

# Additional Requirements for Accreditation of Certification Bodies

**CAN-P-1500M** April 2008



### ADDITIONAL REQUIREMENTS FOR ACCREDITATION OF CERTIFICATION BODIES

#### **CAN-P-1500M**

April 2008

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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 sector.

The mandate of the Council is to promote the participation of Canadians in voluntary standards activities, promote public and private sector cooperation in relation to voluntary standardization in Canada, and coordinate 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 and conformity assessment 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 cooperation in relation to standardization.

The SCC also 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. The SCC also offers several programs for the accreditation of Conformity Assessment Bodies (CAB) and Standards Development Organizations (SDO).

It also promotes and supports the principle of recognition of accreditation or equivalent systems as a means of decreasing the number of 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 Council to help achieve its mandate.

#### Introduction

The Standards Council of Canada (SCC) accredits third-party certification bodies (CBs) according to the general requirements in SCC document CAN-P-3, General Requirements for Bodies Operating Product Certification Systems, the text of which has been taken verbatim from ISO/IEC Guide 65 (latest edition). CAN-P-3 requirements are applied so that all CBs accredited by SCC operate thirdparty certification systems in a consistent and reliable manner. International consistency is further reinforced by SCC adherence to the requirements of the International Accreditation Forum, Inc. as detailed Application in IAF Guidance on the of ISO/IEC Guide 65:1996.

In addition to the uniform, international requirements of ISO/IEC Guide 65, Canada also has several unique requirements for Product Certification Bodies to meet regulatory needs. These additional requirements are contained in this document which serves as a companion to CAN-P-3.

CAN-P-1500M, April 2008, supersedes CAN-P-1500L, January 2006.

A list of all accredited CBs with their scopes of accreditation is available to the public on the SCC Web site at <u>http://www.scc.ca</u>.

Information for CBs wishing to apply for accreditation is available from the Conformity Assessment Branch of SCC.

#### ADDITIONAL REQUIREMENTS FOR ACCREDITATION OF CERTIFICATION BODIES

#### 1 SCOPE

This document serves as a companion to SCC document CAN-P-3 and outlines unique Canadian requirements for third-party product certification bodies (CBs) accredited by the SCC. The criteria in this document will be applied in conjunction with those criteria in CAN-P-3 when conducting accreditation or reaccreditation audit activities under the SCC accreditation program for CBs. SCC accreditation programs are open to any applicant **n** countries that are members of the World Trade Organization (WTO), as mandated by Government Orders-in-Council to the SCC Act.

#### 2 **REFERENCES**

CAN-P-3, General Requirements for Bodies Operating Product Certification Systems (latest edition of ISO/IEC Guide 65)

CAN-P-4, *General Requirements for the Accreditation of Calibration and Testing Laboratories* (latest edition of ISO/IEC 17025)

CAN-P-15, Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings (latest edition)

CAN-P-1501:2006, Certification Body Accreditation Program Handbook - Conditions and Procedures for Accreditation of Bodies Certifying Products and Services

CAN-P-1527, *Guidelines for Corrective Action* (latest edition of ISO/IEC Guide 27)

International Accreditation Forum, Inc: *IAF Guidance on the Application of ISO/IEC Guide 65* (latest edition)

ISO/IEC Guide 7:1994, Guidelines for drafting of standards suitable for use for conformity assessment

ISO 3166: Codes for the representation of the names of countries and their subdivisions –Part 1: Country codes

ISO/IEC 17000:2004, Conformity assessment -- Vocabulary and general principles

ISO/IEC 17030:2003, Conformity assessment – General requirements for third-party marks of conformity (latest edition)

SCC License Agreement (latest edition)

Trade-Marks Act: Canadian Federal Egislation administered by the Canadian Intellectual Property Office (CIPO), Industry Canada.

#### **3 DEFINITIONS**

The definitions as presented in CAN-P-3 and its referenced guides apply. The following conditions also apply:

Accreditation: The formal initial and continuing recognition by SCC of a body to operate a certification program on a continuing basis in a specific subject area(s), in accordance with specific criteria, procedures and requirements.

Advisory Council: A body of concerned Canadian interests (such as regulators, manufacturers, consumers and technical specialists) developed to advise CBs in a specific area of product certification.

Applicant: A CB not yet accredited by SCC.

**Canadian Identifier:** A lower case letter "c" placed at the 8 o'clock position adjacent to a certification mark that demonstrates to regulators and consumers that the product has been certified to Canadian Recognized Standards, ORDs or another normative document that is recognized by a Canadian Regulatory Authority.

**Canadian Recognized Standard**: A standard recognized by a Canadian Regulatory Authority or, in areas not controlled by legislation, a National Standards of Canada, or a voluntary consensus standard developed in accordance with the requirements of ISO/IEC Guide 7 and recognized by the appropriate Canadian industry association(s).

**Certification Body (CB):** An organization that gives third-party written assurance that a product, process or service fulfils specified requirements.

**Certification Mark:** A protected mark, applied or issued under the rules of a certification system, indicating that confidence is provided that the relevant product, process or service is in conformity with specific standards or Other Recognized Documents.

