

MANAGEMENT SYSTEMS BULLETIN No. 6 JULY 2004

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1.0 PROGRAM STATISTICS

1.1 Current Status FY 2004-2005

| Number of clients | QMS | EMS |
|--------------------------|-----|-----|
| Total Accredited RB's | 24 | 10 |
| Applications in process | 3 | 0 |
| Voluntary Withdrawals | 0 | 0 |
| Total CMDCAS Qualified | 15 | - |
| CMDCAS applicants | 2 | |
| CMDCAS Sector Withdrawal | 0 | - |
| Total TE 9000 Qualified | 3 | - |
| Total QS 9000 Qualified | 7 | - |
| Total TL 9000 Qualified | 3 | - |
| Total AS 9000 Qualified | - | - |
| Total SFM Qualified | - | 2 |
| SFM Applicants | - | 1 |

1.2 Acceptance of other AB oversight results under the MLA/MRA's

The SCC has begun collecting statistics on the acceptance of other AB oversight results under MLA/MRA's. Acceptance of other accreditation body oversight results is considered as:

- o Acceptance of audit reports in lieu of performing oversight
- o Conduct of joint audit activities
- o Consideration of other AB oversight results to reduce length of on-site activity

The following statistics are based on 2003-2004 oversight activities conducted for 18 accredited/applicant CRBs who are also accredited by other AB's:

- Percentage of required oversight activities when SCC has accepted other AB oversight results:
 - On-site audit activities: 46%
 - ISO 9001:2000 Witness audits: 47%
 - QS 9000 Witness audits: 50%
 - TE 9000 Witness audits: 67%

Note the majority of acceptance of other AB oversight results under the MLA/MRA's are conducted with ANSI-RAB NAP. Statistics for acceptance of other AB oversight results under the MLA/MRA's will be reported to RB's annually.

2.0 NEW/REVISED PROGRAM POLICIES/CRITERIA

2.1 SCC Policy Cross Frontier Accreditation

The SCC will be issuing a policy related to Cross Frontier Accreditation in Summer 2004. The SCC will implement the IAF Cross Frontier Accreditation Policy, and in collaboration with RAB, will be developing a detailed questionnaire for completion by accredited registration bodies to gather information and establish critical locations. Oversight activities required to maintain accreditation will be determined once the information has been collected and analyzed.

2.2 ISO 19011

At the September 2003 IAF Technical Committee meeting, a working group was established to determine which clauses of ISO 19011 would apply to the various references in Guidance documents. Notation has been made in the revised IAF Guidance documents on the application of ISO/IEC Guides 62 and 66 at the reference points where ISO 19011 is applied and Registration bodies are required to implement the ISO 19011 guidelines. On the application date for IAF GD 2, implementation of ISO 19011 will be required.

However, at the last IAF meetings held in February 2004, the IAF Task Force reported that they had found it difficult to identify the parts of ISO 19011 to be recommended as requirements for 3rd party Certification/Registration auditing. As such, the IAF Technical Committee decided to submit their output to CASCO WG 21 for consideration in the development of ISO/IEC 17021.

2.3 CAN-P-1517B and CAN-P-1518

Within the QMS and EMS Accreditation Programs, the procedures for initial and maintenance of accreditation activities are common. CAN-P-1517B and CAN-P-1518 outline the conditions and procedures for the accreditation of bodies registering quality or environmental management systems. SCC has made a decision to consolidate these common documents to avoid duplication and in anticipation of the new standard ISO/IEC 17021, which is to be finalized in 2006.

The consolidated Management Systems CAN-P will also incorporate recently approved IAF policies to address cross frontier accreditation, exchange and review of information from other IAF MLA signatories, and SCC-ANRI/RAB harmonization committee procedures such as joint audit activities etc. The planned date of completion for drafting of the new CAN-P document is the 3rd quarter of 2004-2005.

2.6 ISO 9001:2000 Interpretations

ISO/TC 176 is providing interpretations of ISO 9001:2000 at the following URL: http://www.tc176.org/Interpre.asp. SCC accredited Registration Bodies should ensure that auditors are reviewing this website on a regular basis, and that interpretations are incorporated into audit activity. During accreditation related oversight activity, the SCC will review CRB mechanisms for ensuring auditors are aware of interpretations (maintenance of professional competence) and that the information has been incorporated into audits.

2.7 ISO 13485:2003 Quality Systems for Medical Devices

The IAF Technical Committee has endorsed the 3 year transition period for ISO 13485:2003. In July 2003, the SCC established transition requirements for Registration Bodies providing SCC accredited registration to ISO 13485/8:1996. In addition, the CMDCAS program has identified specific timelines for transition activities. The SCC transition requirements can be found on the HC CMDCAS Forum site, or by contacting the SCC.

