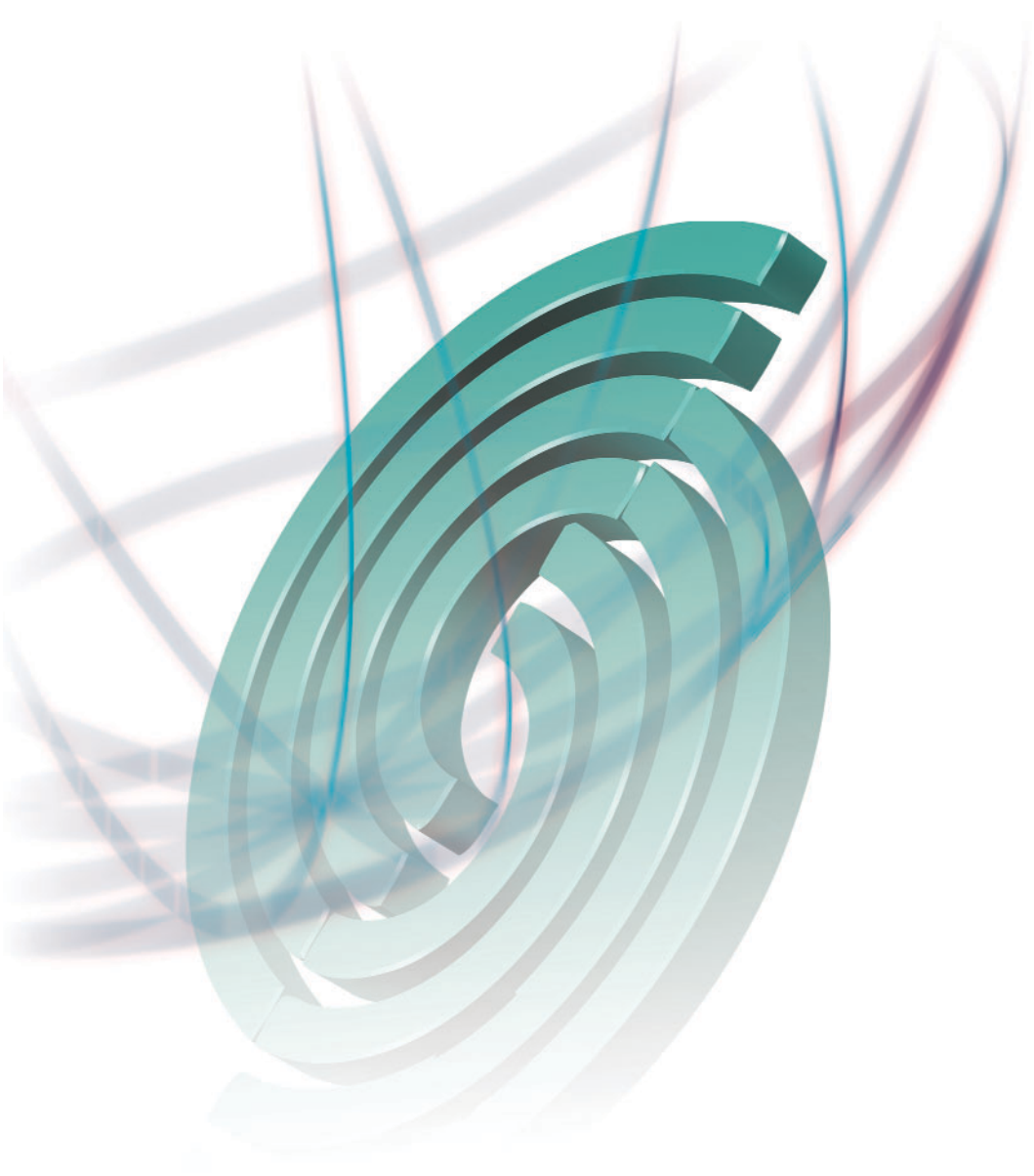

Standards Council of Canada
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CMDCAS Handbook
Policies and Procedures for Sector Qualification under the Canadian Medical Devices Conformity Assessment System (CMDCAS)

June 2003
Standards Council of Canada Quality Management Systems Accreditation Program (QMSAP)

national standards system

Canada

CMDCAS HANDBOOK

POLICIES AND PROCEDURES FOR SECTOR QUALIFICATION UNDER THE CANADIAN MEDICAL DEVICES CONFORMITY ASSESSMENT SYSTEM (CMDCAS)

Standards Council of Canada Quality Management Systems Accreditation Program (QMSAP)

June 2003

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FOREWORD

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

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

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

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

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

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

This document is one of several issued by the Standards Council of Canada to define the policies, plans and procedures established by the SCC to help achieve its mandate. As the subject of this document relates to a sector qualification program with requirements established by a regulatory body, the regulatory body has endorsed the policies and procedures defined by this document.

