Standards Council of Canada
Conseil canadien des normes

REGISTRATION BODIES BULLETIN NO. 4

JUNE 2003

CONTENTS

1.0 PROGRAM STATISTICS AS OF 2003-03-31

Program	*QMS*	*EMS*
Accredited RB's	20	10
New Applicants	9	1
Initial Accreditations	3	3
Reaccreditations	4	6
Voluntary Withdrawals	1	-
Voluntary CMDCAS Sector Withdrawal	1	N/A
TE 9000 Qualified	3	N/A
QS 9000 Qualified	8 + (1 applicant)	N/A
TL 9000 Qualified	3 + (1 applicant)	N/A
CMDCAS Qualified	8 + (9 applicants)	N/A
SFM Qualified	N/A	2
SFM applicants	N/A	1

2.0 MEETINGS

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

2.1 MRA/MLA HARMONIZATION COMMITTEE

The second meeting of the SCC – ANSI/RAB MRA Harmonization Committee was held at the RAB offices in Milwaukee, 2003-02-03. Draft minutes from this meeting are available upon request.

The committee has formed several working groups which are addressing the following subject areas: W/G 1 Communications, W/G 2 MRA Review, W/G 3 Harmonization of recognition of scope procedures, W/G 4 Joint audit procedures, W/G 5 CRB MRA committee.

At this time, the SCC has provided comments on a joint audit procedure, and work is continuing on finalizing TI 93. 9 Scope of Accreditation. Discussion is also continuing on revisions to the MRA. The next meeting of the SCC-ANSI/RAB MRA/MLA Harmonization Committee will be held in August/September 2003.

2.3 CASCO

The next CASCO plenary has been scheduled for 2003-11-06/07. Prior to that meeting the Canadian Advisory Committee to CASCO will be meeting at the SCC offices 2003-10-24 to discuss and determine Canadian positions on agenda items for the CASCO plenary.

Several CASCO work items of interest to Registration Bodies are in process. The CAC/CASCO workplan detailing the status of working groups and their associated work items, including standards under development is attached as Annex 1. Of particular note to Registration Bodies, is the work item associated with:

WG 21 General Requirements for bodies operating assessment and certification of management systems (ISO/CD 17021).

CASCO Working Group 21 Update

The CASCO WG 21 is meeting the week of June 16, 2003. Currently, the draft ISO/CD 17021 document is at the CD 1 stage. Several comments have been provided by interested parties and it expected that the document will pass to the CD 2 stage following the June meeting. An update on the meeting will be provided to Registration Bodies by the SCC representative, Stefan Janhager following the meeting. Registration Bodies will be provided the next version of ISO/CD 17021for review and comment.

Registration Bodies seeking meeting minutes or detailed information related to CASCO work items should contact the CAC/CASCO Secretary Mr. Allan Wilson (awilson@scc.ca)

2.4 IAF

Since the last RB Bulletin, the IAF Technical Committee met in February 2003, and the IAF Executive Committee met in May 2003. At these meetings, several decisions were taken for implementation by Accreditation and Registration bodies as outlined in section 3 of this bulletin. In addition to the items for implementation, Registration bodies should note the following updates:

Well Developed and Implemented Management Systems: The draft method was circulated among members for voting and while the result was positive a number of members had submitted negative votes and/or comments. A decision was made to review all comments and to conduct a new ballot. At this stage the so-called "Alternative Method" will remain IAF's official document. The intent is to resolve all issues before the September 2003 Bratislava meeting.

IAF MLA Mark: The selection process for a modified IAF Seal and MLA Mark is nearing completion. IAF members will be asked to select the final designs by letter-ballot. Once approved, the IAF MLA mark will be available for insertion on registration certificates issued by bodies accredited by an IAF MLA signatory.

Cross Frontier Accreditation

A policy for cross-frontier accreditation has been under development by the IAF Technical Committee for several months. Currently, the document has been released for ballot. The SCC will be providing the draft policy to Registration Bodies for final comment by 2003-07-14. Once approved, the document will be published as an Annex to the IAF Guidance on the application of ISO/IEC Guide 61. A seminar on implementation of the Cross Frontier Accreditation policy will be held in conjunction with the IAF Plenary Meeting in September in Bratislava.

Witness Audit Guidance

The IAF TC has established a sub-committee to develop guidance for accreditation bodies when witnessing audit activity that is based on best practices, and a common report format that would enable accreditation bodies to share and consider other accreditation body results. This is a new work item, and Registration bodies will be provided an opportunity to comment on the guidance document once it is drafted.

Auditor Competency

The IAF TC is currently in process of developing further guidance on Clause 2.2 of the IAF guidance on the application of ISO/IEC Guide 62 related to Auditor competency. When the revised guidance clause 2.2 has been finalized, the result will be inserted into the next revision of the IAF guidance document. In addition, cross-references to ISO 10011 will be replaced by ISO 19011 at that time. Revisions to the IAF Guidance will be finalized before the September IAF plenary meeting in Bratislava.

The next meeting of the IAF Plenary will be held in Bratislava, Slovakia 2003-09-14 to 21. The IAF Technical Committee will also be meeting at that time. Prior to the meetings, the SCC will distribute relevant meeting papers for Registration Body

comment and input. Minutes and Resolutions from IAF meetings are available on the IAF website (www.iaf.nu) or by contacting the SCC.

2.5 IAAC

The Standards Council of Canada (SCC) became a member of the IAAC in 2000. In October 2002, the SCC signed two Multilateral Arrangements for Testing and Calibration Laboratories and for Certification Bodies of Quality Management Systems. David Shortall, Manager, International Trade, SCC represents Canada on the Plenary and the Multilateral Arrangement (MLA) Committees.

Key activities for the IAAC in 2003/2004 are:

1. Expansion of the IAAC MLAs: The IAAC wants to increase the membership of the MLAs for QMS and TCL, and extend the MLA to Environmental Management Systems and Product. There is a critical shortage of internationally recognized peer evaluators, particularly Spanish speaking, required to expand the IAAC MLAs. The SCC has provided a list to the IAAC of peer evaluators.

2. Capacity Building: OAS will contribute an estimated US$112,000 for IAAC capacity building and technical assistance projects. This funding will be used to conduct three pre-peer evaluations (Argentina, Chile and Columbia); undertake a series of interlaboratory comparisons; organize a peer evaluator workshop; continue to provide assistance to members to attend meetings; and continue to develop and host the IAAC Web site.

   In addition, IAAC will submit project proposals to OAS and the Inter-American Development Bank (IDB) to support internships for training on the implementation of accreditation guidelines; a workshop for training of quality managers of accreditation bodies; courses on ISO/IEC 17025 (*General requirements for the competence of testing and calibration laboratories*) and 17011 (*General requirements for bodies providing assessment and accreditation of conformity assessment bodies*); the creation of a regional database on conformity assessment; and the translation, printing and distribution of accreditation documents from English to Spanish.

