Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS BULLETIN NO. 9
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IN THIS ISSUE

1. NEW/REVISED PROGRAM CRITERIA/POLICIES

1.1 Transition to ISO/IEC 17021 (CAN-P-16)

The transition period to *ISO/IEC 17021:2006 Conformity assessment – Requirements for bodies providing audit and certification of management systems* ends September 15, 2008. SCC will begin applying CAN-P-16 (SCC's adoption of ISO\IEC 17021) on May 1, 2007. Complete details on the transition are available on the SCC website (www.scc-ccn.ca/en/programs/iso_reg/iso-iec-17021-transition.shtml).

1.2 Development of ISO/IEC 17021 Part 2

CASCO Working Group 21 began development of *ISO/IEC 17021 Part 2 Conformity assessment – Requirements for third party auditing of management systems* in December 2006. The scope is:

"This international standard will complement the existing requirements of the ISO/IEC 17021 with respect to third party auditing and the management of competence. The generic requirements of this standard will be based in part on the relevant guidance given in ISO 19011. It will also provide a framework to enable competent parties to develop specific criteria for third-party auditing and management of competence for different types of management systems or sector applications."

SCC will provide SCC-accredited certification/registration bodies (and other interested parties) an opportunity to comment on the document throughout its development. Contact Hollie Jarmain (hjarmain@scc.ca) for further information.

1.3 Approval and Implementation *of CAN-P-1517B and CAN-P-1517C*

CAN-P-1517 Conditions and Procedures for Accreditation of Bodies Registering Management Systems contains — in addition to its main purpose — some requirements that SCC applicant and accredited certification/registration bodies are required to meet.

In April 2006, SCC issued an update of CAN-P-1517. CAN-P-1517B included several new sections to reflect the requirements of *ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* and the current process for the accreditation of CABs. CAN-P-1517B also included:

- updated procedures for scope recognition and the resolution of non-conformities,
- use of Sitescape to manage accreditation-related audit activities, and
- the performance of combined audit activities and audit activities conducted with other accreditation bodies.

Following approval of ISO/IEC 17021:2006, CAN-P-1517 was revised and approved in November 2006. Significant changes included:

- Section 1 "General" to include new and additional normative references and to initially identify the process for the addition of standards to the scope of accreditation;
- Section 2 "Normative References" to include ISO/IEC 17021 and accreditation criteria for new programs;

- Addition of references and updated processes throughout the document to include the three new management system accreditation programs;
- Removal of references to the QS 9000 and TE Supplement Sector Qualification programs;
- New section to ensure that CABs identify to their clients that SCC is the final authority for appeals;
- New section to identify the process to add a management systems standard to the CAB's scope of accreditation; and,
- Increased consistency in terminology.

A marked-up version of the document is available by contacting ms@scc.ca. Because there are no additional accreditation requirements contained in CAN-P-1517C, implementation by CABs will be required once translated and published.

2 ITEMS FOR IMPLEMENTATION/INFORMATION

2.1 Launch of New Management Systems Accreditation Programs

SCC plans to launch three new management system accreditation programs by mid-February:

- Food Safety Management Systems (FSMS) — ISO 22000;
- Occupational Health and Safety Management Systems (OHSMS) — CAN/CSA Z1000, ANSI Z10 and BSI 18001; and,
- Information Security Management Systems (ISMS) — ISO 27001

Contact Stefan Janhager for more information (sjanhager@scc.ca, 613-238-3222 ext. 433).

2.2 New SCC Mark of Accreditation: Implementation deadline

Effective December 1, 2006, all SCC- accredited CABs should have signed an updated trademark license agreement for use of the new SCC accreditation mark. CABs and their registered clients may use materials with the old mark until stocks are depleted, however, they may not print new materials with old mark.