2.8 ISO 14001

In January 2004, the ISO 14001 standard was approved at the DIS level Currently it is at the FDIS level and is expected to be published shortly. Transition period will be determined by the IAF and ISO/TC207/SC1.

2.9 ISO 22000

The "ISO/DIS 22000 Food safety management systems – Requirements for organizations throughout the food chain" standard may be of interest to registration bodies delivering or planning to deliver certification programs in the food sector. This management system standard is presently out for vote and SCC is seeking comments on the document. The voting period is from 2004-06-03 to 2004-11-03. Please contact Ginette Grant at: ggrant@scc.ca or tel. (613) 238-3222 ext. 492 to receive a copy of the document and comment template and to provide comments.

2.10 EMS Program: Scoping

To date, the Standards Council of Canada's EMS accreditation program has not required scoping by accredited EMS registration bodies. However, based on a decision by the IAF Executive Committee, it was decided that accreditation bodies shall scope EMS programs. This matter was brought forward and discussed at the SCC-ANSI/RAB Harmonization Committee meeting held in May 2004 where SCC and ANSI-RAB NAP agreed to develop a common approach. The SCC will seek input from accredited bodies to support the design of the scoping system.

2.11 Accredited Registration to Standards other than ISO 9001:2000

At the February 2004 IAF Technical Committee meeting, members discussed the acceptability of registrations to sector oriented standards based on ISO 9001:2000. Members decided that accredited registration can be granted to requirements that are developed with consensus and stakeholder participation (eg. through ISO or National member bodies). However, registration bodies cannot impose conformity to a second sector oriented standard if the contractual requirement is to work only to ISO 9001.

SCC accredited Registration Bodies are required to notify the SCC before offering registration to sector oriented ISO 9001:2000 standards. When a accredited registration certificate is issued to sector oriented ISO 9001:2000 standards (eg. ISO 13485) outside of the recognized sector qualification program (eg. CMDCAS or AAQG), Registration Bodies should ensure that it is clear the certificate has not been issued to satisfy the recognized sector qualification program. In addition, CRB's should have processes in place to ensure assessment personnel competency as it relates to the sector oriented standard.

Prior to offering accredited registration to standards that are not sector oriented applications of ISO 9001:2000, Registration Bodies should notify the SCC.

3.0 ITEMS FOR IMPLEMENTATION / INTERPRETATIONS

3.1 IAF Policy – Use of Consultants

The IAF Technical Committee has determined that Registration Body assessment personnel may be consultants. However, if a body is contracted to represent a CRB and perform the main certification functions on its behalf, it is extremely unlikely that the body can also be a consultant in the same field without giving rise to an unacceptable conflict of interest. Note Accreditation Body auditing of such a situation will involve extensive examination of arrangements to ensure impartiality.

3.2 SCC Definition of Findings

To support program improvement initiatives, and harmonization of audit activities with ANSI-RAB NAP and other accreditation bodies, the SCC has redefined their classification of negative findings and terminology as follows:

Correction: action to eliminate a detected nonconformity (ISO 9000:2000, clause 3.6.6)

Corrective action: action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000: 2000, clause 3.6.5)

Closure of a nonconformity: evidence of acceptable correction and corrective action, or an acceptable plan for correction and corrective action plus evidence of effective implementation of the plan. Note: During any audit, for any nonconformity addressed since the previous audit, continued effective implementation of correction and corrective action shall be verified.

Information request: Request made when further information is required to establish conformity. Note: Information requests will only be identified during document review activities.

Nonconformity: non-fulfillment of a requirement (ISO 9000:2000, clause 3.6.2)

Major nonconformity:

- The absence of, or the failure to implement and maintain, one or more requirements for accreditation, or requirements of the CRB's certification/registration system or the CRB's quality management system, which would, on the basis of available objective evidence raise significant doubt as the to credibility of the certificates issued by the CRB; or
- A number of minor nonconformities against one or more requirements, which when combined, can represent a breakdown of the CRB's systems; or
- A minor nonconformity that was previously issued and not addressed effectively.

Minor nonconformity: a single observed lapse in the CRB's system.

Opportunity for Improvement (OFI): Any finding of potential nonconformity or concern. Note: There may be OFIs that are not potential non-conformities. OFIs do not need to be documented using the finding form and responses to OFIs are not required from the Registration Body.