2.6 ISO 9001 ADVISORY GROUP (IAG)

The International Accreditation Forum, ISO/TC 176 and CASCO have formed the ISO 9001 Advisory Group to review the credibility of ISO 9001 and the certifications granted.

Under the guidance of the IAF, the IAG is responsible for:

- Monitoring the credibility of ISO 9001 for certification and providing feedback to each of the component members of the group
- Providing a forum for discussion of user satisfaction and creating action plans when complaints or indications of concern are identified

- Identifying issues that indicate the need for official ISO/TC 176 interpretations to ISO 9001:2000 or specific IAF guidance
- Providing feedback to ISO/TC 176 on the acceptance of its standards and providing input for future revisions
- Acting as a basis for "shadow" committees on a local or regional basis for ISO member bodies and accreditation body members of IAF.

As a further work item, the IAG will be examining auditor competency. As a related item of note, the TG-QMSRO has also formed a working group to examine auditor competency. Work performed by this group will be provided to the IAG for consideration.

2.7 ISO 9001:2000 Transition

The ISO 9001:2000 transition status was discussed at the February IAF TC meeting and the status of the transition will again be reviewed at the IAF Plenary meeting in September 2003. Informal information received by the IAF to-date indicates acceleration in the transition process.

In April 2003, the Pacific Accreditation Cooperation (PAC) issued a survey for completion by Registration bodies to determine the current status of the ISO 9001:2000 transition. The IAF input, results of this survey and other relevant information were considered by the TG-QMSRO during discussion of the status of the ISO 9001:2000 transition at the 4th meeting of the TG-QMSRO held in May 2003.

At that meeting, the Task Group members confirmed the IAF direction that accredited registrations should not be in the marketplace if they have not been transitioned to ISO 9001:2000 by the deadline and suggested the following actions for the SCC:

- Development of a Registration Body questionnaire to solicit input and gather information;
- Discussion of the issue with Registration Bodies and identification of implementation difficulties
- Development of practical solutions to address the issue should a large number of ISO 9001:1994 registrations not be transitioned by the deadline
- Communication with other Accreditation Bodies to identify their plans should a majority of registrations not be transitioned by the deadline.

In addition, the TG-QMSRO auditors agreed to review the status of the transition of registrations with the Registration bodies during audit activities. Feedback would be provided to the SCC in the audit report.

In accordance with this decision, the SCC and ANSI-RAB have developed a survey to gather information related to the current transition status and the anticipated status of the ISO 9001:2000 transition at 2003-12-15 from accredited registration bodies. The survey has been distributed to registration bodies and return of the survey to Ms. Loreto Lamb (llamb@scc.ca) is requested by 2003-07-02. When survey results have been received and

collated, feedback on the ISO 9001:2000 transition status will be provided to the IAF for information purposes.

3.0 ITEMS FOR IMPLEMENTATION / INTERPRETATIONS

The following interpretations / items for implementation should be reviewed by Registration Bodies and any actions incorporated into program activities. Note interpretations are auditable points and may be reviewed by the SCC during annual audit activity.

3.1 CAN-P-1517B CONDITIONS AND PROCEDURES FOR ACCREDITATION OF ORGANIZATIONS REGISTERING QUALITY SYSTEMS

The next version of CAN-P-1517 is expected to be approved as CAN-P-1517B by the ACCA in July 2003. CAN-P-1517B has been revised to address program changes and activities resulting from the SCC Quality Management Systems Accreditation Program IAF/PAC Peer evaluation in April 2002, the addition of several sector specific programs, further revision to the IAF Guidance on the application of ISO/IEC Guide 61, and SCC participation in several Multi-lateral arrangements. The "B" version of CAN-P-1517 contains several new sections to address application for accreditation under the IAF MLA, procedures for scope extension, and witness audit activity. In addition, some operational requirements have been added. New items that require implementation by Registration bodies were notified in the January 2003 RB Bulletin. As such, implementation of CAN-P-1517B will be upon approval. For those bodies wishing to begin implementation of the document before July, a final draft version of the document highlighting additions is available upon request from the Administrative Assistant (llamb@scc.ca).

As a specific item of note, annual witness audits to support maintenance of accreditation are now required under clause 3.7.2 as follows:

> 3.7.2 For maintenance of accreditation, a minimum of one witness audit will be required annually. For maintenance of accreditation, the witness audit will be requested by the SCC, and selected from the recognized scope of accreditation as defined by the IAF codes.
>
> 3.7.2.1 A required witness audit to support sector qualification activities may be used in lieu of a witness audit selected from the recognized scope of accreditation as defined by the IAF codes once per re-accreditation cycle (one/four years).

As such, all accredited Registration bodies will be subject to an annual witness audit this fiscal year ending 2004-03-31. Ms. Sohini Famili will be contacting each Registration Body shortly to begin coordinating the witness audit activities.

3.2 REQUEST FOR ADDITIONAL DOCUMENTS PRIOR TO AUDIT ACTIVITY

Registration Bodies are now also required to provide the following information prior to each audit activity:

1. A matrix of qualified auditors, including scopes and sectors each auditor has been qualified for. (Scopes and Sectors only applicable to QMS)

2. A complete list of registered clients

For EMS audit activity, please ensure the list of registered clients includes the identified risk categorization (high, medium, or low) as outlined in the IAF Guidance on the Application of ISO/IEC Guide 66, Issue 2 Annex 1-Table 2.

3.3 INCLUSION OF SCC ON DISTRIBUTION LISTS

Currently, several registration bodies have included SCC on distribution lists for updates to quality manuals. As SCC requests up to date documentation prior to each annual audit activity, we request RB's remove the SCC from distribution lists.

3.4 ISO 13485-2003 TRANSITION

Following accreditation by the SCC and recognition in the appropriate IAF scope or sector scheme, Registration bodies can conduct registration activities to internationally recognized quality systems standards, including ISO 13485/88. ISO 13485/88 has recently been revised to be similar in structure and content to ISO 9001:2000. The final ISO 13495:2003 will be published by ISO in July 2003.

The new ISO 13485-2003 contains all of the medical device specific requirements found in ISO 13485-1996 and most of the generic quality management specific requirements found in 90001-2000. ISO 13485:2003 transition guidance for Registration Bodies has been developed to support the 3 year ISO 13485/88-1996 to ISO 13485:2003 transition period established by ISO/TC 210. ISO transition guidance has been accepted by the SCC and is applicable to those applicants and accredited Registration bodies who issue ISO 13485/88 registration certificates (both inside and outside of the CMDCAS program). Transition requirements have been identified in Annex 2 and address three main areas: Documentation, Implementation and Client relations. Oversight will be conducted over the 3 year transition period and consist of the following activities:

- Initial Document review of transition plans;
- Verification of implementation of transition plans (on-site or off-site);
- ISO 13485:2003 witness audit;
- Annual review of implementation of transition plans over the 3 year transition period.