**Market Area:** A national economy or a formalized group of trading nations such as the European Union, which use harmonized product standards across national boundaries.

**National Standard of Canada**<sup>TM</sup> (NSC): A consensus standard prepared or reviewed by an accredited Standards Development Organization and approved by SCC.

**National Standards System:** The coordinated Canadian system of independent, autonomous organizations working towards the development and improvement of voluntary standardization in Canada, as overseen by SCC.

**Other Recognized Document (ORD):** A normative document that is developed when a Canadian Recognized Standard does not cover a new product to be certified. An ORD provides an equivalent level of safety or performance as provided for similar functions in existing standards. The ORD shall be acceptable to the applicable Regulatory Authority. In unregulated areas, the ORD shall be acceptable to the appropriate industry association(s).

**Product Certification Body Advisory Committee:** The committee or equivalent that meets the requirement of Clause 4.2e of CAN-P-3 and the corresponding clauses of the IAF Guidance to Guide 65. The committee is internal to the CB.

**Regulatory Authority Advisory Body:** A Body, Council or Committee, consisting of representatives from various Canadian governmental organizations (Federal, Provincial, Territorial, Municipal or other) that coordinates regulations and promotes consistency among jurisdictions related to regulations, standards and enforcement practices respecting the sale, purchase, safety, performance, use and application of consumer or industrial products within its jurisdiction.

**Witness Testing:** The off-site testing of a product under documented control procedures to ensure the integrity of the testing activity observed by CB personnel competent to perform such testing.

#### 4 ADDITIONAL ACCREDITATION REQUIREMENTS

#### 4.1 Certification Standards

**4.1.1** In regulated areas, CBs shall certify products to Standards, ORDs or another normative document recognized by a Canadian Regulatory Authority.

**4.1.2** In unregulated areas, CBs shall certify products to an NSC, or to a standard developed in accordance with ISO/IEC Guide 7. For products sold in Canada, Canadian Recognized Standards shall be applied.

#### 4.2 Certification Mark

**4.2.1** A CB shall take appropriate steps to register, protect and control its mark, in accordance with Section 4 of ISO/IEC 17030, in particular:

**4.2.1.1** CBs issuing certifications for the Canadian market area shall register their mark in accordance with the *Trade-Marks Act* with the Trade-Marks Branch of the Canadian Intellectual Property Office (CIPO), Industry Canada. The protected mark must be a unique mark pertaining to a specific certification body.

**4.2.1.2** CBs certifying products manufactured for market areas other than Canada, shall demonstrate to the SCC how certification marks are protected and controlled in these areas. It is recommended that the CB register its mark in those market areas where it issues certifications.

<u>Note 1:</u> Provided that all other requirements for accreditation are satisfied, an applicant may be accredited as a CB while the mark registration is still in process. Before accreditation, it shall be confirmed and documented that the mark registration is not being opposed.

**4.2.2** A CB shall identify the market area(s) for which a certified product is designated either by the use of a unique mark for that area or by the use of an appropriate qualifying statement or identifier adjacent to the certification mark. The CB shall, as described in ISO/IEC 17030, ensure qualifying statements are clear and not misleading.

**4.2.2.1** Where the physical size of the product does not permit this, or when the application is not appropriate for the type of product, the certification mark and/or the qualifying statements may be applied on the closest level of packaging to the product or other accompanying information.

**4.2.2.2** If country abbreviations are used, they should be those provided in ISO 3166.

**4.2.2.3** Regulators in some fields demand the use of specific identifiers (such as a small "c" in Canada, or an NRTL identifier in the United States). Regulatory mandated identifiers shall be used in place of market area designators when so required.

**4.2.3** A CB shall take measures to minimize misunderstandings and lack of clarity regarding its certification marks.

**4.2.3.1** Each CB shall have a policy statement and procedures regarding the use, the meaning and the scope of coverage of its marks, encompassing the situations described in 4.2.3.2 and 4.2.3.3 below.

**4.2.3.2** Where a mark on a product can clearly represent, by itself, without further clarification, the standard or requirements for which the product has been certified, no additional markings may be required. Examples include a product that has been certified to all applicable standards, or a product for which there is only one applicable standard.

**4.2.3.3** Where it is necessary to clarify the scope of coverage of a certification mark, e.g., to avoid ambiguity or to indicate a limitation of the certification scope, the CB shall ensure that its marks on the certified products are appropriately qualified. As illustrated in Annex A, this can be done with a qualifying statement that is not part of the registered mark.

<u>Note 2:</u> Misunderstandings often arise when for example, a product can be certified for electrical and gas aspects but only the electrical portion was certified. The identification of aspects could equally be achieved by showing the standard number. The aspects covered can appear on the smallest product packaging or be included in the accompanying literature.

<u>Note 3:</u> CBs may use multiple marks under an SCC certification program; however, each such mark shall have a clearly defined and identified scope.

<u>Note 4:</u> This requirement also applies to certified components.

<u>Note 5:</u> The inclusion of such information in a Certification Body's product directory only, will not satisfy the requirement.

