees will be informed.

- Public training sessions are planned for November 14-15 in Montreal, February 21-22 in Ottawa and May 16-17 in Montreal. In-house sessions are always available on request.

3.3.4 Witness audits

- A revised document clarifying the information requested by SCC and HC for selecting witness audits to be performed as part of the CMDCAS qualification process has been available from the SCC since September 2001.

- A standard document identifying the roles and responsibilities of SCC and HC during witness audits will be available shortly.

3.3.5 Communication activities

- An information sheet on CMDCAS will be inserted in the package given to participants of the RAPS meeting in November (Baltimore).

- A repetition of the CMDCAS workshop given with MEDEC in Toronto last October will be done in French with AQFIM in Montreal November 13 and 14, 2001. Additional workshops are being planned.

- As for MEDEC, CMDCAS guidance documents will be available on the AQFIM website with a link to the HC site.

- Upcoming article on CMDCAS in CAPRA newsletter.

- Actions are in progress to provide CMDCAS information on additional websites.

3.3.6 Health Canada MRAs with the EU and Switzerland

- Both agreements are still in the confidence building phase. It is not anticipated for these MRAs to become operational in a near future.

3.3.7 Miscellaneous

- Clarification: January 1, 2003 is the legal requirement at which all medical device manufacturers must comply with the QS requirements. Manufacturers holding a valid Class II, II or IV device licence on or before December 31, 2002 have until November 1, 2003 to submit evidence of compliance for that licence. November 1, 2003 is considered to be an administrative requirement. Compliance related actions between those two dates will be dealt with on a case-by-case basis.

3.4 Issuing SCC accredited certificates using the IAF MLA words for Sectoral areas

As indicated in section 2.1, the SCC will be revising the SCC accreditation logo and accreditation certificates to incorporate the IAF MLA words. The revised accreditation logo will be available for use by Registration Bodies, pending signature of the trademark agreement.

While Registration Bodies will be permitted to use the SCC logo indicating our status as a signatory to the IAF MLA, this logo will **not** be permitted for use on registration certificates issued in the sector programs for AS 9000, TL 9000, TE 9000, QS 9000 and CMDCAS as the IAF MLA does not encompass Sectoral areas.

4. IAF Information

The IAF Plenary and sub-committees, including W/G 1 met in early November. Prior to this meeting, several supporting documents were distributed to Registration Bodies for comment and input into SCC voting on ballot items. While the results of several of the ballots are not yet available, we would like to take this opportunity to notify Registration Bodies of the following revised documents. It should be noted that the SCC, during audit

activity, would be citing observations to these documents instead of non-conformities during the transition period for implementation:

1. IAF Guidance on the Application of ISO/IEC Guide 62 Issue 1 version 4 (available on IAF Website)
2. IAF Guidance in the Application of ISO 9001:2000
3. IAF Guidance on the Application of ISO/IEC Guide 61 Issue 1 version 4 (available on IAF Website)
4. IAF Guidance on the Application of ISO/IEC Guide 66 Issue 1 version 2

Once they have been uploaded, the latest versions of these documents will be available on the IAF website at www.iaf.nu.

Further information regarding ballot results and resolutions will be distributed to Registration Bodies when the IAF meeting results are made available.

5. IGAT items of interest

The Inter-governmental Affairs and Trade Branch of the SCC began operating in 2000. The following is an excerpt from their IGAT Insider publication, which contains items of interest to Registration Bodies.

IGAT's role is to strengthen policy development and strategic participation with respect to the SCC's participation in international standardization, international trade and intergovernmental affairs. IGAT staff:

- Play a key role in a number of international and regional conformity assessment forums
- Provide standards-related information, policy development and analysis
- Operate the World Trade Organization (WTO) / NAFTA Enquiry Point under contract to the Department of Foreign Affairs and International Trade (DFAIT)
- Manage Canada's largest standards-related document centre.