Once the final ISO 13485:2003 has been published, the SCC will begin accepting transition plans for review. It should be noted that transition plans are not required for Registration Bodies who do not provide registration to ISO 13485/88 under SCC accreditation.

IAF INTERPRETATIONS

Since the last RB Bulletin, the following interpretations have been issued by the IAF:

3.5 IAF GUIDANCE ON THE APPLICATION OF ISO/IEC GUIDE 62 AUDIT TIME ANNEX 2

A paper was presented by RAB requesting an interpretation on the definition of the number of employees, as the starting point of analysis required to determine audit time as

found in Annex 2. The IAF TC determined that this clause referred to the total number of employee within the organization, and was not to be based on the number of employees present at the time of the audit. Official wording will be proposed and changes included in the next revision of the IAF Guidance.

3.6 IAF CLARIFICATION: ISSUANCE OF REGISTRATION CERTIFICATES TO TWO CORPORATE ENTITIES

At the February 2003 meeting of the IAF Technical Committee, the SCC requested an interpretation to determine if a Registration Body could issue a single registration certificate to two separate entities. As clarification, the IAF TC agreed that as long as there was common ownership and one management system subject to certification, a single registration certificate could be issued to two separate corporate entities. All provisions of the IAF Guidance remain applicable.

3.7 EFFECTIVE DATE OF REGISTRATION CERTIFICATES

A clarification was sought related to the date of certification. The IAF TC clarified that the effective date of a registration certification should be the date of decision, not the date of the audit report.

3.8 ISO 19011

The IAF Guidance on the application of ISO/IEC Guides 62 and 66 will be updated to include ISO 19011 guidelines and further guidance related to auditor competency. Once approved, a transition plan for implementation of the revised IAF guidance documents will be established by the IAF. Incorporation of ISO 19011 elements is not required at this time, however registration bodies should begin updating documentation as the IAF Guidance documents are expected to be approved for implementation by September 2003. Currently, the SCC has begun updating program documentation to include ISO 19011 and use of the new standard during audit activity has begun.

3.9 IMPACT OF TRAVEL RESTRICTIONS ON OVERSIGHT PROCESS

With recent world events like the SAR's outbreak, Registration Body oversight of some suppliers may be impacted. The IAF has published advice to Accreditation bodies to assure that the assessment regime for registered bodies is maintained as follows:

"The IAF expects AB's and CRB's to have a policy for the proper maintenance of certificates. These policies should address at least the following factors:

1. Circumstances when visits (differentiated according to the type of visit) can be performed by an available, even if not appropriately qualified, team;
2. Circumstances where visits have to be postponed;
3. Compensating assessment measures to be taken in the event of 1 or 2 above (e.g. visits performed without the capability to assess all aspects, desk top reviews, any other off-site assessment techniques used and their results, any performance metrics);
4. Maintenance of records of the actual assessment regime for each affected body;
5. Reporting of the measures taken by CRBs to ABs and by ABs to IAF;

6. Steps to be taken to restore the assessment profile when restrictions are lifted;
7. Handling of specific sector scheme requirements;
8. Handling of transition from ISO 9001/2/3:1994 certification to ISO 9001:2000 certification.
9. The maximum period for which a certificate may be maintained without an appropriately qualified team performing a site visit.

These policies should result in the same amount of assessment activity being performed over the period of abnormality as would have taken place under normal circumstances. This requires ABs and CRBs to undertake risk assessments, and to compare the effectiveness of any activity not entailing normal assessment visits (e.g. compensating measures as referred to under 3 above) with the normal regime, and to compensate for any deficit at the end of the period (top-up activity). If it becomes impossible to do this after a full assessment cycle of abnormal operation, the certificate should no longer be maintained."

3.10 CMDCAS

The 2nd Health Canada CMDCAS RB Forum was held in Ottawa 2003-06-05/06. At that meeting several items of interpretation/implementation were brought forward to attendees as follows:

IAF decision on placing two legal entities on one certificate

The decision by the IAF to allow two legal entities on one certificate could potentially affect a medical device manufacturer applying for a license if the names of the two entities on the certificate are not clear and that there is some uncertainty as to which entity is considered the legal medical device manufacturer.

Although technically feasible, the practice of putting the name and address of two legal manufacturers could lead to difficulties related to the interpretation of the name and address of the manufacturers that will affect the medical device licensing process.

Schedule 1293 - Regulations Amending the Medical Devices Regulations – Quality Systems

On May 15, 2003, regulatory amendment Schedule 1293, the most recent amendment to the Canadian Medical Devices Regulations, was passed by Order-in-Council and was subsequently published in the Canada Gazette Part II of June 4, 2003.

The official registration number and title of the amendment is SOR 2003-173, Medical Devices Regulations - Amendment - Regulations Amending the Medical Devices Regulations (1293 – Quality Systems) / Règlement sur les instruments médicaux - Modification - le Règlement modifiant le Règlement sur les instruments médicaux (1293 - systèmes qualité) .

The complete text of the amendment can be obtained from the Canada Gazette web site at http://canadagazette.gc.ca/index-e.html and a copy of the December 2002 consolidated

version of the Medical Devices Regulations can be obtained from the Justice of Canada web site at http://laws.justice.gc.ca/en/f-27/sor-98-282/126454.html

Registrar Recognition by December 31, 2003

Certificates from CDMCAS applicants will be accepted by HC until December 31, 2003 (Ref. Guidance document GD 208).

Health Canada does not plan on extending the December 31, 2003 deadline for the CMDCAS recognition of a Registration Body. Health Canada intends to work with the SCC to ensure that there are no delays in the activities related to the processing of a Registration Body's application.

Health Canada is sometimes asked about the status of the CMDCAS qualification status of an applicant RB or what the options available to the manufacturer are if the RB has not been recognized by December 31, 2003. The response to these types of questions is that Health Canada does not plan on extending the December 31, 2003 deadline and that because the status of a RB's application is confidential the manufacturer must contact their registrar to get the required information. If a RB requests it, the SCC can provide a letter to the RB on the status of its application that the RB can give to their clients.

ISO 13485-2003 Transition Plan

Under the CMDCAS program, Health Canada will adopt the 3 year transition period proposed by ISO TC 210/WG1 and will accept during this period, and under the specific conditions listed below, ISO 13485-1996, ISO 13488-1996 and ISO 13485-2003 certificates issued by CMDCAS recognized registrars. After the transition period only ISO 13485-2003 certificates will be accepted as objective evidence of compliance to the regulatory QS requirements. Health Canada and the SCC have been developing conditions for acceptance of accredited ISO 13485-2003 certificates during the transition period as detailed in the transition requirements (section 3.4).

