Health Canada Santé Canada

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00-017095

To: Medical Device Manufacturers, Importers and other interested parties

Subject: Policy on the Canadian Medical Devices Conformity Assessment System (CMDCAS) - Quality Systems

The attached Policy document addresses the quality system requirements found in Section 32 of the ***Medical Devices Regulations***. It describes the requirements and process that Therapeutic Products Programme (TPP) will use to recognize a Registrar as being competent to perform a conformity assessment of a medical device manufacturer's ISO 13485 or ISO 13488 quality system. The Policy becomes effective on the date of publication on TPP's website: www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php.

In December 1999, TPP issued the draft policy document ***Q19R16 :Policy on CMDCAS*** for public comment. Following a 30 day comment period, TPP received many responses which were subsequently used to prepare this final version of the CMDCAS Policy. The most significant change that TPP has made to the Policy is the removal of the Canadian incorporation requirement for Registrars. This revision means that TPP will now recognize ISO 13485 or ISO 13488 certificates issued by foreign based Registrars as long as they have been accredited by the Standards Council of Canada to the CMDCAS scope.

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TPP is preparing guidance documents on the CMDCAS registrar accreditation and manufacturers' quality systems registration processes that will be issued over the next several months.

For further information on this Policy document please contact : Beth Pieterson, A/Director, Medical Devices Bureau, Room 1605, Main Statistics Canada Building, Tunney's Pasture, A.L. 0301H1, Ottawa, Ontario, K1A 0L2.

Original signed by

Dann M. Michols
Director General

Attachment

Health Canada Santé Canada

PROGRAMME DES PRODUITS THÉRAPEUTIQUES THERAPEUTIC PRODUCTS PROGRAMME

Therapeutic Products Programme

OUR MISSION: To ensure that the drugs, medical devices, and other therapeutic products available in Canada are safe, effective and of high quality.

Programme des produits thérapeutiques

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

Therapeutic Products Programme

Policy on CMDCAS

Canadian Medical Devices Conformity Assessment System (CMDCAS)

to address the Medical Devices Regulations' Quality Systems Requirements

Q90R0e : 2000-04-19

Canada

NOTE TO THE READER

This Canadian Medical Devices Assessment System (CMDCAS) document sets out the Therapeutic Products Programme's policy on the roles and responsibilities of the Therapeutic Products Programme (TPP), Standards Council of Canada (SCC) and Registrars in the accreditation and registration processes leading to the registration of a medical device manufacturer's quality system.

TPP's interpretation of the requirements found in this document is provided in CMDCAS guidance documents and procedures. Application of CMDCAS by TPP, SCC and Registrars shall be done in conjunction with the guidance and procedures given in these documents.

Q90R0 : 2000-04-19

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1. Purpose

The purpose of this policy is to state the requirements that the Therapeutic Products Programme (TPP) will require to be met in the accreditation and registration processes leading to the registration of a medical device manufacturer's quality system (QS).

Under Section 32(2)(f) of the *Medical Devices Regulations*, manufacturers of Class II medical devices must attest that the quality system under which their devices are manufactured satisfies the quality system requirement ISO/IEC 13488.

Under Sections 32(3)(j) and 32(4)(p) of the *Medical Devices Regulations*, manufacturers of Class III and IV medical devices must attest that the quality system under which their devices are designed and manufactured, satisfies the quality system requirement ISO 13485.

2. Scope

This policy applies to the quality systems licensing provisions for Class II, III and IV medical devices as described in the *Medical Devices Regulations* of 1998.

3. Foreword

This document sets forth, in three sections, the Therapeutic Products Programme's (TPP) approach to the accreditation of medical device QS Registrars and to the registration of a medical device manufacturer's quality system.

Section 5.2 specifies the responsibilities of the TPP in the management of CMDCAS.

Sections 5.3 and 5.4 state the responsibilities and operational requirements of the accreditation body for Registrars (Standards Council of Canada (SCC)) and Registrars. These requirements include those found in ISO/IEC Guide 61, CAN-P-10B, CAN-P-1517, ISO 10011, Global Harmonization Task Force (GHTF) documents, plus additional TPP requirements contained in this document.

4. Background

To sell a medical device in Canada, manufacturers must meet the regulatory requirements as defined in the *Medical Devices Regulations*. Manufacturers of Class II, III, and IV medical devices must obtain a licence before selling them in Canada. After July 1, 2001, one element of the licensing process will involve manufacturers of Class II devices attesting that the quality system under which their devices are manufactured satisfy the quality system requirement: ISO 13488 and, manufacturers of Class III and IV devices attesting that the quality system under which their devices are designed and manufactured satisfy the quality system requirement: ISO 13485. To verify that these manufacturing processes meet the required standard, TPP will require manufacturers to have their QS registered by a Registrar accredited to the CMDCAS scope.