Preventive action: action to eliminate the cause of a potential nonconformity or other undesirable situation (ISO 9000:2000, clause 3.6.4)

Requirements for accreditation: As applicable, ISO/IEC Guide 61: 1996, ISO/IEC Guide 62: 1996, ISO/IEC Guide 66: 1999, related IAF Guidance, MS Bulletin interpretations, and applicable industry sector requirements.

Negative findings can be identified as a result of document review, on-site and witness audit activities. Negative findings related to witness audit activity can also be identified following review of the Registration Body audit report post witness audit activity. SCC staff can also cite non-conformities outside of audit activities when objective evidence of non-conformity to accreditation requirements is identified.

In addition to the above definitions, the SCC has confirmed the following process for citation and resolution of non-conformities as follows:

- Non-conformities will documented using a non-conformance report (NCR).
 - o The NCR will identify the requirement, statement of finding and objective evidence of non-conformity.
- The NCR will be sent electronically to the Registration Body for response.

- The Registration body shall respond to the non-conformity using the NCR. Completed NCR forms should be sent to the SCC. For each non-conformity, the RB shall identify the:
 - o Correction.
 - o Cause. It is necessary to determine the cause in order to take appropriate corrective action. A CRB should use an appropriate process, such as root cause analysis to determine cause.
 - o Corrective action.
 - o Evidence of correction and/or corrective action (can be provided as an attachment)
- The SCC auditor will review the response and document the review on the NCR.
 - The review shall include justification for not accepting the response or justification for accepting the response and indication of closure of the nonconformity.
- If the response is not accepted, the form will be returned to the Registration Body and the RB shall add any new information that may be required to the previous response on the NCR.
- Each response to the nonconformity should be dated, and if a there is a series of responses back and forth between the SCC and the RB, each new comment/response added in sequence to prior responses. This will maintain the history of actions leading to resolution.
- In the case of audit activities conducted jointly with ANSI-RAB NAP, the ANSI-RAB NAP NCR may be used.
- Continued effective implementation of correction and corrective action shall be verified during subsequent audit activities for any non-conformity addressed since the previous audit.

The SCC will be implementing the definitions of findings and process for resolution of CAR's by 2004-11-01. However, major and minor CAR's may be identified during joint SCC/ANSI-RAB NAP audit activities effective immediately. Timelines for resolution of non-conformities will be identified at a later date.

3.3 Publicizing ISO Registration

ISO has recently updated guidelines on publicizing ISO registration. The updated document, entitled "Publicizing your ISO 9001:2000 or ISO 14001 certification / La publicite pour votre certification ISO 9001:2000 ou ISO 14001" can be ordered from ISO or downloaded from the ISO website (http://www.iso.ch).

SCC accredited and applicant Registration Bodies should ensure clients are aware of the new ISO guidelines regarding publicizing registration.

4.0 MEETINGS

The following provides an overview of meetings of interest to Registration bodies and auditors related to the Management Systems program.

4.1 IAF Meetings

The IAF Executive Committee and IAF Technical Committee met in Vancouver Canada 2004-02-25 to 2004-03-02 and 2004-06-14 to 2004-06-18 in Bern Switzerland.

The majority of items of note from these meetings have been addressed elsewhere in the Management Systems Bulletin. In addition to these items, Registration Bodies should note the following:

- o The IAF Policies and Procedures for Industry Specific Programs (eg. AS 9100) was balloted in March/April and approved on 2004-04-13.
- o An IAF task force, to be administered by the IAF MLA Committee, has been formed to improve/refine the MCAA.
- The IAF TC Chair, UKAS representative Roger Brockway, has resigned. Mr. Randy Dougherty of ANSI-RAB NAP will replace Mr. Brockway as Chair of the IAF Technical Committee effective immediately.
- o IAF Technical Committee members endorsed a longer consultation period (60 days) and shorter voting period (30 days) for IAF documents.
- O Applications to register the IAF MLA Mark have been completed for 41 countries with another 15 pending. A license agreements needs to be signed by each country before the mark can be used.

Other IAF projects currently in process include:

- IAF policy for accreditation of multi-site CRB's
- Grading of non-conformities
- Witness audit Guidance
- Identification of Temporary sites
- Auditor Competency

ISO/ILAC/IAF Joint Efforts

A Memorandum of Understanding (MoU) between IAF/ILAC/ISO was signed 2003-03-25. The MoU will consolidate practices that are largely already implemented by the three organizations, and will enable ISO to better manage and monitor the relationships of its various components with the international accreditation community. It provides an ongoing mechanism for technical cooperation between ISO and international accreditors in order to contribute to the development, and subsequent implementation of ISO/IEC Standards and Guides. It will also provide IAF and ILAC with a formal means to interact with ISO at the strategic level, in addition to work that is already carried out the technical level.