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

POLICIES AND PROCEDURES FOR SECTOR QUALIFICATION UNDER THE CANADIAN MEDICAL DEVICES CONFORMITY ASSESSMENT SYSTEM (CMDCAS)

1. GENERAL

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

The Standards Council of Canada (SCC) accredits bodies to register quality systems. In addition, SCC formally qualifies the expertise of a Registration Body to perform ISO 13485/88:1996 and ISO 13485:2003 quality system registrations under the *Canadian Medical Devices Conformity Assessment System* (CMDCAS) sector qualification program. A Registration Body's CMDCAS sector qualification is achieved through an SCC assessment of conformance to the requirements of the Canadian National Standard System procedural documents CAN-P-10 (ISO/IEC Guide 62), CAN-P-1517, the IAF Guidance on the application of ISO/IEC Guide 62 (as amended from time to time) and the specific CMDCAS requirements defined by the Therapeutic Products Directorate (TPD), Health Canada. These requirements include Q 90RO Policy on CMDCAS and associated Guidance.

CMDCAS sector qualification criteria layers on top of the criteria for accreditation of Quality Systems Registration/Certification Bodies (CAN-P-10), Procedures and Requirements for the accreditation of Registration/Bodies (CAN-P-1517) and the IAF Guidance on the application of ISO/IEC Guide 62. As such, Registration Bodies should incorporate the Q90R0 requirements and accompanying guide documents into their existing registration procedures and audit activities.

CMDCAS is a national regulatory based sector qualification program. As such, it falls outside of the International Accreditation Forum (IAF) purview and therefore, the IAF MLA is not applicable to sector qualification activities. Acceptance of other medical device regulatory programs to satisfy the Medical Device Regulation (MDR), like the EU notified body program, is the responsibility of Health Canada through government to government agreements.

The role of the SCC within the CMDCAS program is established by a SCC-Health Canada Memorandum of Understanding (MOU). The MOU was signed in 1999 and also describes the terms, conditions and implementation of the CMDCAS program.

The MOU defines the role and responsibilities of the SCC QMSAP as such:

- SCC shall accredit Registrars to perform Quality Systems registrations that meet the requirements of CMDCAS;
- SCC shall develop the accreditation requirements, and procedures that comprise CMDCAS;

- SCC shall conform to the requirements of CMDCAS;
- SCC shall include TPD recommendations in its CMDCAS accreditation process.

Under the MOU, the Health Canada, TPD is responsible for administering and enforcing the MDR including compliance by manufacturers with the appropriate provisions of the MDR. The MOU also defines the role and responsibilities of Health Canada to include:

- TPD shall develop the regulatory requirements and criteria that comprise CMDCAS and keep copies of all CMDCAS controlled documents;
- TPD shall conform to the requirements of CMDCAS;
- TPD may, at its discretion, participate in the SCC accreditation process via assessment, reassessment or surveillance audits of Registration Bodies.
- TPD shall provide recommendations on the qualification of a CMDCAS Registration Body;
- TPD shall recognize in its medical device licensing process the registration of a manufacturers quality system by a Registration Body accredited by the SCC and qualified under CMDCAS, unless TPD considers that public health and safety may be compromised;
- TPD shall provide training to SCC and its assessors, on the requirements found in the Policy on CMDCAS and the MDR.

CMDCAS requirements are developed by Health Canada. Each registration body, applicant or qualified, under the CMDCAS program, will be assigned one Health Canada representative by the Section Head, Quality Systems, TPD. Health Canada representatives work with SCC staff and auditors, and participate in all stages of the CMDCAS sector qualification process. This also includes activities related to maintenance of the CMDCAS sector qualification. The Health Canada representative reserves the right to attend each CMDCAS related audit activity, and may attend accreditation related audit activities. In addition, the Health Canada representative must provide sign-off for each stage of the sector qualification process for CMDCAS.

The Health Canada Section Head, Quality Systems provides the final recognition for each applicant. This recognition is in the form of a vote during the SCC sector qualification approval process.

SCC accredited CMDCAS qualified Registration Bodies will be considered by TPD as meeting the requirements of section 32(1) of Schedule 1293 of the amended Canadian *Medical Devices Regulations* (MDR).