During the development of the new regulations it was decided that the TPP would not conduct these audits itself, but rather a third-party Registrar programme would be developed. While such a third-party approach has been developed, it is important to note that the TPP will retain an oversight role over the accreditation and registration processes as described in this Policy document. TPP has selected SCC to be the accreditation body for Registrars.

This CMDCAS document outlines TPP's policy on the processes leading to SCC's accreditation of CMDCAS third party Registrars, and the registration of a medical device manufacturers's QS by these accredited Registrars. A TPP-SCC CMDCAS Management Committee is responsible for managing CMDCAS accreditation related issues.

CMDCAS uses the general requirements found in Canada's National Standard System for third-party voluntary accreditation and registration, and supplements them with additional requirements. The general requirements are based on current international standards (or their Canadian equivalent), and are supplemented with additional requirements to fulfill TPP's oversight role.

CMDCAS can be divided into the following three levels of responsibility:

Level 1 TPP

As the national regulatory agency, TPP is responsible for ensuring that devices sold in Canada are safe, effective and of high quality. TPP oversees the third-party QS conformity assessment scheme by:

- developing and maintaining the CMDCAS requirements;
- selecting an accreditation body competent to carry out the accreditation of Registrars as articulated in the specific requirements of CMDCAS;
- participating, at its discretion, in the SCC accreditation process, and providing TPP's recommendation on SCC accreditation of a Registrar to CMDCAS;
- observing, at its discretion, a Registrar's registration process of medical device QS in place at a manufacturer;
- providing training to SCC and Registrars on the Medical Devices Regulations and CMDCAS.

Level 2 SCC

As the TPP selected accreditation body, the Standards Council of Canada (SCC) is responsible for accrediting Registrars to be competent to carry out the registration of a quality system as articulated in the specific requirements of CMDCAS. SCC's accreditation of a Registrar to CMDCAS will lead to the recognition by TPP of the competency of that Registrar and of the QS certificates that it issues. If TPP determines that an SCC accredited Registrar is not complying with the requirements of CMDCAS or if public health and safety is being compromised, TPP will not recognize that Registrar and will recommend that SCC to take corrective actions, suspend or withdraw the Registrar's accreditation.

Level 3 Registrars

Registrars who audit medical device manufacturers within the scope of CMDCAS are responsible for assessing the conformity of a medical device manufacturer's QS to the standards ISO 13485 or ISO 13488.

4.1 Description of standards and guidelines used by CMDCAS

The following table lists national and international standards and guides currently used by TPP, SCC and Registrars in the *Canadian Medical Devices Conformity Assessment System* for QS accreditation, registration, and auditing activities.

International Standard or Guide	Canadian Equivalent in National Standard System
ISO/IEC Guide 61: General requirements for assessment and accreditation of certification/registration bodies	No Canadian equivalent. International document used in CMDCAS
IAF Guidance on the Application of ISO/IEC Guide 61: Issue 1, 22 January 1998	No Canadian equivalent. International document used in CMDCAS
ISO/IEC Guide 62 : General requirements for bodies operating assessment and certification/registration of quality systems	CAN-P-10B : Criteria for Accreditation of Organizations Registering Quality Systems
No International equivalent	CAN-P-1517 : Conditions and Procedures for Accreditation of Organizations Registering Quality Systems
IAF Guidance on the Application of ISO/IEC Guide 62 - Issue 1, 2 June 1997	No Canadian equivalent. International document used in CMDCAS
ISO 13485:1996 Quality systems - Medical Devices - Particular requirements for the application of ISO 9001	CAN/CSA-ISO 13485:1998 Quality systems - Medical Devices - Particular requirements for the application of ISO 9001
ISO 13488:1996 Quality systems - Medical Devices - Particular requirements for the application of ISO 9002	CAN/CSA-ISO 13488:1998 Quality systems - Medical Devices - Particular requirements for the application of ISO 9002
ISO 10011-1:1990 Guidelines for auditing quality systems - Part 1: Auditing	CAN/CSA-ISO 10011-1 :1994 Guidelines for auditing quality systems - Part 1: Auditing
ISO 10011-2:1991 Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors	CAN/CSA-ISO 10011-2 :1994 Guidelines for auditing quality systems - Part 2: Qualification criteria for quality systems auditors

International Standard or Guide	Canadian Equivalent in National Standard System
ISO 10011-3:1991 Guidelines for Auditing quality systems - Part 3: Management of audit programmes	CAN/CSA-ISO 10011-3 :1994 Guidelines for auditing quality systems - Part 3: Management of audit programmes
The complete series of final GHTF Guidelines dealing with quality requirements and auditing process is available at www.ghtf.org	No Canadian equivalent. GHTF documents used in CMDCAS
No International equivalent	Q90 : Canadian Medical Devices Conformity Assessment System (CMDCAS)

The International document ISO/IEC Guide 61 sets out general requirements for bodies (e.g. SCC) operating accreditation systems. Its companion guidance document "IAF Guidance on Application of ISO/IEC Guide 61 - Issue 1, 22 January 1998" provides guidance on its application.