Upcoming Meetings:

The 2004 IAF General Assembly will be hosted by the South African National Accreditation System (SANAS) in Cape Town, South Africa 2003-10-4 to 10. The IAF Technical Committee meeting is scheduled to also take place at that time.

4.2 IAAC

The IAAC Executive Committee Meeting held their last meeting in Ottawa, Canada 2004-07-21 to 23. At that meeting, the SCC Director, Conformity Assessment, Pat Paladino was nominated for the position of Vice-Chair. The IAAC has recently been assessed by the IAF for recognition as a regional body. Minutes from IAAC meetings are available on IAAC website at the following URL: http://iaac-accreditation.org/.

4.3 CASCO

The Canadian Advisory Committee on ISO Conformity Assessment Matters (CAC/CASCO), a subcommittee of the Advisory Committee on Conformity Assessment (ACCA), provides Canadian input on ISO/CASCO matters.

The roles of CAC/CASCO include reviewing and commenting on ISO/CASCO activities (namely the preparation of International Standards and Guides related to conformity assessment), and preparing the Canadian delegation to the annual ISO/CASCO plenary meeting with Canadian positions on decision and discussion items. Canadian positions on matters slated for discussion at the annual ISO/CASCO plenary are developed at a full meeting of the CAC/CASCO.

Summary of CASCO activities:

CAC/CASCO will hold its annual meeting on 2004-10-22. At that meeting, members will review the ISO document package for the 2004-11-09/10 ISO/CASCO Plenary (Amsterdam) and prepare positions for the Canadian delegation. The Canadian delegation for the 2004-11-09/10 ISO/CASCO Plenary includes Mr. William Cunningham (CAC/CASCO Chair), Mr. David Shortall (Convenor of ISO/CASCO Working Group 22 – *Code of Good Practice for Conformity Assessment*), M. Gilles Béland (Canadian Expert ISO/CASCO WG 5 – *Conformity Assessment* – *General Vocabulary*) and Mr. Allan Wilson (Secretary, CAC/CASCO).

Ongoing ISO/CASCO Working Group Activities

Canadian experts continue to participate in several ISO/CASCO WGs and promote the work of ISO/CASCO in Canada. Some recent and ongoing activities of interest to Registration Bodies include:

• ISO/International Electrotechnical Commission (IEC) Final Draft International Standard (FDIS) 17011 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies – vote closed on 2004-05-25 (Canadian WG 18 expert – Ms. Joan Brough-Kerrebyn – SCC). Canada voted in favour of the FDIS with comments. This document is expected to be published by November of 2004.

- ISO/IEC Draft Guide 60 Code of Good Practice for Conformity Assessment vote closed on 2004-05-26 (Convenor of WG 22 Mr. David Shortall SCC). Canada voted in favour of the Draft Guide with comments. The document was approved and will be published later in 2004.
- Draft Amendment ISO/IEC 17025:1999 / Amendment 1 General requirements for the competence of testing and calibration laboratories vote closed on 2004-04-14 (Canadian WG 25 expert Mr. Ned Gravel Canadian Association for Environmental Analytical Laboratories (CAEAL). Canada voted in favour of the Draft Amendment. The document will undergo another round of voting as a Final Draft Amendment later in 2004.
- ISO/IEC Draft International Standard (DIS) 17021 Conformity assessment General requirements for bodies providing assessment and certification of management systems has been released for DIS voting for a 3 month comment/voting period. Comments/votes will be reviewed in December 2004 by the WG 21's drafting group and the next WG 21 meeting is scheduled for January 2005. ISO/IEC DIS 17021 and the commenting template are available by contacting Mr. Stefan Janhager (sjanhager@scc.ca). Comments should be submitted to Mr. Janhager by 2004-11-10.
- ISO/IEC DIS 17040, General requirements for peer assessment of conformity assessment bodies and accreditation bodies vote closed on 2004-04-20 (Canadian WG 19 delegate and technical expert Mr. Joe Gryn Canadian Standards Association). Canada voted in favour of the DIS. An FDIS will be circulated for vote later in 2004.
- 2004-03-02 Presentation by ISO/CASCO Secretary The SCC arranged for the ISO/CASCO Secretary Mr. Graeme Drake to give a presentation on the structure and function of ISO/CASCO in Ottawa on 2004-03-02. The presentation was held at the Industry Canada Office of Consumer Affairs (255 Albert Street 10th Floor). Approximately twenty-five (25) people attended the session and engaged in a subsequent question and answer session with Mr. Drake. Copies of the presentation can be received by contacting the CAC/CASCO Secretary Mr. Alan Wilson.
- ISO/CASCO has established a Chairman's Policy and Coordination Group (CPC). This group is composed of WG convenors, ISO/CASCO liaison members and other ISO/CASCO stakeholders. Other members include representatives of the ISO/CASCO National Committees from Brazil, Spain, Mexico, Malaysia, Turkey & China. Canada (Mr. Stephen Cross SCC) has been invited to participate in an observer capacity.