The new **International Trade section of the SCC Web site** is your source for information on trade-related and standards issues, international agreements, and the activities of IGAT committees. In November, the first issue of the **IGAT *Insider***, an electronic newsletter on IGAT issues and activities will be published. Bookmark our location to keep up-to-date on these issues. http://www.scc.ca/igat/index_e.html

5.1 Pursuing new regional arrangements: Pacific Accreditation Cooperation (PAC) peer review for EMS MLA and IAF/PAC peer review for Product Certification MLAs

Most recognition agreements require a peer evaluation to help assure participants that their policies and practices are comparable. The SCC is preparing to undergo a number of evaluations by the end of the year. We'll undergo an initial evaluation by PAC as an

EMS MLA signatory. In addition, IAF and PAC will evaluate SCC as a potential signatory to their Product Certification MLAs.
PAC: http://www.apec-pac.org/home.htm
IAAC: http://www.ibpinetsp.com.br/iaac/

5.2 Reevaluating regional arrangements PAC QMS MLA

In 1998, the SCC was one of the first signatories to the PAC QMS MLA, which now has 11 accreditation bodies as signatories. As part of this agreement, the SCC must be re-evaluated every four years. This comprehensive peer re-evaluation of the QMS program will be undertaken in December.

5.3 IAF Plenary Meeting and International Laboratory Accreditation Cooperation (ILAC) General Assembly Kyoto, Japan October 28 – November 10, 2001

This meeting is the first joint General Meeting of these two international accreditation organizations. Agenda items include:

- Discussing progress in extending the IAF MLA to accreditation of EMS Registrars and Product Certification organizations.
- Discussing IAF guidance on the application of ISO/IEC Guides.
- Tabling of a new quality manual for IAF.

Elva Nilsen, Director, IGAT, and Joan Brough-Kerrebyn, SCC's Quality Manager, will represent the SCC at these meetings. Resolutions and decisions resulting from this meeting will be distributed to registration bodies when available.

Web-sites
IAF: http://www.iaf.nu/
ILAC: http://www.ilac.org/

6. Standards Development items of interest

6.1 Sector Policy of ISO TC 176

Below is an excerpt from the ISO/IEC Directives Part II, 4th Edition outlining the approved sector policy of ISO TC 176 which may be of interest to Registration Bodies in Canada and abroad. One of the key aims of having this sector policy incorporated into the Directives is to preserve the integrity of the ISO 9000 series of standards:

When an ISO or IEC committee wishes to develop quality management system requirements or guidance for a particular product or industry/economic sector it shall respect the following rules.

a) Normative reference shall be made to ISO 9001:2000 in its entirety or, subject to the "applicability" provisions detailed in the scope of ISO 9001:2000, to its clauses or

subclauses. Alternatively, subject to the "applicability" provisions detailed in the scope of ISO 9001:2000, the clauses or subclauses may be reproduced verbatim.

b) If text from ISO 9001:2000 is reproduced in the sector document, it shall be distinguished from the other elements of the sector document [see d)].
c) Terms and definitions specified in ISO 9000:2000 shall be referred to in a normative manner or reproduced verbatim.
d) The guidance and criteria provided in Quality management systems — Guidance and criteria for the development of documents to meet needs of specific product and industry/economic sectors, approved by ISO/TC 176, shall be considered not only when determining the need for a sector-specific requirements or guidance document but also in the document development process.

Any requests for guidance on this sector policy or for interpretation of ISO 9000:2000 terms and definitions, ISO 9001:2000 or ISO 9004:2000 shall be submitted to the secretariat of ISO TC 176.

6.2 ISO TC 176 Meeting:

ISO TC 176 and its sub committees and working groups held their meetings in Birmingham, UK in early October. A Sector Liaison Forum was formally established that will report to the Chairman's Strategic Advisory Group (CSAG). The Sector Liaison Forum will finalize its terms of reference by March 2002. This group represents all Liaison Organizations that have official liaison status with the technical committee. One of the key items being addressed by this group is to help reduce proliferation & promoting the harmonization of sector-specific quality management system documents.

6.3 ISO 9001:2000 Interpretations

Registration Bodies are requested to note that a resource is available to determine specific ISO 9001:2000 interpretations. Mr. Denis Pronovost from Accademia Qualitas is the Canadian contact for ISO 9001:2000 interpretations. Mr. Pronovost can be reached by e-mail at: denis@accademia.com.

Standards Council of Canada
Conseil canadien des normes

Conditions and Procedures for Accreditation of Bodies Registering Quality Systems

CAN-P-1517A
November 2001

national standards system

Canada

CONDITIONS AND PROCEDURES FOR ACCREDITATION OF BODIES REGISTERING QUALITY SYSTEMS

CAN-P-1517A

November 2001

Note: This document, together with the current approved CAN-P-10, supersedes CAN-P-10A and CAN-P-1517

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FOREWORD

The Standards Council of Canada ("Council") is a Crown corporation established by an Act of Parliament in 1970 to foster and promote voluntary standardization in Canada. It is independent of government in its policies and operations, although it is financed partially by parliamentary appropriation. The Council consists of members from government and the private sectors.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public and private sector co-operation in relation to voluntary standardization in Canada, and co-ordinate and oversee the efforts of the persons and organizations involved in the National Standards System. In addition, SCC fosters quality, performance and technological innovation in Canadian goods and services through standards-related activities, and develops standards-related strategies and long-term objectives.