The criteria document, CAN-P-10B sets out general requirements for a Registrar to meet if it is to be accredited by SCC. SCC uses CAN-P-10B and CAN-P-1517 along with the IAF Guidance to Guide 62 when it accredits a Registrar.

The International auditing documents, ISO 10011, Parts 1, 2, and 3 give general requirements governing the audit process, the qualification criteria for auditors, and the management of audit programmes. These requirements apply when assessing the conformity of a manufacturer's QS to a specific QS standard like ISO 9001 or ISO 13485.

The medical devices Global Harmonization Task Force guidance document GHTF/SG4(99)28: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements : 1999 Final Document" also addresses the auditing process. This GHTF document gives guidance on establishing, planning, carrying out and documenting audits of a medical device manufacturer's QS.

5. Policy Statement

5.1 CMDCAS Responsibilities

This document states the Canadian medical device QS conformity assessment requirements that the TPP, the SCC and accredited Registrars must meet.

5.2 TPP's Responsibility

5.2.1 General Requirements

5.2.1.1 As the national regulatory authority, TPP evaluates and monitors the safety, effectiveness and quality of medical devices available to Canadians.

5.2.1.2 TPP shall develop and maintain the regulatory requirements and procedures that comprise CMDCAS.

5.2.1.3 TPP shall conform to the requirements of CMDCAS.

5.2.1.4 TPP shall select the accreditation body to accredit Registrars according to the requirements of CMDCAS.

5.2.1.5 TPP shall co-chair the "TPP-SCC CMDCAS Management Committee" responsible for managing CMDCAS issues and procedures related to the accreditation of Registrars.

5.2.1.6 TPP may, at its discretion, participate as technical experts in the SCC CMDCAS accreditation assessment, reassessment or surveillance audits of Registrars. TPP will provide input to the recommendations on SCC accreditation of a Registrar to the CMDCAS scope.

5.2.1.7 TPP shall recognize in its medical device licensing process the registration of a manufacturer's quality system by a Registrar accredited to the requirements of CMDCAS, unless TPP considers that public health and safety may be compromised.

5.2.1.8 Information held by TPP from a CMDCAS accreditation assessment, reassessment or surveillance audit of a Registrar, and from a Registrar's assessment, reassessment or surveillance audit of a manufacturer will be treated in accordance with appropriate Federal regulations and guidelines dealing with confidential or proprietary information.

5.2.1.9 TPP shall make accessible to Registrars, by way of the manufacturer, a current manufacturer's regulatory profile of medical device manufacturers selling licensed medical devices in Canada.

5.2.1.10 TPP shall provide training to SCC and Registrars on the requirements found in CMDCAS and on the *Medical Devices Regulations*, and any significant changes thereto.

5.2.1.11 TPP may, at its discretion, observe a registration assessment, reassessment or surveillance audits of medical device manufacturers conducted by CMDCAS accredited Registrars.

5.2.1.12 TPP shall resolve complaints, appeals and disputes by medical device manufacturers related to the *Medical Devices Regulations* and to CMDCAS where applicable according to the TPP appeal process.

5.2.1.13 If TPP determines that an SCC CMDCAS accredited Registrar is not complying with the requirements of CMDCAS or if public health and safety is being compromised, TPP will not recognize that Registrar and will recommend that SCC take corrective actions, suspend or withdraw the Registrar's CMDCAS accreditation. TPP shall notify SCC in writing if it does not recognize a SCC CMDCAS accredited Registrar.

5.3 SCC's Responsibility

5.3.1 General Requirements

5.3.1.1 As the selected CMDCAS accreditation body, the SCC will accredit Registrars to perform QS registrations that meet the requirements of CMDCAS.

5.3.1.2 SCC shall develop and maintain the accreditation requirements and procedures that comprise CMDCAS.

5.3.1.3 SCC shall conform to the requirements of CMDCAS.

5.3.1.4 SCC shall include TPP recommendations in its CMDCAS accreditation process.

5.3.1.5 SCC shall co-chair the "TPP-SCC CMDCAS Management Committee" responsible for managing CMDCAS issues and procedures related to the accreditation of Registrars.