Additional information on any of these items is available upon request from Mr. Bill Cunningham (bill.cunningham@pwgsc.gc.ca) or Mr. Allan Wilson (awilson@scc.ca).

4.4 SCC-ANSI/RAB MRA/MLA Harmonization Committee

This committee, which has a mandate to increase the harmonization of the two organizations' accreditation programs, and thereby reduce redundancies for clients, held a face to face meeting in May 2004. Among the issues discussed were the following:

Joint Audit Procedures

ANSI-RAB and SCC are moving towards the development of procedures for joint audit activities to address audit coordination and planning, conduct of joint audits, sharing of information, and audit reporting. In addition, the SCC has adopted ANSI-RAB NAP definitions of findings.

IAF Scope Category – Harmonization of process

The SCC and ANSI/RAB have finalized a procedure for extension of QMS scope of accreditation. A common application form has been developed and the new scope extension process will be implemented following training of AB auditors. A policy for mutual recognition of IAF scopes will be developed shortly following approval of the procedure by the ANSI-RAB QMS Council in August 2004.

MRA: The SCC and ANSI/RAB have extended the existing SCC-ANSI/RAB Mutual Recognition Arrangement until 31 December 2004. The SCC is currently in discussions with RAB to enter the Multilateral Cooperative Accreditation arrangement (MCAA). The MCCA will increase co-operation between accreditation bodies and demonstrate implementation of the IAF Cross Frontier Policy. To date, RAB, JAB and JAS-ANZ have signed the MCAA.

5.0 SECTOR UPDATES

5.1 QS9000 AND TE Supplement

The QS 9000 and TE 9000 program continue to wind down, and registrations to QS 9000 are decreasing in anticipation of the 2006 cessation of the program.

Since the last Bulletin, the AIAG have issued a letter dated 2003-12-11, clarifying the information required to be reported to Ford, DaimlerChrysler and General Motors when a QS 9000 registered supplier is put on probation. Registration bodies should note they are required to provide the following information by e-mail:

- Name of site and physical site address (not mailing address)
- OS 9000 Certificate Number
- Supplier code for Ford, DaimlerChrysler, and/or General Motors (Manufacturing DUNS number)
- Reason for suspension (Major Nonconformance or Special Status Notification)
- Date suspension was initiated
- A copy of the letter sent to the supplier.

Note: Probation notifications must be sent to all three (Ford, DaimlerChrysler and General Motors) every time a probation is issued regardless of whether the supplier provides products or services to all three.

5.2 CMDCAS

HC CMDCAS RB Forum

The 4th CMDCAS HC RB Forum was held 2003-06-25/26 at the Health Canada offices located in Tunney's Pasture in Ottawa. The Agenda and minutes for the 4th HC CMDCAS RB Forum

can be received by contacting Ms. Anne-Marie Coutu at Health Canada (Anne-Marie_Coutu@hc-sc.gc.ca).

Registration Body representatives should be registered to the HC CMDCAS RB Forum sitescape area and are required by Health Canada to attend meetings. Participation in the HC CMDCAS RB Forum is mandatory and supports Registration Body maintenance of competency to operate in the CMDCAS program.

ISO 13485:2003 Transition Status

The following provides an update on the status of the ISO 13485:2003 transition for year one of the transition period ending July 15th 2004.

| Item | |
|---|----|
| Total Applicant and Qualified CMDCAS RB's | 17 |
| Number of Transition Plans Received for Review To-Date | 16 |
| Registration Bodies who have not responded | 1 |
| Number of Registration Bodies approved for ISO 13485:2003 | 10 |

Note the SCC has updated the CMDCAS area of the website to include information related to the ISO 13485:2003 transition which includes a list of bodies that are approved to issue ISO 13485:2003 registration certificates. This information can be found at the following URL: http://www.scc.ca/en/programs/iso_reg/iso_13485-2003.shtml.