CMDCAS Handbook and revised application form

In June 2003, the SCC released the CMDCAS Handbook *Policies and Procedures for Sector Qualification under the Canadian Medical Devices Conformity Assessment System (CMDCAS).* The CMDCAS Handbook outlines the processes and policies under which the CMDCAS program operates. Also included are limitations for applicants, information related to the Health Canada CMDCAS RB Forum, approval processes, information related to the HC-SCC Memorandum of understanding etc. An overview of the contents of the CMDCAS Handbook and copies were provided to applicant and recognized CMDCAS registration bodies at the 2nd HC CMDCAS RB Forum.

In addition, a revised CMDCAS application form is now available. Registration bodies submitting applications for CMDCAS sector qualification after July 5, 2003 will be required to use the new form.

Additional copies of the CMDCAS Handbook and the new application form can be obtained by contacting Ms. Loreto Lamb (llamb@scc.ca).

Impact of travel restrictions on regulatory quality system requirements

As part of their SCC terms of accreditation, all RBs are required to advise the SCC of any intended change in the organization, including policies and procedures, which may affect compliance with the criteria and requirements for accreditation.

Even though an RB's client may be affected because of recent global events which restrict travel, the RB is still bound to meet the requirements for registration and accreditation. Therefore, in the event that an RB cannot perform on-site assessment of an affected client under the CMDCAS program, the RB must establish an alternate method of ensuring the continuing validity of the existing registration. This alternate method must address the RB's accreditation requirements and be rationalized and documented in the client files. The rationale shall take into account the risk classes of the medical devices covered by the manufacturer's QS.

The alternate methods for maintenance of registration cannot be used for an initial registration of a manufacturer under CMDCAS. QS Certificates issued under conditions that do not meet this restriction will not be considered valid by Health Canada.

Impact on device licences because of delays in the issuance of quality system certificates by registrars

Now that Schedule 1293 has come into force, all new medical device licence applications and certain types of licence amendments will require a valid QS certificate be included with the application. The immediate effect of an RB unnecessarily delaying the issuance of a QS certificate is the delay in a medical device manufacturer obtaining a new or amended medical device licence. RBs are encouraged and reminded not to unnecessarily delay the issuance of a valid quality system certificate following the successful audit, review and approval of a QS.

Upcoming guidance documents

Health Canada is currently working on four new guidance documents and a one page reporting form to support the CMDCAS policy document and to help CMDCAS recognized registrars comply with the Sections 32.3 and 32.4 of the Medical Devices Regulations.

Draft copies of these new documents will be posed on the Therapeutic Products Directorate website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_devices_quality_e.html

The working titles of the new documents are:

a) Form - Notification by a Registrar of a Change in a Manufacturer's Registration Status
b) Guidance on the submission of new and modified certificates by medical device manufacturers
c) Guidance on the suspension and withdrawal of a registrar's CMDCAS recognition by Health Canada

d) Guidance on the CMDCAS Auditor Qualification Program
e) Mandatory Reporting by a registrar of non-conformities and other QS issues to Health Canada

Interactions between European Notified Bodies and affiliated quality system Registration Bodies

A number of issues related to the interaction between European Notified Bodies and their North American based CMDCAS recognized registrar affiliate have been brought to the attention of Health Canada. The issues and Health Canada's guidance on the topic are:

a) It is not always clear to some medical device manufacturers which entity - the European Notified Body affiliate, or the North American based CMDCAS recognized registrar - is providing the registration services and who is responsible for the assessments. In some cases, there appears to be little involvement of the CMDCAS recognized registrar.

CMDCAS recognized registrars are requested to inform their clients as to who is performing which services and the administrative responsibilities involved. CMDCAS recognized registrars are reminded that it is their responsibility to maintain direct control and oversight of all CMDCAS activities at all times.

b) A number of joint audit reports (including CMDCAS) have not been issued by the CMDCAS recognized registrar or in other cases, only fleeting remarks regarding the Canadian Medical Device Regulations are made in the report.

CMDCAS recognized registrars are reminded to:

i. issue CMDCAS reports themselves;
ii. ensure that CMDCAS reports are comprehensive; and
iii. that the reports meet the requirements of the relevant standards and guidance

c) Some subcontracted RB's or related bodies are contacting Health Canada directly with questions regarding ISO 13485 audits under CMDCAS and are requesting interpretations of the CMDCAS requirements or for permission to implement new or different procedures from those originally submitted by the CMDCAS recognized registrar, without the knowledge of the recognized entity.

Registrars are reminded that they are responsible for the activities performed by their subcontractors or related bodies that are under their control. Registrars are encouraged to inform their subcontractors/related bodies not to contact HC directly but to direct their questions through the appropriate representative at the CMDCAS recognized registrar. Health Canada will redirect all requests from subcontractors/related bodies to the CMDCAS recognized registrar.

Auditing of an ISO 13485-1996 by a CMDCAS recognized registrar - guidance document GD 210

Health Canada would like to remind all CMDCAS recognized registrars that even though guidance document GD210 is described as Draft, it is Health Canada's expectation that they incorporate, by September 1, 2003, the guidance found in this document in their existing auditing practices and checklists. The document contains guidance on:

- audit process;
- sampling;
- auditing of subcontractors;
- reasons for visiting or not visiting subcontractors and Canadian locations of a foreign based manufacturer; and
- auditing of virtual manufacturers.

Copies of the document can be obtained from the Therapeutic Products Directorate at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_devices_quality_e.html#Guidance

3.11 SUSTAINABLE FOREST MANAGEMENT

CAN/CSA Z809 standard for Sustainable Forest Management Program has been revised and will be published shortly. The SCC will be releasing an implementation guideline as soon as the new standard is released. Note: Canada has the most certified forest areas in the world.

4.0 ADMINISTRATIVE ITEMS

4.1 RESPONSES TO AUDIT ACTIVITIES:

When responding to SCC correspondence, including post audit letters, Registration Bodies should include some guidance as to what activity the response is applicable. This will create less confusion and speed up the processing of your responses. Also please keep in mind that all attending auditors require a copy of your responses – please ensure the appropriate numbers of copies are provided.

4.2 TIMELINESS OF RB PROVISION OF DOCUMENTATION TO SUPPORT AUDIT ACTIVITIES

As requested in the SCC audit notification letter, Registration bodies are required to provide supporting documentation to the SCC at least 3 weeks before the date of the audit If the documents are not received in a timely fashion, the audit may be cancelled and costs incurred to date applicable.

4.3 PROVISION OF RB AUDIT REPORTS FOLLOWING A WITNESS AUDIT

As a reminder, please ensure the Registration body audit report is provided to the SCC within one week of the witness audit activity. Audit reports provided by RB auditors on site will not be accepted as they may not be considered the final audit report.