2.3 ISO/IEC 17025 Certification/Registration versus Accreditation

SCC reminds accredited CABs that ISO 17025 is an accreditation standard that contains the *General requirements for the competence of testing and calibration laboratories.*

- Under clause G 3.5.8 of the IAF Guidance on the application of ISO/IEC Guide 62, CABs may be accredited to register the quality management systems of test and calibration laboratories to ISO 9001:2000, but should make it clear to the client that such registration is not equivalent to accreditation of the testing or calibration laboratory.
- The Registration body practice of issuing certificates of conformity to ISO 17025 is not acceptable as it contravenes an IAF resolution and may cause confusion in the marketplace
- CABs should ensure clients are aware that unaccredited certificates of conformity issued to ISO 17025 by registration bodies will not be accepted as evidence of laboratory accreditation

At the November 2006 IAF Technical Committee meeting, a working group was established to develop a policy and identify actions towards CABs who issue certification/registration to ISO/IEC 17025. Stephen Cross, Manager Conformity Assessment, is SCC's representative to this committee.

2.4 Non-conformity resolution process: Deadlines for provision of evidence of resolution

Annex B of CAN-P-1517C defines the process and expectations for the resolution of non-conformities identified during audits and clearly identifies timelines for identification of cause, correction and corrective action. CABs are required to post a response to the non-conformity within 30 days of its issuance. Evidence of resolution of the non-conformity is required within 60 days (Major) or 90 days (Minor) after the date of initial issuance.

Extensions are possible by making a request to your Senior Program Officer, but extensions cannot exceed 30 additional days. Deadlines for resolution of NCRs will be strictly enforced and failure to adhere to the identified timelines may result in suspension of accreditation.

2.5 Cross Frontier Accreditation: Deadline for completion of initial on-site assessments of critical locations

At the IAF General Assembly held in November 2006, members agreed that all Foreign Critical Locations (FCLs) for ISO 9001 QMS and ISO 14001 EMS are required to be initially assessed on-site at least once by an IAF MLA member AB for all scopes of accreditation, no later than December 12, 2007. All FCLs included for product certification are required to be initially assessed on-site at least once by an IAF MLA member AB, no later than December 12, 2008.

Additionally, the IAF MLA Management Committee will carry out a survey regarding FCLs/foreign premises by 2007-05-01 for the assessment of FCLs for QMS/EMS and Product Certification by the IAF MLA Signatories and present a report on the survey at the 2007 IAF Annual Meetings.

The SCC anticipates meeting the IAF deadline for initial assessment on-site of all Critical Foreign Locations. The following table provides information regarding SCC implementation of the IAF Guidance on Cross Frontier Accreditation:

Number of management system audits anticipated to be performed for 2006-2007:

	On-site Audit activities		Witness Audit Activities	
	Head Office	Critical Locations	Linked to Head Office	Linked to Critical Location
	22	32	36	16
Total audit activities	54		52	

Breakdown of audit methodology

	Onsite Total	Witness Audits
SCC only	28	44
Joint with other accreditation bodies	4	0
Review/Accept other accreditation body report	22	9
Total audits	54	53

(Note: CFA does not include sector programs unless the sector has mutual recognition; 6 witness audits are to support SFM and SFI; 17 witness audits are to support CMDCAS; 30 on-site audits include CMDCAS).

2.6 SCC focus for 2007-2008 oversight activities

Each year SCC identifies areas that need strengthening by SCC applicant and accredited CABs. These areas are identified based on a market feedback, complaints received, and on-site audit activities. SCC assessors receive in-depth training as it relates to these areas, and these areas will be examined in depth during annual audit activities. For 2007-2008, SCC has identified:

- CAB Identification of non-conformities
  - Citation of non-conformities
  - Grading of non-conformities
  - CAB auditor competency for the acceptance of cause, correction and corrective action

- Competency of the CAB for their area of operations
  - Competency analysis
  - Use of non-qualified auditors for sector programs

- Sufficiency of the content of audit reports to make a registration/certification decision

3. MEETINGS

3.1 IAF

IAF held its 20th General Assembly and Technical Committee meetings on November 6-14, 2007 in Cancun, Mexico. The following items may be relevant to CABs:

New IAF Strategic Plan 2010. The IAF General Assembly endorsed a new strategic plan. Main themes included increased input from end-users, becoming more outcome focused, more consistent application of requirements, and more effective communication with stakeholders.