It should be noted that manufacturers registered to ISO 13485/88:1996 or ISO 13485:2003 to satisfy the Canadian Medical Device Regulations are not “registered to CMDCAS” but registered to ISO 13485/88:1996 or ISO 13485:2003 under the CMDCAS Program.

Registration bodies should note that the ISO 13485:2003 has been published. Applicant and qualified Registration Bodies are required to follow transition requirements established by the SCC and Health Canada during the 3 year transition period.

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

2. DEFINITIONS

The relevant definitions from current versions of CAN-P-10 (ISO/IEC Guide 62), CAN-P-1517, ISO 13485/88:1996, ISO 13485:2003, ISO 19011:2002, the IAF Guidance on the Application of ISO/IEC Guide 62, Q90R0 Policy on CMDCAS and accompanying Guidance documents are applicable.

3. CMDCAS SECTOR QUALIFICATION PROCESS

3.1 Registration Bodies seeking CMDCAS Sector Qualification must be accredited to register quality system standards (or in the application process for initial accreditation) by the Standards Council of Canada. Applications should be submitted using the CMDCAS sector application form.

3.2 The application form should be complete and include all attachments, and be accompanied by the sector application fee as outlined in the SCC Management Systems Program Fee Structure. The application form and supporting documents are required to be submitted in either official languages of Canada (French or English).

3.3 CMDCAS sector qualification can be processed with initial accreditation, but the document review stage for initial accreditation must be complete before the CMDCAS sector qualification application is submitted by the Registration Body and accepted by the SCC.

3.4 Corrective Action from each stage of the sector qualification process must be accepted by the audit team, including the Health Canada representative, and closed before the next stage of the sector qualification process can be addressed.

3.5 Initial qualification for the CMDCAS sector consists of 4 main activities:

3.5.1 Document review (Section 6);
3.5.2 On-site assessment (incorporating CMDCAS) (Section 7);
3.5.3 Witness audit activity (Section 8);
3.5.4 Approval (Section 9).

4. MAINTENANCE OF CMDCAS SECTOR QUALIFICATION

4.1 As part of the accreditation oversight process, CMDCAS requirements will be incorporated into annual on-site assessment activity for maintenance of accreditation. CMDCAS will also be reviewed as part of re-accreditation audit activities. For

Maintenance of CMDCAS sector qualification, procedures for the CMDCAS on-site assessment process as outlined in Section 7 of this document are applicable.

4.2 A minimum of one witness audit activity is required annually for maintenance of CMDCAS sector qualification. Witness audit procedures to maintain CMDCAS sector Qualification are consistent with those defined in this document under Section 8 Witness audit.

4.3 Additional CMDCAS audit activity may be requested at any time by the SCC or Health Canada representative. Requests for additional CMDCAS audit activity will be accompanied by written rationale.

4.4 Registration bodies recognized by Health Canada under the CMDCAS program are required to maintain and make available upon request a list of ISO 13485/88 registrations issued under the CMDCAS program. This list shall contain the name of the manufacturer, coordinates, scope of the registration.

4.5 CMDCAS sector qualification can be suspended / withdrawn by the SCC and/or Health Canada at any time. Procedures for SCC Suspension/Withdrawal under the CMDCAS program are defined under Section 10 of this document.

5. LIMITATIONS FOR CMDCAS SECTOR QUALIFICATION APPLICANTS

5.1 In some cases, application packages are submitted incomplete. If some items from the application package for CMDCAS Sector Qualification are missing, the Program Officer will correspond with the applicant until a complete application is received. If more than 2 further submissions are required to complete the application, the Registration Body will be required to resubmit a new application in full.

5.2 If the new application is still not complete, the application will be rejected by the SCC and no refund of the application fee will be provided. The applicant will be required to re-apply for CMDCAS sector qualification and pay a further sector application fee.

5.3 Except under unusual circumstances, the Registration Body is required to complete the CMDCAS sector qualification process within 1 year of applying. This includes those applicants undergoing initial accreditation at the same time.

5.4 For those applicants who have not completed all stages of the sector qualification process within one year, the SCC will provide 30 days notice of the rejection of the CMDCAS application. If registration body activities related to the CMDCAS sector qualification process are not complete within the 30 days, the application will be withdrawn by the SCC and the registration body will be required to reapply for CMDCAS sector qualification and incur a further application fee.

5.5 A request for an extension may be made by the applicant registration body to the Senior Program Officer and Section Head, Quality Systems at least 30 days before the

application period has expired. The request for extension must be accompanied by a rationale. A response to the request will be made to the applicant in writing.