5.3.2 Additional CMDCAS Requirements to ISO/IEC Guide 61

5.3.2.1 Clause 2.1.1.3 : *Accreditation body - general provision*
SCC shall use CAN-P-10B, CAN-P-1517 and the additional requirements found in Section 5.4.2 of CMDCAS when doing an assessment of a Registrar.

5.3.2.2 Clause 2.1.5.1 : *Condition for granting, maintaining, extending, reducing, suspending and withdrawing accreditation*
SCC shall be trained by TPP on the requirements found in CMDCAS and on the *Medical Devices Regulations*, and any significant changes thereto.

SCC shall ensure that at least one member of the audit team has successfully completed the TPP training on the requirements found in CMDCAS and on the *Medical Devices Regulations*, and any significant changes thereto.

5.3.2.3 Clause 2.1.5.1 : *Condition for granting, maintaining, extending, reducing, suspending and withdrawing accreditation*
SCC shall notify TPP in writing of any change in a Registrar's accreditation status, including scope of accreditation.

5.3.2.4 Clause 2.1.7.1 : *Documentation*
SCC shall notify TPP in writing of any change in its status as the national accreditation body of Canada.

5.3.2.5 Clause 2.3.3 : *Decision on accreditation*

SCC shall use, in addition to their existing criteria, the CMDCAS criteria when accrediting a Registrar.

5.3.2.6 Clause 2.5 : *Changes in the accreditation requirements*
SCC shall inform TPP of any significant change to its accreditation requirements.

5.4 Registrar's Responsibility

5.4.1 General Requirements

5.4.1.1 Registrars shall conform to the requirements of CMDCAS.

5.4.1.2 If a Registrar is a corporate body which is part of a larger organization or uses the services of a subcontractor, it maintains responsibility for all contracted actions of the larger organization or its subcontractor and shall be liable for them as if the Registrar itself performed the actions.

5.4.1.3 Upon request by TPP, a Registrar shall allow TPP to observe a registration audit of medical device manufacturers conducted by accredited CMDCAS Registrars.

5.4.1.4 Registrars will perform the third-party conformity assessments of medical device manufacturer's QS to satisfy the QS requirements of the *Medical Devices Regulations*.

5.4.1.5 Upon request by TPP, a Registrar shall authorize SCC to provide TPP with a copy of SCC's assessment, reassessment or surveillance audit reports on their findings as to the conformity or non-conformity of that Registrar to the requirements of CMDCAS.

5.4.2 Additional CMDCAS Requirements to CAN-P-10B

5.4.2.1 Clause 2.1.5 : *Conditions for granting, maintaining, extending, reducing, suspending and withdrawing certification/registration*
Registrars shall notify TPP in writing of any change in a manufacturer's registration certificate status relating to an extension, reduction, suspension and withdrawal of that certificate.

5.4.2.2 Clause 2.2.2.1 : *Qualification criteria for auditors and technical experts*
Registrars shall ensure that at least one member of the audit team has successfully completed the TPP training on the requirements found in CMDCAS and on the *Medical Devices Regulations*, and any significant changes thereto.

In addition to clause 2.2.2.1, auditors shall meet the criteria found in clauses 10.2.1 and 10.2.3 of the GHTF guidance document GHTF/SG4(99)28: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements : 1999 Final Document". See Appendix 2.

5.4.2.3 Clause 2.2.2.3 : *Qualification criteria for auditors and technical experts*

Technical experts subcontracted by a Registrar and who are not qualified as auditors, should only assess the processes related to their specialized knowledge and under the supervision of an auditor.

5.4.2.4 Clause 3.1.2 : *The Application*
Registrars shall review TPP's manufacturer's regulatory profile, if one has been issued by TPP to the manufacturer, prior to performing a QS assessment, surveillance, or reassessment registration audit. Any audit work related to the regulatory profile will be included in the audit plan and the auditor's report on the regulatory profile will be submitted to TPP in a specified format.

5.4.2.5 Clause 3.4.1 b, c, d, e : *Assessment report*
Registrars shall, upon written request, provide TPP with a copy of their audit team's reports on their findings as to the conformity or non-conformity of a manufacturer's QS to the requirements of ISO 13485 or ISO 13488.

5.4.2.6 TPP may, at its discretion, observe a registration audit of medical device manufacturers conducted by accredited Registrars.

6. Effective Date

Upon issuance of final TPP policy.