Impact of the IAF Cross Frontier Policy/MRAs/MLAs on CMDCAS

CMDCAS is a program linked to Canadian Regulations; therefore, the IAF Cross Frontier Policy and MRAs/MLAs are applicable to those Registration Bodies qualified under the CMDCAS program in a limited capacity. As such, an SCC auditor and Health Canada representative are required to participate in oversight activities conducted under MRAs/MLAs and at RB critical locations.

The following provides an overview of decisions taken by Health Canada with regards to audit activities conducted under the IAF Cross Frontier Policy and MRAs/MLAs:

- Joint audit activities can be performed to support the Cross Frontier Policy and MRAs/MLAs:
- SCC must lead audit activities and when CMDCAS is included in the scope of the audit activity;
- Assessors from other AB's can complement audit team.

Scheduling of Office Audits Conducted under the CMDCAS Program

A new process has been put in place for scheduling of office audits conducted under the CMDCAS program as follows:

- SCC and HC will meet prior to beginning of each fiscal year to establish office audit activity dates;
- Dates will be confirmed with the RB several months in advance;
- Office audit activity dates will be established for the 4 year accreditation cycle;
- Dates and audit team will be confirmed approximately 8 weeks before the audit activity;
- Documents to support audit activity will be requested to be submitted to the SCC 4-6 weeks before the audit activity.

Annual Witness Audit Activities to Support Maintenance of CMDCAS Sector Qualification

Witness audit activity to support maintenance of CMDCAS sector qualification is required to be completed each year by December 31st. Suspension of CMDCAS sector qualification will be initiated if the required witness audit activity is not completed by this date.

In addition, a new process has been put in place to support the scheduling of CMDCAS witness audits as follows:

- CMDCAS Witness audit activity to be selected 4 months prior to "target date" (Note- this deadline has been put in place to accommodate the Health Canada travel approval process)
- A list of scheduled audits to be conducted under the CMDCAS program will be requested by the SCC Scheduler.
 - The list is required to take the form of a Matrix and include:
 - 1. Name and Address of CRB client
 - 2. Applicable sites
 - 3. Locations of the scheduled audit activity
 - 4. Dates of the audit for each location
 - 5. Type of audit (eg. Initial/surveillance)
 - 6. Applicable criteria
 - 7. Applicable IAF Scope codes
 - 8. Lead auditor and audit team
- In addition to the above items, Health Canada has requested the following information be included in the matrix for each audit activity:
 - 9. Description of medical devices manufactured by CRB client
 - 10. Class of medical device
 - 11. Indication if design and product realization processes will be included in the audit activity
- Note: The matrix is required to include audits conducted by related bodies and sub-contractors

The above information should be relayed to those RB personnel who participate in the witness audit scheduling process.

5.3 Aerospace

The Americas Aerospace Quality Group (AAQG) Registrar Management Committee (RMC) last met June 8 to 10, 2004. At that meeting, several items of note were discussed as follows:

Oasis Database

- An initial registration fee of \$500 USD has been established for initial entry of a registered company in the Oasis database. A fee of \$375 USD has been confirmed for entry of recertification of registered companies in the database.
- The Oasis database will allow suppliers to select who will have access to tier 2 data results (eg. Audit results, scores, NCRs, auditor remarks)
- Entry of information in Oasis database by the Registration Body is a requirement for sector qualification as of July 2003.

RB Audit activities

- RB auditors should be performing process based audit activities. When conducting audit activities, RBs should be using the applicable AS checklist, standard, and the organization's quality system documentation.
- When conducting registration activities, the RB auditor should ensure implementation of a process-based QMS by the manufacturer. Attention should be paid to linkages between identified processes and performance measures and to customer satisfaction.
- Registration certificates issued by RBs under the AAQG program should include all required information (eg. Reference to AIR 5359, complete address of manufacturer)
- The RB should ensure that corrective action taken by the manufacturer includes identification of root-cause analysis and action taken to prevent reoccurrence. Corrective action should be verified.
- Contracts for registration audit activities shall include clauses for right of access for OEMs, AAQG member companies and regulatory authorities.
- RB audit activities should include lower level and support processes.
- The RB should ensure the organizations contract review process, including quality system requirements imposed by customer and/or applicable regulatory authorities is reviewed during audit activities.

The above items should be relayed to all RB auditors performing audit activities under the AAQG program.

The next AAQG-RMC meeting will be held 2004-08-28/19 in Washington D.C. Registration bodies qualified under the AAQG program are welcome to attend AAQG-RMC meetings.