4.4 AUDITOR FEEDBACK FORMS

Since the beginning of the year, auditor feedback forms have been provided to Registration bodies following each head office audit activity.

The objective of this confidential survey is to assist the SCC in evaluating both the quality of audit services conducted and the professionalism of the Task Group on Quality/Environmental Management Systems Registration Organizations (TG Q/EMSRO) representative conducting the audit activity.

Our intent is to use the feedback to enhance the overall quality of our Program(s) by improving the service provided to our clients, as well as evaluating the efficiency and effectiveness of the TG Q/EMSRO members.

We would appreciate your taking the time to complete the form and our thanks to those of you who have taken the time to provide feedback.

4.5 STAFFING IN CONFORMITY ASSESSMENT

Two new Program Officers are to be hired shortly and we would like to welcome the appointment of Craig Camplong as our newest TG-QMSRO auditor (pending approval by ACCA).

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

Loreto Lamb
Tel: (613) 238-3222 (ext. 439)
Fax: (613)569-7808
llamb@scc.ca

ANNEX 1

Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) Workplan – 2003-2004

Work Description	Responsibility / Working Group (WG) Expert	Liaison with Other Committees	Expected Outcomes	Status
1. ISO/IEC Guides:				
1.1 Revision of **ISO/IEC Guide 53: 1998 – An approach to the utilization of a supplier's quality system in third party product certification** – to update references therein and to bring its technical contents into line with ISO 9001:2000	G. Bartels WG 26	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Revised ISO/IEC Guide 53	Estimated Completion Date (ECD) – May 2004 Current: Voted against Committee Draft (CD) on 2002-09-12 – awaiting results of CD vote
1.2 Revision of **ISO/IEC Guide 60:1994 – Code of good practice for conformity assessment**	D. Shortall WG 22	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Revised ISO/IEC Guide 60	ECD – December 2004 Current: Working Draft (WD) # 4 reviewed at 2003-03-17 WG 22 meeting – CD now under preparation
1.3 Development of guidelines for mutual recognition agreements (MRAs) – future **ISO/IEC Guide 68 – Arrangements for the recognition and acceptance of conformity assessment results**	E. Nilsen WG 11	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC Guide 68	Published January 2003 Current: Voted in favour of Draft Guide – 2002-05-10
2. International Standards:				
2.1 Revision of conformity assessment part of the current Guide 2:1996 as an International Standard – Future **ISO/IEC 17000 - Conformity assessment – General vocabulary**	G. D. Béland WG 5	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17000	ECD – December 2004 Current: Canada voted in favour of CD2 with comments on 2002-09-16 – DIS expected by mid 2003

ANNEX 1

Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) Workplan – 2003-2004

Work Description	Responsibility / Working Group (WG) Expert	Liaison with Other Committees	Expected Outcomes	Status
2.2 Revision of ISO/IEC Guide 7:1994 as an International Standard – future **ISO/IEC 17001 - Guidelines for drafting standards suitable for use for conformity assessment**	A. Kempthorne WG 20	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17001	ECD – N/A Current: WG to be disbanded (CASCO Resolution 16/2002) and clause 4.2 of Guide 7 to be considered as a common element under WG 23 activity
2.3 Development of an International Standard for assessment and accreditation on the basis of ISO/IEC Guides 58, 61 and ISO/IEC TR 17010 – future **ISO/IEC 17011 - General requirements for bodies providing assessment and accreditation of conformity assessment bodies**	E. Nilsen WG 18	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17011	ECD – February 2004 Current: Canada voted in favour of Draft International Standard (DIS) on 2002-09-18 – FDIS expected mid 2003
2.4 Development of an International Standard for assessment and registration/certification of QMS or EMS based on ISO/IEC Guides 62 & 66 – future **ISO/IEC 17021 - General requirements for bodies operating assessment and certification of management systems**	S. Janhager WG 21	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17021	ECD – 2005 Current: Voted against CD 17021 with comments on 2003-01-15 – awaiting CD2
2.5 Development of an International Standard for requirements of personnel certification bodies – future **ISO/IEC 17024 - General requirements for**	P. Silberhorn WG 17	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17024	ECD – March 2003 Current: Voted in favour of FDIS – 2003-01-28 –

ANNEX 1

Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) Workplan – 2003-2004

Work Description	Responsibility / Working Group (WG) Expert	Liaison with Other Committees	Expected Outcomes	Status
bodies operating certification of persons				Publication March 2003
2.6 Alignment of **ISO/IEC 17025:1999 - General requirements for the competence of testing and calibration laboratories**, with ISO 9001:2000	N. Gravel WG 25	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Revised ISO/IEC 17025:1999	ECD – June 2004 Current: 3rd WG meeting held on 2002-12-12 – Draft Amendment (DAM) for vote amongst all ISO members by Fall 2003
2.7 Development of an International Standard for the proper use of marks of conformity - future **ISO/IEC 17030 - Third party marks of conformity and their use**	Dr. E. Nielsen WG 12	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17030	ECD – April 2004 Current: Voted in favour of DIS on 2002-10-16 & awaiting publication of FDIS
2.8 Development of an International Standard for peer assessment of conformity assessment bodies - future **ISO/IEC 17040 - General requirements for peer assessment of conformity assessment bodies**	J. Gryn WG 19	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17040	ECD – June 2005 Current: Voted in favour of CD on 2002-01-25 & CD2 vote due on 2003-05-02
2.9 Revision of ISO/IEC Guide 22:1996 as an International Standard for SDoC and development of an International Standard for SDoC supporting documentation, future **ISO/IEC 17050-1 -General requirements for suppliers' declaration of conformity & ISO/IEC**	M. de Grood WG 24	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	New ISO/IEC 17049 & 17050	ECD – August 2004 Current: Voted in favour of CDs on 2002-07-16 – DIS expected by mid 2003

Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) Workplan – 2003-2004

Work Description	Responsibility / Working Group (WG) Expert	Liaison with Other Committees	Expected Outcomes	Status
17050-2 Supporting documentation for suppliers' declaration of conformity				
2.10 Identify common elements in ISO/IEC Standards for conformity assessment bodies and their activities – **Common elements in ISO/IEC Standards for conformity assessment activities**	S. Cross WG 23	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Implementation of the ISO/CASCO policy on common elements in CASCO Standards	ECD – N/A Current: New Work Item Proposals (NPs) on the development of Publicly Available Specifications (PASs) for (1) impartiality and related bodies (2) confidentiality and (3) complaints and appeals due on 2003-07-07