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

In addition, the Council serves as the government's focal point for voluntary standardization, represents Canada in international standardization activities, sets out policies and procedures for the development of National Standards of Canada, and for the accreditation of:

a) standards development organizations;
b) product certification bodies;
c) calibration and testing laboratories;
d) environmental management systems and quality management systems Registration Bodies; and
e) environmental management systems and quality management systems auditor certifiers and auditor training course providers.

The SCC also promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing multiple assessments and audits, both in Canada and with Canada's trading partners.

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

Requests for clarification and recommendations for amendment of this document should be addressed to the publisher. Additional copies of this document and other CAN-Ps can be obtained by contacting the publisher directly.

CONDITIONS AND PROCEDURES FOR ACCREDITATION OF ORGANIZATIONS REGISTERING QUALITY SYSTEMS

1. GENERAL

Accreditation policies and procedures under which the Standards Council of Canada (SCC) operates are non discriminatory and administered in a non-discriminatory manner. Accreditation procedures do not impede or inhibit access by applicant bodies other than as specified in Quality Management Systems Accreditation Program (QMSAP) requirements. The SCC QMSAP program is accessible to all applicants as defined in the Standards Council of Canada Act.

This companion document to CAN-P-10 (*Criteria for Accreditation of Organizations Registering Quality Systems*) applies to organizations seeking Standards Council of Canada (SCC) accreditation. Conformity with the conditions that are stated in this document is a prerequisite to obtaining accreditation. Conformity must also be demonstrated with the requirements found in CAN-P-10 (ISO/IEC Guide 62:1996), relevant provisions of ISO/IEC Guide 61, and the International Accreditation Forum (IAF) Guidance on Application of ISO/IEC Guide 62, as amended from time to time. Specific requirements and procedures for suspension and withdrawal, complaints, appeals and hearings can be found in CAN-P-15 *Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings*. It should be noted that references to criteria within this document should be considered to be the current applicable version of the document, as amended from time to time.

Accredited Registrars are recognized in specific industry sectors as defined in the 39 scopes described in the common statistical classification of economic activities (NACE Rev.1) (nomenclature des activités économiques) – as per Annex A.

Finally, applicant and accredited Registration Bodies are required to pay the applicable SCC fees as detailed in the fee structure for activities related to SCC accreditation. The current program fee structure is available from the Standards Council of Canada.

2. DEFINITIONS

The relevant definitions from CAN-P-10 (ISO/IEC Guide 62), ISO 9000:2000, and the IAF Guidance on the Application of ISO/IEC Guide 62, are applicable, together with the following supplementary terms:

2.1.1 **assessment:** the investigation and analysis of an organization to evaluate its conformity to all the requirements of CAN-P-10 (ISO/IEC Guide 62), CAN-P-1517, the relevant provisions of ISO/IEC Guide 61, and the IAF Guidance on the application of ISO/IEC Guide 62, as amended from time to time.

NOTE: Assessments may be conducted for accreditation or registration purposes.

2.1.2 **audit:** means [R1]the investigation and analysis of a sample portion of an organization to evaluate its conformity to the requirements of CAN-P-10 (ISO/IEC Guide 62), CAN-P-1517, the relevant provisions of ISO/IEC Guide 61, and the IAF Guidance on the application of ISO/IEC Guide 62, as amended from time to time.

NOTE: Audits conducted for accreditation or registration purposes are sometimes referred to as surveillance audits.

2.1.3 **conformity:** means fulfilment of a requirement.

2.1.4 **reassessment:** means an evaluation of the same nature as an initial assessment, to determine continued conformity with established criteria.

2.1.5 **scope of accreditation:** means the areas of expertise recognized within the Registration Body, as described in the common statistical classification of economic activities (NACE Rev.1) *(nomenclature des activités économiques)* as provided in Annex A.

3. ACCREDITATION PROCESS

3.1 Application

3.1.1 The Registration Body requesting accreditation shall make application in writing by completing an official application form, which is to be signed by a duly authorized representative of the applicant.