5.4 TL 9000

The TL 9000 Measurements Handbook was revised and published in March 2003 as version 3.5. Copies of the revised Handbook can be purchased by contacting the QuEST Forum (http://www.questforum.org) or ASQ at 1-800-248-1946.

In April 2004, QuEST Forum announced a mandatory electronic training class and examination for RB and AB TL 9000 auditors. The notice is attached.

English speaking auditors are required to take the class and pass the examination by 2004-07-31. Classes will be offered in other languages by June 2004, with a requirement for successful completion by 2004-10-31. The examination is open book and the passing grade is 75%.

For those bodies qualified by the SCC under the TL 9000 program, accreditation body oversight will include verification that TL 9000 auditors have taken and passed the course as follows:

- Until 2003-10-31 a non-conformity will be identified during oversight activities for resolution by the RB if it found that a TL 9000 audit activity has been performed by an auditor who has not taken the required training.
- After 2004-10-31, TL 9000 sector qualification may be suspended if it is found that a TL 9000 audit has been conducted by an auditor that has not taken the required training.

Upcoming QuEST meetings:

The QuEst Latin American Regional Conference will be held at the Hotel Intercontinental in Buenos Aires, Argentina 2004-08-14 to 26;

The 5th Annual Best Practices Conference will be held at the Renaissance Dallas-Richardson Hotel in Richardson, Texas 2004-09-21-22;

The Registrar and Accreditation Body Sub-Team Meeting to promote improved Registrar/AB/QuEST Forum Communications and to promote TL 9000 Registrar Assessment Continuing Improvement Practices will be held at the Renaissance Dallas-Richardson Hotel in Richardson, Texas 2004-09-23.

Additional information on QuEST Forum meetings can be found on the QuEST Forum website at http://www.questform.org.

5.5 Sustainable Forest Management

Current forestry statistics regarding the Canadian SFM market can be found on the http://www.CertificationCanada.org – click on the icon entitled "Certification Status and Intentions" or go directly to http://www.CertificationCanada.org/status.htm.

The Canadian PEFC Council submitted its application to the PEFC applying for recognition in MRA-SFM. Further information about the Mutual Recognition Arrangement and the SFM certification scheme at large can be found at http://www.pefc.org/internet/html/. Note: PEFC has become an associate member to IAF.

Some more news, the Ontario Ministry of Natural Resources (OMNR) is promoting forestry certification. The goal of the OMNR is that all Sustainable Forest License (SFL) holders will be required to be certified by the end of 2007 by an independent third-party based on established criteria and standards. For more information see the news release titled *Ontario Promotes Forest Certification* – date 1 April 2004 at http://www.mnr.gov.on.ca/MNR/. This news is an example of the Government assisting in driving the forest certification in the country, and as a result supporting SCC's accredited ISO 14001 EMS registration body. Currently, SCC has a MOU with

OMNR and is working on a joint program regarding SCC's EMSAP's SFM program and OMNR's independent forestry audit program for license holder on Ontario Crown Land.

Erratum: in the MS Bulletin 5, dated December 2003, item 5.5. International SFM work "SCC stated the following: "... However, it was recognized that IAF members are working strongly in the SFM field and will most likely become another EMS industry sector scheme for IAF in the future." It should read that: *IAF will not set up a SFM industry sector scheme at this time*.

5.6 EMS Industry Sector Program for Hog Operations

The CAN/CSA-Z771-04 Environmental Management Systems for Hog Operations: Requirements standard was approved as a National Standard of Canada in March 2003. The Pork Council of Canada has requested SCC to set up an industry sector program for 3rd party registration of EMS for Hog Farms to the national standard CAN/CSA Z771. Canada has some 15,000 pork producers, which may seek certification. "According to Statistics Canada, Canada's hog industry was worth approximately C\$3.32 billion in 2002 and currently consists of nearly 14.6 million hogs, making it one of Canada's most significant agricultural industries. (*) In 2001, Canadian hog farmers invested an average of \$6,224 each on environmental improvements, compared to an average of \$1,091 invested by other farmers" (CSA NEWS RELEASE MARCH 2004). EMS registration bodies interested in this program should contact Stefan Janhager at sjanhager@scc.ca. SCC is planning to launch its accreditation program during the summer of 2004.

5.7 Climate Change

ISO TC 207 working group 5 and CASCO joint work item has been proposed and was out for vote among members. The joint working group is expected to address the certification/verification requirements in the draft ISO 14064 standard. The vote is due to come in on 2004-07-27.