3. Ongoing Activities:

3.1 Review and comment on ISO/CASCO documents (draft international guides and standards) and prepare Canadian responses action items as required	CAC/CASCO Chair & Secretary with input of all CAC/CASCO members	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Canadian positions on ISO/CASCO issues	Ongoing
3.2 Promote CAC/CASCO and ISO/CASCO activities among Canadian stakeholders and audiences via presentations, articles and other media	CAC/CASCO Chair & Secretary with input of all CAC/CASCO members	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Increased awareness of ISO/CASCO & CAC/CASCO activities & issues	Ongoing
3.3 Review ISO/CASCO Plenary documents and prepare Canadian	CAC/CASCO Chair, Secretary	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS	Canadian positions on ISO/CASCO issues; Canadian	Ongoing

Canadian Advisory Committee for ISO/CASCO (CAC/CASCO) Workplan – 2003-2004

Work Description	Responsibility / Working Group (WG) Expert	Liaison with Other Committees	Expected Outcomes	Status
positions in advance of annual Plenary Meetings Lead Canadian delegation to ISO/CASCO Plenary	with input from all CAC/CASCO members	stakeholders as appropriate	participation in ISO/CASCO Plenary	
3.4 Maintain current ISO/CASCO documents and information on the CAC/CASCO SiteScape forum	CAC/CASCO Secretary	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Up-to-date documents and information available on CAC/CASCO SiteScape	Ongoing
3.5 Develop and approve CAC/CASCO Workplans	CAC/CASCO Chair, Secretary with input from all CAC/CASCO members	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Current and accurate CAC/CASCO Workplan	Ongoing
3.6 Liaison activities with CAC/TC 176 (ISO 9000) and CAC/TC 207 (ISO 14000)	CAC/CASCO Chair, Secretary with input from all CAC/CASCO members	ACCA, CNC/ISO, CNC/IEC, other ACs and NSS stakeholders as appropriate	Improved knowledge of activities of mutual interest and effective information exchanges	Ongoing

COMMUNIQUÉ

New ideas and tough issues - CASCO's 18th meeting, 7-8 November 2002

The 18th meeting of the ISO Council policy committee on conformity assessment (ISO/CASCO) that took place on 6-7 November 2002 was significant for three reasons. The first was a return to a policy focus, the second was more outspoken involvement by developing countries members, and third was a change in the administration. During the two-day meeting, which was attended by over 100 delegates from 54 ISO members and liaison bodies, the Committee considered some 55 reports.

Increased policy focus

In terms of increasing its policy focus, the agenda this year was rearranged along the lines of the CASCO Strategies 2002-2004 which are reflective of the ISO strategies, adopted by ISO Council for the same period. The Committee discussed the topics of market relevance, leadership, communication, and optimisation. This was followed by reports from the technical working groups of CASCO preparing or revising international standards and guides covering conformity assessment practice and then the reports of liaison bodies. Having discussed and digested this information CASCO finished the meeting by approving the CASCO Implementation Plan 2003 and associated CASCO Technical Work Program 2003 (both of which can be viewed and downloaded from the ISO website (www.iso.org/casco)).

Highlights related to ***market relevance*** and ***leadership*** included:

- tasking the CASCO Standing Group on Strategic Planning (SGSP) to investigate the possibility of CASCO working with other technical committees and external groups to produce sector specific conformity assessment guidance;
- endorsing the recommendations of the CASCO Ad hoc Group on Regulator's Interface (AHGRI) that will extend the Group's endeavours to involve more directly regulators in the development and subsequent use of the ISO/IEC standards and guides, especially in their mandatory conformity assessment regimes, and the use of regional frameworks to increase this dialogue (examples of regional frameworks being the Asia Pacific Economic Cooperation Sub-Committee on Standards and Conformance (APEC SCSC), and the United Nations Economic Commission for Europe (UNECE);
- consideration of the report of the Joint Working Group on Image and Integrity of Conformity Assessment, prepared by representatives of the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC) and ISO/CASCO. This report has provided specific actions for the three bodies involved to promote good conformity assessment practice worldwide, including ways to deal with the minor number of complaints, and ensure the revision of the ISO brochure on “publicising your ISO 9001 and ISO 14001 certifications”. At the ISO/CASCO meeting an invitation was extended to ISO/TC 176 *Quality management and quality assurance* to be more actively involved. The Committee also noted with interest the recently released communiqué from the JWG on the *Role and objectives of accreditation and certification for laboratories* (see CASCO 95/2002) .

Highlights related to ***communication*** and ***optimisation*** included approval of the CASCO Communication Plan 2003 that will establish a generic set of presentations on CASCO for free public download from the ISO website, and the selection and guidance of appointed CASCO communicators. Reports were also received from the CASCO Advisory Group on Standards and Conformity Assessment (CASCO AGSCA) on its task of reviewing ISO/TC drafts referred to it for compliance with and guidance on the clause in the Directives on conformity assessment (Clause 6.7 of Part 2 of the ISO/IEC Directives (4th Edition) 2001). Work Group 23 reported on their continuing work is establishing a set of common understandings or elements that would feature in all CASCO documents of the future.

Lastly in terms of policy focus, there was a vigorous and lengthy exchange of views on two policy papers, one from the ISO President and the other from the CASCO Chairperson. The result of this discussion was agreement for CASCO to undertake two policy development efforts in 2003. The first would look at the credibility of certification activities and the second at the credibility of suppliers making declarations of conformity. The end product of these work efforts are expected to be reported back to CASCO at its next plenary for endorsement, prior to submitting them to the ISO Council for ISO's general adoption.

Developing countries tell how it really is

It was in discussion of the policy papers of the ISO President and ISO Chairman that developing countries spoke most strongly. The discussion highlighted a number of concerns found in the developing countries about the activities of foreign conformity assessment bodies, including those that have accreditation for their activities from developed country accreditation bodies. The discussion touched upon cross-border accreditation issues; balancing the need for training, consultancy and actual conformity assessment activities in the developing world faced with the reality of a shortage of resources and lack of competent staff; and the desirability expressed by some to allow time for developing countries to build up technical capacity in certification and accreditation activities prior to exposing themselves to wholesale competition by foreign organisations. These issues are fundamental to the future development of internationally recognised conformity assessment structures in developing countries, and will be a topic for discussion in the reinvigorated DEVCO/CASCO working group on conformity assessment strategies.

CASCO heard from the ISO/DEVCO Secretary on the recently completed needs assessment within ISO, and the subsequent ISO Council Developing Countries Task Force. The representative from the WTO highlighted a similar needs assessment recently undertaken by the WTO Committee on Technical Barriers to Trade. CASCO members were encouraged to attend, as part of the their country delegations, a planned workshop on technical capacity building to implement the WTO TBT Agreement, due to be held in March 2003. This has been one of the reasons for scheduling the second of four CASCO meeting weeks for 2003 in the same week, making it easier for developing countries members to attend both activities while in Geneva.