European Commission (EC) review of the "New Approach". The EC has launched public consultation on improving the "New Approach" in areas of conformity assessment, accreditation, CE marking and market surveillance. The latest documentation, along with a summary of results of the initial call for public input, is available at ec.europa.eu/enterprise/newapproach/review_en.htm. There is a proposal for one accreditation body per country. Canada has asked whether the "New Approach" would affect acceptance of accredited results from bodies outside of Europe.

New IAF Members. The Hellenic Accreditation System (Greece), the Egyptian Accreditation Council, the Portuguese Institute for Accreditation and the Dubai Accreditation Centre have joined IAF.

New IAF MLA Signatories: InterAmerican Accreditation Cooperation (IAAC) signed the IAF MLA for quality management systems. IAF members who are signatories of the IAAC, EA and PAC regional MLAs are automatically accepted into the IAF MLA. The addition of IAAC to the IAF MLA has the potential to facilitate increased input from the America and to facilitate joint assessments.

Other new signatories include:

- DSM (Malaysia, PAC) for environment management systems
- ESYD (Greece, EA), IPAC (Portugal, EA) and SA (Slovenia, EA) for quality and environment management systems and product certification

A complete list of IAF MLA signatories can be found at www.iaf.nu.

Election of Directors. Dr. Thomas Facklam of the German Accreditation Council (DAR) was re-elected unopposed as Chairman for a three-year term ending 2009. SCC's Elva Nilsen remains Vice-Chair.

IAF Technical Committee. In addition to those projects previously mentioned, the following are ongoing:

- Development of a log of key IAF Technical Committee decisions
- Improving accredited certification

Upcoming Meetings:

- IAF Technical and Executive Committee and PAC Executive meetings —San Francisco (March 24-30, 2007)
- IAF/ILAC and PAC Executive Committee meetings —Beijing (June 10-15, 2007)
- PAC annual meetings — Singapore (July 07-15, 2007)
- IAF/ILAC annual meetings — Australia (October 19-31, 2007) and Sweden (September 8-18, 2008)

The Canadian Association of Environmental Analytical Laboratories (CAEAL) will be hosting the 2009 Annual IAF/ILAC meetings in Vancouver, Canada (date TBC).

3.2 CASCO

A report on the recent meeting in Argentina is available by contacting Anneke Olvera (aolvera@scc.ca).

4.0 SECTOR QUALIFICATION PROGRAM UPDATES

4.1 QS9000 AND TE Supplement

The QS-9000 and the TE Supplement ceased on December 15, 2006. SCC-accredited certifications to these programs are no longer recognized. SCC has requested CABs qualified under the QS 9000 and TE 9000 sector qualification programs provide:

- Written confirmation of the transfer or withdrawal of all affected SCC certificates; and
- Original SCC issued sector qualification certificate(s).

4.2 TL 9000

The following TL 9000 Handbook Alerts have been issued by the QuEST Forum since December 2005:

Information Alert 06-004A (12 December 2006)
Numerous questions have been submitted to QuEST Forum about the implementation of the R4 Handbooks. This Alert clarifies the rules set forth in the handbooks, the requirements for training on R4, and the expectations of the Forum regarding timing of the implementation of R4.

Information Alert 06-003A (27 October 2006)
Notification of implementation of automated enforcement of TL 9000 data submission timeliness rules. Violation of these rules will lead to probation or suspension of the TL 9000 registration.

Information Alert 06-002A (16 October 2006)
Announcement of a new requirement for Certification Bodies (CBs) to report summary TL 9000 audit statistics to the QuEST Forum. These are summary statistics only. Results of individual audits are not reported.