3.1.2 The applicant must specify a minimum of one scope of accreditation on the separate scope application form.

3.1.3 The applicant shall provide substantiating information and evidence to demonstrate conformity to the criteria and requirements of CAN-P-10 (ISO/IEC Guide 62), as amended from time to time, and this document. At a minimum the applicant prior to the on-site assessment shall provide the following information:

a) general information concerning the applicant, such as name, addresses of its physical locations, legal status, corporate entity and its relationship in a larger corporate entity, its functions, and its human and technical resources;

b) a description of the systems it registers and the standards or other normative documents applicable;

c) a copy of the quality manual and, where required the associated documentation;

d) a copy of the completed CAN-P-10 Matrix; and,

e) a copy of the completed Corporate Profile form.

The information gathered from the application documentation and the quality manual review will be used for the preparation of the on-site assessment.

3.1.4 Each site from which registration decisions are taken will be considered a separate centre for the purposes of assessment and audit activities.

3.1.5 To assist in consideration of the application, the information should refer to the specific criteria and requirements in the same numerical sequence as in CAN-P-10 and this document.

3.1.6 On receipt, the SCC program staff will review the application for completeness and responsiveness. The applicant may be asked to provide additional information or clarification.

3.1.7 The SCC, without the written consent of the applicant, shall not disclose information about an applicant body to a third party[R2]. Where the law requires information to be disclosed to a third party, the body shall be informed of the information provided, as permitted by the law.

3.2 Preparation for assessment

3.2.1 Before proceeding with the assessment, SCC staff and the Task Group on Quality Management Systems Registration Organizations (TG-QMSRO) assessor shall conduct, and maintain records of, a review of the application for accreditation to ensure that:

a) the requirements for application are clearly defined, documented and understood; and,

b) any difference in understanding between SCC and the applicant is resolved.

3.2.2 The applicant can request a pre-assessment visit if desired and the TG-QMSRO assessment team may recommend a pre-assessment based on the results of the initial document review. In either case it is the applicants option to have a pre-assessment visit.

3.2.3 The SCC shall prepare a plan for its assessment activities to allow for the necessary arrangements to be made.

3.2.4 The SCC shall nominate a qualified audit team to evaluate all material collected from the applicant and to conduct the audit on its behalf.

3.2.5 The applicant shall be informed of the names of the members of the audit team who will carry out the assessment, with sufficient notice to appeal against the appointment of any particular auditors or experts.

3.2.6 The audit team shall be formally appointed and provided with the appropriate working documents. The plan for and the date of the audit shall be agreed with the applicant. Specifically, the plan [R3]shall require that the audit team examine the organizational structure, policies and procedures of the applicant, and confirm that these meet all the requirements relevant to the scope of accreditation. As well, the audit team will verify that the procedures are implemented and are such as to give confidence in the services of the applicant.

3.3 On-Site Assessment

3.3.1 At this stage in the processing of the application, a formal on-site assessment of the applicant establishment shall be carried out by a SCC assessment team. The timing of such a visit will be arranged by discussion with the applicant to ensure mutual agreement.

3.3.2 The purpose of the formal on-site assessment is to verify the information submitted by the applicant Registration Body and to confirm the adequacy of its registration activities in all scopes applied for in the application. The assessment team will examine registration records, files and other related documentation. The applicant is responsible for making all necessary on-site arrangements for the conduct of the assessment, including the provision to allow the assessment team to examine documentation and access to all areas, records (including internal audit reports) and personnel for the purposes of assessment.

3.3.3 The applicant Registration Body will be given the opportunity to correct any items identified by the assessment team as not conforming with the requirements for accreditation.

3.3.4 As part of the assessment process, a minimum of two randomly selected complete registration assessments/audits will be witnessed by the assessment team.

3. 4 Approval

3.4.1 When, in the opinion of TG-QMSRO and SCC staff, the applicant has demonstrated that all accreditation requirements have been met, the lead auditor will prepare a report containing a summary of the assessment findings. This summary is presented to the TG-QMSRO for vote [R4]on whether or not it shall recommend the accreditation of the applicant to the SCC Senior Program Officer.

3.4.2 The SCC Senior Program Officer reviews the results and supporting documentation of the TG-QMSRO assessment and subsequent recommendation for accreditation. Based on this review, the Senior Program Officer makes a decision to recommend or not the application for accreditation to the SCC Manager of Conformity Assessment.