Lastly the representation from the Bureau International des Poids et Measures (BIPM) noted the formation of the Joint Committee on Coordination of Assistance to Developing Countries for Metrology, Accreditation and Standards (JCDCMAS). The CASCO Secretary clarified that this group will seek to coordinate the technical assistance activities of its constituent bodies. These constituent bodies include BIPM, International Organization for Legal

Metrology (OIML), ISO/DEVCO, ISO/CASCO, IAF, ILAC, IEC, International Telecommunications Union (ITU-T), and the United Nations Industrial Development Office (UNIDO). For clarity, it was stressed that while 'conformity assessment' itself did not feature in the title of the Committee, the Committee would indeed focus on the full gambit of conformity assessment activities, including suppliers declaration of conformity and peer assessment activities.

Changing of the guard

Continuing with the developing country connection, this meeting was the last for Mr John Donaldson (formerly ANSI Vice President, Conformity Assessment), who was retiring after 20 years in conformity assessment practice. The new Chairman will be the first from a developing country in the history of CASCO. Mr Mario Wittner, Deputy Director General of IRAM (Argentina), takes up the role of CASCO Chairman from 1 January 2003. The Committee passed resolutions of thanks to Mr Donaldson, adding to the one previously passed by the ISO Council, a framed version of which was presented to him by the ISO Secretary General, Dr Christian Favre.

Praise was also given to the past Secretary, Yasukazu Fukuda who returned to Japan in mid 2002. The new Secretary, Graeme Drake, noted the appointment of Karen Cullilas to the Secretariat, bringing the current staff complement to 4. This team now services the Committee, its 24 sub groups, and manages CASCO's activities with its 16 internal and external liaison bodies. The team also provides policy advice in response to enquiries and undertakes training for developing countries and countries in transition when requested.

Technical work update

On the technical work side progress was demonstrated across all working groups. Highlights included:

- the move from CD2 to DIS stage for ISO/IEC DIS 17000 by WG 5 Definitions;
- the completion of WG 11's work with publication of ISO/IEC Guide 68:2002 on mutual recognition arrangements;
- completion of the DIS ballots by WG 12 on ISO/IEC DIS 17030 Third party marks of conformity and WG 18 on ISO/IEC 17011 on accreditation activities;
- movement to FDIS stage of future standard ISO/IEC 17024 on certification of personnel; and
- movement to DIS stage for the new future standards, ISO/IEC 17050 and ISO/IEC 17049 covering declarations of conformity (which include supplier's declaration of conformity).

A further highlight was the closer relationship between the leadership of ISO/TC 176 and ISO/CASCO. This was welcomed, with CASCO approving a number of steps to ensure active implementation of the Cooperation Framework between the two committees.

Finally in relation to technical work, the Secretary reported on the outcome of two systematic reviews that took place in 2002. These have resulted in the confirmation of ISO/IEC Guide 43:1997 *Proficiency testing by interlaboratory comparisons* (Parts 1 and 2), and ISO/IEC 17020:1998 *General criteria for the operation of various types of bodies performing inspection*. This means these documents will continue unchanged until their next systematic

review due in 2007, or until a new work item proposal is accepted by CASCO to review or change the documents in the interim.

CASCO confirmed the meeting weeks in 2003 would be as follows. All meetings are to be held in Geneva, Switzerland.

- 20-24 January 2003
  Working Group 12 *Marks of conformity*
  Working Group 14 *Product certification*
  Working Group 23 *Common elements*
  Working Group 24 *Declarations of conformity* (previously, Supplier's declaration of conformity)

- 17-21 March 2003
  Chairman's Advisory Group (CAG)
  IAF-ILAC-ISO/CASCO Joint Working Group on Image and Integrity
  Standing Group on Strategic Planning (SGSP)
  Working Group 22 *Principles of conformity assessment*
  Working Group 21 *Management systems*

- 9-13 June 2003
  Working Group 19 *Peer assessment*
  More working group meetings to be confirmed

- 3-7 November 2003
  Adhoc Group on Guide 53
  CASCO Plenary (6-7 November 2003)
  Chairman's Advisory Group (CAG)
  Working Group 5 *Definitions*
  Working Group 14 *Product certification*

ANNEX 2

Final
Quality Management Systems Accreditation Program

ISO 13485:2003 Transition requirements

Background

- Following accreditation by the SCC and recognition in the appropriate IAF scope or sector scheme, Registration bodies will be able to conduct registration activities to internationally recognized quality systems standards, including ISO 13485/88.

- ISO 13485/88 has recently been revised to be similar in structure and content to ISO 9001:2000. The new ISO 13485-2003 contains all of the medical device specific requirements found in ISO 13485-1996 and most of the generic quality management specific requirements found in 90001-2000.

- ISO/TC 210 has publicized transition planning guidance for ISO 13485:2003 which is available at the following URL: (http://www.aami.org/Applications/CommitteeCentral-app/Documents/210n218.pdf)

- SCC transition requirements for Registration Bodies have been developed to support the ISO 13485/88-1996 to ISO 13485:2003 transition period established by ISO/TC 210 and as outlined in clause 4.2 of the transition planning guidance which states:

  > "During the transition (co-existence) period, ISO 13485:2003 will co-exist with ISO 13485:1996, ISO 13485:1996, ISO 9001:1994 and ISO 9002:1994…. ISO TC 210 recommends that users have three years in which to adapt their quality management systems to meet the requirements of ISO 13485:2003."

- ISO transition guidance has been accepted by the SCC and is applicable to those applicants and accredited Registration bodies who issue ISO 13485/88 registration certificates (both inside and outside of the CMDCAS program).

- SCC transition requirements have been developed to support the 3 year transition period.

- Transition requirements are applicable to Registration Bodies who issue 13485/88 registration certificates including those applicant and qualified bodies under the CMDCAS program.

- Transition plans are not required for Registration Bodies who do not provide registration to ISO 13485/88 under SCC accreditation.

Overview:

- At the end of the 3 year transition period, registration certificates shall no longer be issued to ISO 13485/88:1996 under SCC accreditation.

- Registration certificates to ISO 13485:2003 shall not be issued until transition plans, and their implementation have been reviewed and found satisfactory.

- Oversight during the 3 year transition period will address three main areas: Documentation, Implementation and Client relations. Oversight will be conducted over the 3 year transition period and consist of the following activities:

    - Initial Document review of transition plans;
    - Verification of implementation of transition plans (on-site or off-site);
    - ISO 13485:2003 witness audit;
    - Annual review of implementation of transition plans over the 3 year transition period.

- Registration bodies issuing ISO 13485 certificates outside the CMDCAS program, shall complete their transition activities by the end of the 3 year transition period.

- Specific timelines for the ISO 13485 transition under the CMDCAS program have been established by Health Canada.

- For those RB's issuing ISO 13485/88 certificates under CMDCAS, the required witness audit activity shall be an ISO 13485:2003 registration under the CMDCAS program. Transition witness audits are required to be complete by the end of the second year of the transition period.