Information Alert 06-001A (16 August 2006)
The QuEST Forum Integrated Global Quality Requirements and Measurements Work Group is revising the Measurements Handbook to Release 4.0 and significant changes will be made to the software measurements. This alert provides a justifiable exclusion to Release 3.5 software measurements for new or expanded registrations.

Information Alert 05-007B (19 December 2005)
The QuEST Forum has found there to be significant differences between Certification Bodies (CB's) in the classification of audit findings and the process for handling any non-conformities and the resolution process. The "TL 9000 Nonconformity Process" document has been developed to foster more consistency across the TL 9000 CB's and to improve the TL 9000 audit process overall.

Information Alert 05-006A (9 December 2005)
In order to adequately oversee the TL 9000 program, organizations that utilize the program need to work together to confirm that TL 9000 certifications remain valid and that TL 9000 meets customers' expectations. It is therefore the desire of the QuEST Forum to utilize and facilitate customer feedback to the certification bodies (CBs) and accreditation bodies (ABs) of any apparent failure by a TL 9000 certified organization to meet the TL 9000 requirements. This additional oversight will strengthen the third party audit process and increase confidence in TL 9000 certifications.

Detailed information and a complete list of Handbook Alerts and Errata can be found on the QuEST Forum website at the following URL: http://www.questforum.org/tl9000/tl_changes_HB-errata.htm

4.3 Report from the 7th Canadian Medical Device Conformity Assessment System (CMDCAS) Health Canada Registration Bodies Forum

The forum was held October 25-26, 2006 in Ottawa. The following summarizes the main discussions:

Address and fax change. The Medical Devices Bureau's postal address has changed to:

150 Tunney's Pasture Driveway
Ottawa ON K1A 0K9

The new fax is 613-946-6758. All other phone numbers and e-mail addresses remain the same.

MDALL. www.MDALL.CA now lists active and archived medical device licences.

Auditor Qualification. Health Canada will automatically renew an auditor's qualification for three years without further action by the CABs at this time. CABs and auditors are requested to inform *Accademia Qualitas* of any changes in their contact information (denis@accademia.com).

Recent amendment to the QS provisions of the Medical Devices Regulations. Project 1484 amended the *Medical Devices Regulations* to reference ISO 13485:2003 for classes II, III and IV devices. This amendment was effective August 29, 2006 and was published in Canada Gazette Part II on September 20, 2006. Auditors are expected to have a copy of the latest consolidated version of the *Medical Devices Regulations*.

Health Canada is currently working on Project 1461 relating to the present QS provisions. CABs will be given an opportunity to comment on this amendment as part of a 75-day public consultation period in the Canada Gazette Part I. Publication date for Project 1461 in the Canada Gazette has not been set.

Transition to ISO 13485:2003. Health Canada has begun action to suspend the licenses of those manufacturers who have not transitioned to ISO 13485:2003. As of July 15, 2006, approximately 96% of certified device manufacturers had transitioned to the new standard and by October 2006 this had increased to 98%. Those manufacturers that have not transitioned hold approximately 120 medical device licenses.

Guidance Document GD 210 "Audits performed by Health Canada-Recognized Registrars". The revision of GD 210 is intended to remove all reference to ISO13485:1996 and ISO 13488:1996 and to provide guidance on how Part 1 of the Medical Devices Regulations can be incorporated into an ISO 13485. The revision also updates guidance on the auditing of an ISO 13485-compliant quality management systems for Canadian regulatory purposes. A final version of the revised document is expected by December 2006.

Guidance Document GD207 "Content of a QS certificate". Final draft should be completed by late January 2007.

Audit Reporting. Health Canada will work with SCC to address observations on the reporting of audits by CABs in support of an ISO 13485 audit of a medical device manufacturer. The main observations were:

- Reports are getting smaller and contain less information.
- Audit scopes are not clear.
- Audit criteria are not clear.
- Audit conclusion is not given.
- Non-conformities are weak.

CABs advised not use the words "accessory" or "accessories". CABs are not use the words "accessory" or "accessories" to describe one or more devices that are intended to be licensed for sale in Canada in the scope of certification/registration. Using these words in such a manner will result in a delay in the manufacturer's license application until a proper certificate can be re-submitted.