Appendix 1 : Abbreviations and Definitions

CAN-P	Canadian Procedural Document
CMDCAS	Canadian Medical Devices Conformity Assessment System
GHTF	Global Harmonization Task Force
IEC	International Electro-technical Commission
ISO	International Organization for Standardization
MDR	Medical Devices Regulations
MRP	Manufacturer's regulatory profile
NSS	National Standards System of Canada
QS	Quality System
SCC	Standards Council of Canada
TPP	Therapeutic Products Programme, Health Canada, Health Protection Branch

Accreditation :

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (ISO/IEC Guide 2:1996)

National Standards System of Canada :

The system for voluntary standards development, promotion and implementation in Canada. The Standards Council of Canada coordinates and oversees the efforts of the NSS.

Manufacturer :

A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. (*MDR* P.C. 1998-783, 7 May 1998)

Quality System :

Organizational structure, procedures, processes and resources needed to implement quality management. (ISO 8402:1994)

Quality Audit :

Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangement are implemented effectively and are suitable to achieve objectives. (ISO 8402:1994)

Registrar :

Organization that assesses and certifies or registers the quality system of manufacturers with respect to published quality system standards.

Examples of quality system standards include ISO 9001, ISO 13485.

Note 1 : Refer to ISO Guide 2, ISO Guide 62 and CAN-P-10B for further clarification of related terms like "conformity assessment body" and "certification/registration body".

Note 2 : In countries other than Canada, a registrar may be called certification body, registration body, assessment and registration body, or certification/registration body.

Appendix 2 : Qualification Criteria for Medical Device Quality System Auditors

Criteria taken from the Global Harmonization Task Force guidance document "*GHTF/SG4(99)28 : Guidelines For Regulatory Auditing of Quality Systems of Medical Device Manufacturers, Part 1: General Requirements : 1999*"

"10.2.1 Audit team competence criteria

The competence requirements for all auditors in the team should be based on the qualification criteria for quality system auditors (ISO 10011-2:1991, Qualification criteria for quality system auditors) as well as personal attributes (e.g. tact, diplomacy, effective communication skills).

The competence of the team as a whole should be appropriate to cover the scope of the audit. In particular:

a) The team should have competence (i.e. training and knowledge/experience) in the following:
- *i) assessment of the quality system for medical device manufacturers and determination of the effectiveness of its implementation;*
- *ii) understanding the regulations and applicable standards specific to quality system requirements for medical device manufacturers;*
- *iii) intended use of and risks associated with the devices being produced;*
- *iv) the assessment of the design, manufacturing processes and the technologies involved.*

b) The competence must be present within the audit team as a whole but not necessarily by each member of it. In assessing the quality systems of manufacturers the audit team may include additional experts in processes and technology relevant to the scope of the audit and ideally these experts should meet the requirements of clause 10.2.1 (a). The experts authorised by the auditing organisation and who are not qualified as auditors should only assess the processes related to their specialised knowledge and under the supervision of an auditor.

Alternatively, the members of the audit team may be given additional training and/or specialised knowledge related to those processes and technology (e.g. the achievement of a controlled environment and validation of the sterilisation process).

c) The lead auditor shall be competent to plan and direct the team members so that in carrying out their separate tasks, the appropriate competence is applied effectively and fairly.

10.2.2 Audit team competence records

The auditing organisation shall maintain records to demonstrate the competence of its auditors.

10.2.3 Auditor qualifications, training and experience

In addition to basic auditing skills (clause 10.2.1), the competencies specifically required for auditing medical device manufacturers may be achieved through a variety of means including a combination of qualification and one or more of the training or experience elements listed below.

a) Qualification
Auditor qualification is most likely to be in one or more of the following:

i) biology or microbiology;
ii) chemistry or biochemistry;
iii) computer and software technology;
iv) electrical, mechanical or bioengineering;
v) human physiology;
vi) medicine;
vii) pharmacy;
viii) physics or biophysics.

b) Training
Special programmes may be established for training technically qualified staff in the following:

i) understanding the regulatory requirements and related laws/ordinances/statutes etc.;
ii) auditing of medical device manufacturers' quality systems;
iii) understanding the design and manufacturing processes and the technologies involved;
iv) safety aspects relating to the intended use of medical devices.

c) Experience
Auditor experience is most likely to be in the following:

i) working in closely related industries and the workplace such as research and development, manufacturing;
ii) working in the application of the device technology and its use in health care services and with patients;
iii) testing the devices concerned for compliance with the relevant national or international standards;
iv) conducting performance testing, evaluation studies or clinical trials of the devices.

These competencies are to be regarded as the tools to address the relevant safety and performance aspects of the quality system being audited arising from the way in which the devices:

- *are made, and*
- *how they work, and*
- *how they are used."*