6. CMDCAS SECTOR QUALIFICATION - DOCUMENT REVIEW

6.1 When the Registration Body has submitted a complete application for CMDCAS sector qualification, a TG-QMSRO auditor and Health Canada representative are assigned to the sector qualification activity. The application is reviewed for responsiveness to the items identified in the application form and the Q90R0 Policy on CMDCAS.

6.2 A CMDCAS sector qualification document review report is prepared by the audit team. As a member of the audit team, concurrence on the document review results is provided by the Health Canada representative and the document review report is issued by the SCC for response by the Registration Body.

6.3 When the Registration Body has responded and information requests/non-conformities resolved to the satisfaction of the audit team, the on-site assessment portion of the sector qualification process is scheduled.

7. CMDCAS SECTOR QUALIFICATION - ON-SITE ASSESSMENT

7.1 If the applicant is also in process of initial accreditation, the CMDCAS on-site assessment portion of the sector qualification activity will be conducted with the on-site assessment for initial accreditation. CMDCAS requirements will be incorporated into the audit plan.

7.2 For those bodies qualified under the CMDCAS program, CMDCAS will be addressed at the next due accreditation related on-site assessment activity. The on-site assessment activity will be scheduled by the Program Officer.

7.3 Once the on-site assessment date has been confirmed by the SCC with the registration body, the SCC auditor will plan and conduct the on-site assessment. A Health Canada representative may or may not attend the activity. In both cases, the Health Canada representative reviews all documentation and provides a sign-off for the activity.

7.4 CMDCAS elements will be incorporated into the audit plan for review during the on-site assessment for accreditation / re-accreditation / continued accreditation.

7.5 The on-site assessment report will include a section for CMDCAS and corrective action requests related to CMDCAS elements will be cited as applicable.

7.6 When the on-site assessment is complete, a report is prepared and non-conformities identified for response by the registration body. Typically, two (2) weeks are provided for the registration body response.

7.7 For those registration bodies in process of initial CMDCAS sector qualification, the CMDCAS witness audit will be scheduled once the on-site assessment non-conformities have been resolved to the satisfaction of the SCC auditor and Health Canada representative.

8. CMDCAS SECTOR QUALIFICATION - WITNESS AUDIT

8.1 The SCC staff and Health Canada representative select the witness audit activity for initial CMDCAS sector qualification or maintenance of CMDCAS sector qualification from a list provided by the registration body.

8.2 Witness audits will only be performed of an ISO 13485 registration audit under the CMDCAS program, of a Class 2, 3 or 4 medical device manufacturer who sells the product in Canada as defined by the Medical Device Regulations.

8.3 If no registration audit is available, surveillance audit that includes, as a minimum, the following ISO 13485 elements: 4.1, 4.2, 4.4, 4.6, 4.9, 4.11, 4.14, 4.16, 4.17 will be considered.

8.4 The list of ISO 13485 audit activities should include all applicable audits scheduled for the next six (6) months. The list must include the following information for each listed audit activity:

8.4.1 Scope of the audit;
8.4.2 Name and address of the medical device manufacturer;
8.4.3 Medical Device License(s) number and brief description of the medical device being manufactured;
8.4.4 Location of the audit;
8.4.5 Name of the assigned registration body auditor(s).

8.5 Once the Witness audit has been selected and dates confirmed, the Program Officer will provide the Registration Body with a witness audit organizational profile (SCC Form 93.4.1) for completion and return to the SCC at least 3 weeks before the witness audit. A notice of the roles of the SCC and Health Canada during the audit activity will also be provided to the registration body.

8.6 The scope of the witness audit is limited to the collection of objective evidence to support the registration body's application and CMDCAS related procedures. Witness audits will be conducted in accordance with the SCC Guidelines for witness audits (Guidance Document 93.4.1). A Health Canada representative may or may not attend the activity. In both cases, the Health Canada representative provides a sign-off for the activity and reviews all documentation.

8.7 The witness audit activity is not complete until the registration report is forwarded to the SCC by the registration body, within 1 week subsequent to date of the closing meeting of the witness audit.

8.8 When the witness audit activity is complete, the SCC audit team will prepare a witness audit report, and any non-conformities will be sent for resolution to the registration body.

8.9 Once the non-conformities have been resolved to the satisfaction of the SCC auditor and Health Canada representative, a recommendation for sector qualification or further audit activities will be put forward by the audit team (in the case of initial qualification).

9. CMDCAS SECTOR QUALIFICATION - APPROVAL

9.1 When a recommendation for CMDCAS sector qualification has been put forward by the audit team and Health Canada representative, a report on the CMDCAS sector qualification process and finding is prepared by the SCC and sent to the TG-QMSRO members and Health Canada Section Head, Quality Systems, TPD for ballot.