- Transition requirements, including the required ISO 13485:2003 witness audit, are applicable to applicants within the CMDCAS program. If the applicant is issuing certificates to ISO 13485/88:1996 under the CMDCAS program during the transition period, an ISO 13485:1996 witness audit for initial CMDCAS sector qualification is also required.

- Witness audits to satisfy the SCC transition requirement will replace the annual maintenance witness audits required under CMDCAS.

- When the applicant or accredited Registration Body is operating under the CMDCAS program, Health Canada representatives shall participate in transition oversight.

- The SCC will annually review the number of ISO 13485:2003 registration certificates issued by RBs. Transition requirements may be modified based on the status of the transition.

Transition requirements	Explanatory Information
Stage 1 **Document Review** **1.1 Transition Plans** Registration Bodies are required to provide ISO 13485:2003 transition plans for review by the SCC. Registration certificates to ISO 13485:2003 may not be issued until the SCC has found transition plans satisfactory. Transition plans should address procedures and documentation, assessment personnel competency and client relations for the 3 year transition period. Transition plans should also include timelines for implementation. 1.1.1 For those Registration Bodies participating in the CMDCAS program, the review of transition plans must be complete within the first year of the 3 year transition period. The deadline for submitting the plan to SCC is 3 months before the end of year one. The transition plan shall include a process to ensure that all ISO 13485/88:1996 certificates under the CMDCAS program have been converted to ISO 13485-2003 certificates at least 4 months before the end of year three.	To avoid duplication of activities, when developing transition plans, Registration bodies should consider activities already undertaken to satisfy the ISO 9001:2000 transition (e.g. Plans based on the identification of the differences between 9001:2003 and 13485:2003, Process audit training, and procedures for upgrades). Transition plans should provide an overview of activities and timelines to address the following: **1. Documentation** ▪ Identification of procedures / documentation that require revision to address ISO 13485:2003 ▪ Development of procedures to address upgrade audits (ISO 13485/88 1996 to ISO 13485:2003) **2. Assessment Personnel Competency** ▪ Identification of training needs and plans for assessment personnel and those involved in decision making process ▪ If the Registration body has already demonstrated competency to audit to ISO 9001:2000, plans should indicate how this experience and knowledge is applicable to ISO 13485:2003. ▪ Identification of plans to evaluate and monitor auditor competency for ISO 13485:2003 **3. Client relations** ▪ Identification of clients currently registered to ISO 13485/88:1996 ▪ Identification of Communications plans which address the following: o Registered clients notified of the new standard

	o RB ISO 13485:2003 transition plans relayed to clients o Existing contracts reviewed and updated with clients as applicable o ISO 13485:2003 audit activity date is confirmed with the client o Ongoing communication activities over transition period Note: In the case of CMDCAS, Health Canada will provide further guidance on acceptance of ISO 13485:2003 certificates and the deadline for submitting 2003 certificates to HC which the RB should be communicating to affected clients once available.
1.2 Implementation of transition plans will be reviewed and found satisfactory by the SCC before proceeding with the witness audit. 1.2.1 For those Registration Bodies participating in the CMDCAS program, the review of implementation of transition plans must be completed within the first year of the 3 year transition period.	Registration bodies will be provided two options for oversight of the SCC review of implementation of transition plans. **Option 1: On site review** Transition plans reviewed as part of the annual on-site audit activity. Non-conformities may be issued and require resolution. For those registration bodies wishing to have the ISO 13485:2003 transition plans reviewed on-site and as part of accreditation related audit activities, transition plans should be submitted as part of the documentation requested prior to annual audit activity. The TG-QMSRO auditor will review the plans prior to the on-site activity, and verify implementation (eg. completion of auditor training, updating of procedures) as part of the annual on-site audit activity. Results of this review and indication of effectiveness will be provided by the TG-QMSRO auditor within the on-site audit report. **Option 2 Off-site review** Transition plans and their implementation reviewed as an independant activity. Non-conformities may be issued and will require resolution. For those registration bodies who wish to begin issuing ISO 13485 certificates as soon as

	possible, transition plans can be reviewed and approved outside of the regular oversight process and upon the request of the registration body. For this option, Registration bodies are required to submit the transition plans, **and** evidence of implementation (eg. Training records, updated procedures) to the SCC for document review. The information will be reviewed independently of the annual audit activity process and a report on the review will be issued.
Stage 2 **Witness audit activity** 2.1 A minimum of one ISO 13485:2003 registration / upgrade audit shall be witnessed to support the transition process. 2.1.1 For those registration bodies qualified under the CMDCAS program, the audit witnessed shall be applicable to the CMDCAS program and conducted before the end of year two of the transition period.	The witness audit activity shall be conducted once the transition plans have been reviewed and accepted by the SCC. The witness audit activity will be conducted once procedures to support ISO 13485:2003 registration activities have been implemented and reviewed. ISO 13485:2003 witness audits shall be coordinated with the Program Officer QMS/EMS. For witness audits under the CMDCAS program, criteria for the selection of CMDCAS witness audits are applicable.
Stage 3 **On-going Client relations** 3.1 Communications activities as identified in the ISO 13485:2003 transition plans developed by the Registration Body should be implemented over the transition period. 3.2 Registration bodies are required to notify clients currently registered to ISO 13485/88:1996 of the publication of ISO 13485:2003 and transition plans within 6 months of publication of the revised standard. 3.3 Plans for upgrading / transitioning of the manufacturer / suppliers registration shall be determined in the transition plans. This includes identification of the date for the ISO 13485:2003 transition/upgrade audit.	The SCC will review RB communications activities including notification to clients of publication of the revised standard and scheduling of transition audits as part of the review of implementation of transition plans during the document review (Stage 1). The transition / upgrade audit activity should be integrated into audit activities to support continuation of registration. No additional audits should be added unless a rationale is documented.

3.4 Client relations to ensure manufacturers/suppliers registered to ISO 13485/88:1996 are transitioned to ISO 13485:2003 before May 2006 will be verified annually during the 3 year transition period.	The implementation of communications activities and status of client relations, including conductance of planned ISO 13485:2003 upgrade/transition audits will be verified annually during the 3 year transition period.
Stage 4 **Transition oversight** 4.1 The implementation and effectiveness of transition plans will be verified annually during the 3 year transition period. 4.2 Registration bodies shall keep current a list of those suppliers/manufacturers registered to ISO 13485/88:1996 and ISO 13485:2003, including an indication of those clients registered under the CMDCAS program. The number of suppliers/manufacturers who have upgraded/transitioned to ISO 13485:2003 and number of remaining ISO 13485/88:1996 registrations to be transitioned shall be provided to the SCC annually.	Implementation and effectiveness of transition plans will be addressed during annual audit activity. This information should be provided to the SCC as part of the documentation requested prior to the annual on-site audit activity during the 3 year transition period.