Registrar's Group. CABs were given an opportunity to hold an *in camera* meeting to discuss issues of common concern, and to elect a group spokesperson. Mr. Brian Ludovico (TUV – Rheinland NA) was chosen.

Date of Next Forum. The next two- day CMDCAS Health Canada RB Forum will be held the week of April 23, 2007. The specific meeting dates have not been identified.

4.4 Aerospace

The Americas Aerospace Quality Group (AAQG) Registrar Management Committee (RMC) met September 12-13, 2006 in Mystic, Connecticut. The International Aerospace Quality Group (IAQG) last met October 3-6, 2006 in Seville, Spain. The following list provides an update on relevant items:

IAQG Resolutions Log. The IAQG Resolutions Log is now publicly available through the OASIS database (www.sae.org/iaqgdb/oasishelp/IAQGResolutionLog.pdf). The log contains key decisions made by all three sectors (Americas, Asia-–Pacific and Europe) and identifies resolutions no longer in force. AAQG–RMC recognized CABs are responsible for reviewing the IAQG resolutions log and implementing actions as applicable.

AS 9014 and AS 9101C: Date of effectiveness. AS 9014 AAQG - Requirements for Aerospace Quality Management System Certification/Registrations Programs was published in July 2006. This standard replaces AIR 5359B, incorporates AS 9104A and adds specific requirements applicable to the Americas sector. AS 9101C the AS9100 checklist, has also been published. Both documents became effective January 1, 2007.

Next meetings: The next meeting of the RMC will be held January 23-24, 2007 in Dallas, Texas. A workshop for Aerospace and CAB auditors will be held at the same location on January 25.

4.5 Sustainable Forest Management Program (SFMP)

The SFMP scope has expanded from CAN/CSA Z809 to include the Sustainable Forest Initiatives standard - SFI 2005–2009. An applicant or accredited certification body can now to be qualified to deliver certification to SFI 2005-2009 and/or CAN/CSA Z809.

In addition, under SCC's new accreditation program for the Forest-based Chain of Custody, SCC will accredit organizations to assess wood flow from certified forests to workshops or factories, and from there on to retailers, using the *PEFC Annex 4 international standard and SFI Annex 2*. A separate accreditation application is required.

For further information, contact Susan Cadorette (scarodette@scc.ca).

4.6 Program for the Endorsement of Forest Certification schemes (PEFC)

The PEFC Canada Governing Board became a signatory member to the PEFC MRA in March 2005. The Canadian Governing Board meets on a regular basis and SCC-accredited CABs are represented by a member elected by the Canadian Conformity Assessment Conference. PEFC Canada's Governing Board has adopted the PEFC Chain of Custody document for Canada. This document shall be applied by accredited product certification organizations.

CSA and the Canadian Forest Industry have agreed to transfer the PEFC MRA to SCC. SCC is currently in the final stages to become the signatory to the PEFC MRA on behalf of the PEFC Canada Governing Board (transferring responsibility from CSA International).

Further information about the MRA and the SFM certification scheme, visit www.pefc.org/internet/html/.

4.8 Climate Change

SCC is currently exploring with the Government of Canada to establish an accreditation program for greenhouse gas emissions, according to the following international standards:

- ISO/IEC 14064-1: *Specifications with guidance at the organization level for qualification and reporting of greenhouse gas emissions and removals*;
- ISO/IEC 14064-2: *Specifications with guidance at the project level for qualification, monitoring and reporting of greenhouse gas emission reductions or removal enhancement*; and,
- ISO/IEC 14064-3: *Specifications with guidance for the validation and verification of greenhouse gas assertions*.
- ISO/FDIS 14065: *Greenhouse gases -- Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition.*

5.0 ADMINISTRATIVE ITEMS

We appreciate all suggestions, feedback and questions. Kindly forward any comments, questions and suggestions to ms@scc.ca.