5.8 Personnel Certification Body Accreditation Program (PCBAP)

The SCC's Personnel Certification Body Accreditation Program was launched in January 2004. Currently, SCC has accredited two PCB's (i.e. meeting ISO/IEC 17024) that are qualified to certify QMS and EMS auditors – the Canadian Environmental Auditing Association (CEAA) and the National Quality Institute (NQI). For further information regarding the PCBAP program or to access the list of bodies accredited under the PCBAP, please see http://www.scc.ca.

6.0 STAFFING IN CONFORMITY ASSESSMENT

SCC Program Officer, Ms. Sohini Famili, is currently on maternity leave until June 2005. In her absence, Ms. Sylvia Bienvenu will be responsible for scheduling audit activities and Ms. Kim Astle will be responsible for all balloting activities. Ms. Bienvenu can be contacted by phone at (613) 238-3222 ext. 429 or by e-mail at (sbienvenu@scc.ca) and Ms. Astle can be contacted at (613) 238-3222 ext. 313 or by e-mail at (kastle@scc.ca). In addition, Tasha Charette has joined the SCC as an Administrative Assistant effective June 14, 2004.

We appreciate all suggestions, feedback and questions. Kindly forward any comments, questions and/or suggestions to:

Sylvia Bienvenu

Tel: (613) 238-3222 (ext. 429)

Fax: (613)569-7808 sbienvenu@scc.ca

QUEST FORUM ANNOUNCES NEW REGISTRAR TRAINING CLASS SUPPORTING MEASUREMENTS HANDBOOK VERSION 3.5 ALL REGISTRAR AUDITORS ARE REQUIRED TO COMPLETE ELECTRONIC TRAINING AND EXAMINATION SEE SCHEDULE BELOW

PURPOSE:

In order to provide instruction and guidance for Quality Management Systems Measurements Handbook Release 3.5, the QuEST Forum has developed a new sanctioned training module. This training class will be provided via e learning. This class dives further into the depth of the measurements definitions, counting rules, and interpretations vs. our previous training materials. It is expected that students will gain an improved understanding and appreciation of the interactions between the measurements and the overall quality system as well as better appreciate some of the subtle yet important aspects of the measurements themselves. It is anticipated that after applying this knowledge, TL 9000 registered organizations will benefit by seeing stronger and more consistent TL 9000 implementations. Originally planned as a course for registrars, this module can also provide added value for any organization registered to or considering TL 9000 registration.

E LEARNING:

This course is the first non-lecture based class in the sanctioned curriculum. The e-Learning format was chosen, in preference to an instructor-led event, based on user requests, to minimize costs, and provide Registrar Auditors maximum flexibility in scheduling studies and taking the examination. Excel Partnership Inc has developed all the material in cooperation with a QuEST Forum review team comprising Registrars, Suppliers, Service Providers and Subject Matter Experts. Based on the feedback and experience, we may consider this option for future training.

COMPLETION DATES - ENGLISH SPEAKING AND OTHER LANGUAGE TRANSLATIONS:

To improve consistency of Registrar audits for TL 9000 Organizations, the QuEST Forum Oversight Workgroup has set a requirement date for Registrar Auditors and Accreditation Body (AB) Auditors to successfully complete this class.

English: All English-speaking Registrar or AB Auditors must pass the electronic exam by July 31st, 2004.

Other Languages: Translated versions of the class are targeted for June, with a requirement for successful completion prior to October 31, 2004. Registrar or AB Auditors will not be qualified perform TL 9000 audits after these dates without successful completion of the examination. The examination is open book and the passing grade is 75%.

FEES:

The e-Learning tutorial and the exam fee per person is \$250 for QuEST Forum members (full and liaison), or \$325 for Non-Members. The fee includes a downloadable copy of the electronic tutorial (Adobe Acrobat .pdf file) and unlimited attempts at the examination until successful completion of the course.

Fees are to be paid on-line with a major credit card; or for orders of 10 people or more, by special arrangement. All payments made to: Excel Partnership – contact Gloria Morris for details at 203 426 3281 x247.

SUMMARY:

This training underwent a rigorous review of Subject Matter Experts and a comprehensive Beta test with a representative sample of students. All suggestions for improvement were formally documented, reviewed, and incorporated into our launched product. The Beta student's feedback was extremely positive and we're optimistic that the class will greatly assist the Organizations and Registrars who take it.

Instructions for accessing the electronic materials follow below.

We thank you for your continued commitment to the QuEST Forum's work.

Regards,

Kevin Calhoun – Quest Forum 2004 Project Director Patrick Brendan Pelan – Oversight Workgroup Chair Dave Sanicola – Registrar Committee Chair Ken Koffman – Executive Contributor