3.4.3 The SCC Manager of Conformity Assessment reviews the results and supporting documentation of the TG-QMSRO assessment and recommendation for accreditation by the Senior Program Officer. Based on this review, the Manager makes a decision to

recommend or not the application for accreditation to the SCC Director of Conformity Assessment.

3.4.4 The SCC Director of Conformity Assessment reviews the:

a) results and supporting documentation of the TG-QMSRO assessment and subsequent recommendation for accreditation;

b) recommendation for accreditation by the SCC Senior Program Officer; and,

c) recommendation for accreditation by the Manager of Conformity Assessment.

The Director then makes a decision to recommend or not the application for accreditation to SCC Council.

3.4.5 SCC Council reviews the recommendation for accreditation and supporting documentation. SCC Council then votes whether or not to approve the accreditation.

3.4.6 The SCC advises the applicant of the SCC Council decision in writing. In case of rejection, the applicant will be advised of the reasons. A process exists for any applicant registrar wishing to appeal a SCC decision. As well, a rejected application will not preclude a Registration Body from applying again at a later date.

NOTE: If there are any negative votes at any stage of the approval process they must be resolved before proceeding to the next level of approval.

3.4.7 Once Council approves accreditation, an accreditation agreement is to be signed by the Registration Body and SCC Director of Conformity Assessment.

3.5 Maintenance of Accreditation

3.5.1 SCC will conduct annual audits of accredited Registration Bodies and may perform other audits at appropriate intervals to confirm conformity to the criteria and requirements for accreditation defined in this document and as amended by SCC from time to time.

3.5.2 It is the responsibility of the Registration Body to advise SCC of any pertinent information or intended change in the organization, such as legal status, structure, policies, procedures, resources, key personnel or facilities, which may affect conformity with the criteria and requirements for accreditation or their scope of accreditation.

3.5.3 The Registration Body continues to be responsible for providing access to records, files and other related documentation and personnel related to the maintenance of accreditation activities and is required to make available to SCC, when requested, the records of all complaints, appeals and disputes, and subsequent actions.

3.5.4 The Registration Body shall have available, a copy of the list of it's registered Quality Management Systems, and describe the procedure by which the list is maintained and distributed. This list is to be provided to the SCC upon request.

3.6 Reassessments

3.6.1 SCC will conduct reassessments of accredited Registration Bodies every four years. Reassessments shall be of the same nature as the initial assessment, and shall involve assessment against all applicable requirements as defined in Section 1: General.

3.6.2 As part of the reassessment process, a minimum of one randomly selected complete registration assessment/audit will be witnessed by the assessment team.

3.7 Extension of Scope of Accreditation

3.7.1 An accredited Registration Body may apply for an extension of its scope of accreditation at any time.

3.7.2 The scope application form and the required documentation must be submitted for each scope.

3.7.3 The scope application form and supporting documentation is reviewed for completeness and responsiveness by the TG-QMSRO assessor and a report prepared.

3.7.4 As part of the assessment process, the TG-QMSRO assessor may request a witness audit if necessary.

3.7.5 When, in the opinion of the TG-QMSRO assessor and SCC staff, the applicant has demonstrated their ability to register to the applicable scope, the scope extension is balloted to the TG-QMSRO, then the Senior Program Officer and Manager, Conformity Assessment, for final approval by the Director, Conformity Assessment.

4. PUBLICITY GUIDELINES

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

4.1 SCC Sponsored Publicity

The SCC will publicize the accreditation of Registration Bodies in the following ways:

a) an official Certificate of Accreditation, for public display, will be presented to each Registration Body following accreditation;

b) a "New Accreditation" notice, will be published under "Accreditation and Recognition Notices" on the SCC website;

c) a current list of accredited Registration Bodies will be maintained on the SCC website;

d) publication of accredited status and the scopes of accreditation for which each Registration Body is recognized, will be made available to the public on the SCC website.

4.2 Restrictions

4.2.1 An accredited Registration Body must comply with specified publicity requirements in making reference to its accreditation status in communication media such as documents, brochures, websites or advertising literature. An accredited Registration Body shall submit to the SCC program staff, any advertising or promotional material related to the accredited status of the organization for approval before publication. SCC program staff will review such submissions and provide a response in the form of approval or required amendments.