9.2 Once the ballot has been approved at the Task Group and Health Canada level, the Senior Program Officer and Manager, Conformity Assessment reviews the sector qualification process and findings, and a recommendation for CMDCAS sector qualification is then sent to the SCC Director, Conformity Assessment for final approval.

9.3 Upon approval, a notice of qualification, updated scope listing and certificate of qualification is forwarded to the registration body by the SCC.

10. CMDCAS SECTOR QUALIFICATION - SUSPENSION / WITHDRAWAL

10.1 CMDCAS sector qualification can be suspended or withdrawn by the SCC.

Note: Suspension and withdrawal of CMDCAS recognition by Health Canada is addressed in a separate document issued by Health Canada.

10.2 CMDCAS sector qualification will be suspended when objective evidence is found that the Registration Body is no longer meeting the requirements for sector qualification and non-conformities are not addressed within a defined timeframe.

10.3 CMDCAS sector qualification may also be suspended when objective evidence is found of a breakdown in the Registration Body's management system for CMDCAS.

10.3.1 A Registration Body's CMDCAS sector qualification may be withdrawn when it is found that the health and safety of the Canadian public may be compromised as a result of Registration Body activities. Withdrawal of sector qualification may also occur if it is found that the Registration Body has not adequately responded to identified issues following suspension of sector qualification.

10.4 Procedures for suspension, withdrawal and appeal procedures are detailed in CAN-P-15. Registration Bodies will be provided thirty (30) days to resolve SCC concerns and non-conformities.

11. CMDCAS REQUIREMENTS AND INTERPRETATIONS

11.1 CMDCAS requirements and guidance are established by Health Canada. This includes timelines for implementation. Once available publicly and unless otherwise indicated, new or revised CMDCAS requirements shall be implemented by the Registration Body as per the deadline provided by Health Canada for that specific requirement.

11.2 Timelines provided by Health Canada for the implementation of a CMDCAS requirement will vary depending on the type, regulatory impact of the requirements, and availability of previous drafts in the case of a guidance document. Implementation period may vary from upon publication up to several months after the coming into force of the requirement.

11.3 From time to time, interpretations may be issued by the SCC or Health Canada. Interpretations are auditable points and will be incorporated into audit activity by the TG-QMSRO auditor or Health Canada representative as applicable.

11.4 A current list of CMDCAS interpretations (I 93.3) is maintained by the SCC. Registration Bodies will be notified of any CMDCAS interpretations in the RB Bulletin and on the CMDCAS RB Electronic Forum.

11.5 Registration Bodies are responsible for incorporating CMDCAS requirements, which include interpretations, drafts and final guidance documents, into their CMDCAS procedures to maintain CMDCAS qualification.

12. HEALTH CANADA CMDCAS REGISTRATION BODY FORUM

12.1 As part of the CMDCAS program, Health Canada has established the CMDCAS Registration Body Forum. This forum is operated electronically and accessed through the CMDCAS area of the SCC website at the following URL: http://www.scc.ca/cmdcas/index_e.html. From time to time, in person meetings may also be held of the HC CMDCAS RB Forum membership.

12.2 The electronic HC CMDCAS RB Forum serves as the official central repository for CMDCAS related documents, interpretations, information, meeting minutes, presentations, notices, etc. The CMDCAS RB Forum is password protected. All new program information including notification of new or revised requirements and guidelines will be performed using the CMDCAS RB Forum.

12.3 Registration bodies are required to have at least one person who will be a member of this electronic forum, and who will be responsible for ensuring relevant information is available to registration body assessment personnel who work under CMDCAS. This individual should be a senior level staff person with expertise and authority for the Registration body CMDCAS program.

12.4 In person meetings of the CMDCAS RB Forum membership will be called by Health Canada. At these meetings, updates on the status of the CMDCAS program, interpretations, Health Canada expectations, regulations and consultation on new and existing requirements will be discussed. The Registration Body representative at these face to face meetings should be the same individual who is designated as the Registration body representative for the electronic forum. Only one representative from each registration body may attend the in person meetings of the HC CMDCAS RB Forum.

12.5 All Applicant and qualified Registration Bodies are required to participate in the Health Canada CMDCAS Registration Body Forum.

13. LISTING OF APPLICANT AND QUALIFIED CMDCAS REGISTRATION BODIES

13.1 The SCC maintains a listing of CMDCAS qualified and applicant registration bodies on the SCC website at the following URL: http://www.scc.ca/cmdcas/index_e.html.

13.2 This list is updated when Registration Bodies are qualified, suspended or withdrawn.