4.2.1.1 The following are the publicity guidelines for review of submissions.

An accredited Registration Body shall:

a) only make claims of accreditation in respect of activities for which it has been granted accreditation.

b) not use its accreditation in a manner as to bring SCC into disrepute and does not make any statement regarding accreditation that the SCC may consider misleading and unauthorized.

c) not allow the fact of its accreditation to be used to imply that a product, process, system or person is approved by SCC.

d) ensure that an accreditation document, logo mark, report of any part thereof is not used in a misleading manner.

4.2.2 Conditions for the use of the SCC logo (Registration Program) are established in a "Trade-Mark Licence Agreement". Permission for the use of the SCC logo is conditional upon the accredited Registration Body's signing and conforming with the Agreement.

4.2.3 Upon suspension or withdrawal of accreditation, the organization must discontinue its use of all advertising matter that contains any reference thereto, and return any accreditation documents to the SCC.

5. APPEALS

5.1 Applicants of Registration

5.1.1 If an application of registration is rejected, the Registration Body will inform the applicant in writing of the rejection, stating the reasons for the rejection and advising that the decision may be appealed using the Registration Body appeal procedure.

5.1.2 If the appeal procedure results in a rejection being confirmed by the senior management of the Registration Body, the applicant is to be advised that the rejection may then be appealed to SCC. A copy of all documentation supporting the rejection, including all correspondence is then to be provided to SCC. Such reviews will be limited to a determination of whether the Registration Body followed their own procedures in the processing of the appeal.

5.2 Registration Bodies

5.2.1 Appeals procedures for Registration Bodies shall conform to CAN-P-15 *Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings.*

5.2.2 Registration Bodies shall inform their clients that SCC is the final level of appeal.

6. VOLUNTARY WITHDRAWALS

6.1 A Registration Body may voluntarily terminate its accreditation at any time by providing written notice to the SCC.

6.2 Any unpaid fees must be paid upon notice of voluntary termination and the certificate of accreditation returned to SCC.

6.3 Registration Bodies that voluntarily withdraw from accreditation are responsible for remedies of any registrant affected by the withdrawal, appropriate to the nature of the problem, and that are acceptable to SCC.

Annex A

SCOPES OF ACCREDITATION

This list of scopes of accreditation is based on the statistical nomenclature for economic activities (NACE Rev.1) 1994 published by the Commission of European Communities (official Journal L 083 1993).

No.	Description	NACE Code
1	Agriculture, Fishing	A, B
2	Mining and Quarrying	C
3	Food Products, Beverages and Tobacco	DA
4	Textiles and Textile Products	DB
5	Leather and Leather Products	DC
6	Wood and Wood Products	DD
7	Pulp, Paper and Paper Products	DE 21
8	Publishing Companies	DE 22.1
9	Printing Companies	DE 22.2,3
10	Manufacture of Coke and Refined Petroleum Products	DF 23.1,2
11	Nuclear Fuel	DF 23.3
12	Chemicals, Chemical Products and Fibres	DG minus 24.4
13	Pharmaceuticals	DG 24.4
14	Rubber and Plastic Products	DH
15	Non-Metallic Mineral Products	DI minus 26.5,6
16	Concrete, Cement, Lime, Plaster, etc.	DI 26.5,6
17	Basic Metals and Fabricated Metal Products	DJ
18	Machinery and Equipment	DK
19	Electrical and Optical Equipment	DL
20	Shipbuilding	DM 35.1
21	Aerospace	DM 35.3
22	Other Transport Equipment	DM 34, 35.2,4,5
23	Manufacturing Not Elsewhere Classified	DN 36
24	Recycling	DN 37
25	Electricity Supply	E 40.1
26	Gas Supply	E 40.2
27	Water Supply	E 41, 40.3
28	Construction	F

29	Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods	G
30	Hotels and Restaurants	H
31	Transport, Storage and Communication	I
32	Financial Intermediation; Real Estate; Renting	J, K 70, K 71
33	Information Technology	K 72
34	Engineering Services	K 73, 74.2
35	Other Services	K 74 minus 74.2
36	Public Administration	L
37	Education	M
38	Health and Social Work	N
39	Other Social Services	O

Page: 6
[R1] Suggest using the ISO 9000:2000 terminology "**audit** systematic, independent and documented **process** for obtaining **audit evidence** and evaluating itobjectively to determine the extent to which **audit criteria** are fulfilled."
Page: 7
[R2]check grammar
Page: 8
[R3]mandate versus plan???
Page: 8
[R4]Change of tense, the text is in the future