**4.2.4** A CB shall have procedures in accordance with CAN-P-1527 (ISO/IEC Guide 27 ed. 1983-03-15), to handle and record any reported misuse of the certification mark, or situation in which a certified product is subsequently found to be hazardous. A CB shall require suppliers to notify the CB of any situation where a product bearing the mark could lead to a potential hazard.

**4.2.5** A CB providing certification of telecommunication equipment under government regulations for spectrum management and interconnection, need not have, or apply a registered mark on such equipment. This is allowed provided that the certification mark is not required by the Regulatory Authority, and that control mechanisms approved by the Regulatory Authority are applied to allow the certified product to be traced back to the certifier.

<u>Note 6:</u> Clause 4.2.5 applies to subject areas covered only by Telecommunication Regulator Specifications and does not extend to other areas such as electrical safety.

#### 4.3 Testing Capabilities

**4.3.1** The testing facilities available to a CB shall correspond to its full scope of CB accreditation. A CB shall, if requested by the SCC, identify all standards or ORDs used in support of its certification program.

**4.3.2** A CB shall demonstrate that its internal test facilities, external test facilities and certification bodies with whom test data are exchanged, meet the appropriate requirements of CAN-P-4. This shall be demonstrated by one or more of the following:

- a) A test facility accredited by SCC.
- b) A test facility accredited by an agency that is part of an organization with which SCC has signed a Mutual Recognition Agreement (MRA).
- c) An internal test facility owned or controlled by the CB. The CB shall demonstrate that it maintains procedures for evaluation and conducts evaluations of such facilities for conformance with the appropriate requirements of CAN-P-4. Such evaluations should occur at regular intervals that shall not exceed two years.
- d) An external test facility approved by the CB. The CB shall demonstrate that it maintains acceptable procedures for the assessment of such facilities, and evaluates those facilities for conformance to the appropriate requirements of CAN-P-4. Such evaluations should occur at regular intervals and shall not exceed two years.
- e) A supplier's facility used for witness testing. The CB shall demonstrate that it has acceptable procedures and evaluates suppliers' facilities to the appropriate requirements of CAN-P-4. The CB shall be able to demonstrate that for any use of a supplier's facility, the facility was assessed to have met the appropriate requirements of CAN-P-4 at the time.

<u>Note 7:</u> More information on meeting requirements for testing and calibration subcontractors is found in Cause 6.2.15 of the Certification Body Accreditation Program Handbook, (CAN-P-1501) available on www.scc.ca.

#### 4.4 Final Level of Appeals

CBs shall have procedures to inform suppliers that SCC is the final level of appeal in disputes with a CB regarding conformance with accreditation criteria. CBs shall abide by all SCC decisions pertaining to accreditation criteria.

#### 4.5 Other Recognized Documents

CAN-P-1500M April 2008 **4.5.1** CBs may develop Other Recognized Documents (ORDs) to provide certification services within their accredited scope in areas where Canadian recognized standards do not exist or are not applicable.

**4.5.2** CBs electing to use ORDs, shall develop and implement procedures that address the requirements of Clauses 4.5.3 through 4.5.7 below.

**4.5.3** When determining the need for an ORD, a CB shall assess whether:

- a) applicable standards or ORDs already exist for the product; and,
- b) products are currently being approved through the interpretation of existing standards by other CBs.

**4.5.4** For products to be sold in Canada, the ORD should be based on Canadian Recognized Standards where those standards exist.

- **4.5.5** If an ORD is required, the CB shall:
- a) determine if test requirements can be utilized from other standards;
- b) submit a copy of the proposed ORD to the CBs Product Certification Advisory Committee for approval;
- c) submit a copy of the proposed ORD to the appropriate Regulatory Authority Advisory Body and request an acknowledgement of the need for the ORD. This submission shall:
  - 1. summarize the research conducted to establish the need for an ORD;
  - 2. provide details on the new product and reasons why this product cannot be certified according to existing standards;
  - 3. include the proposed detailed test / performance requirements;
  - 4. provide evidence of reproducible test data;
  - 5. provide evidence of test facility conformance with CAN-P-4 for the new identified test requirements; and,
  - 6. include the proposed effective date for its application.

**4.5.6** No certification shall be conducted in regulated areas until the need for the ORD has been acknowledged by the appropriate Regulatory Authority Advisory Body. In unregulated areas, no certification shall be conducted before consultation with and endorsement of the ORD by the industry association(s).

**4.5.7** The CB developing the ORD shall, within 30 days of its acknowledgement, provide copies of the ORD to SCC and make copies available to other CBs whose scope of accreditation includes the same subject area, to appropriate industry associations and to the appropriate Standards Development Organization (SDO), with a request to amend the existing standard where one exists, or create a standard where none exists.

**4.5.8** At Regulatory Authority Advisory Body meetings, the CB shall report usage and any issues arising from its application.

**4.5.9** If an ORD has not been incorporated into a standard within five years of use, the CB shall resubmit it to its Regulatory Authority Advisory Body. This resubmission shall include a justification for the ORD's continued use. If the ORD is no longer used, or if the Regulatory Authority Advisory Body no longer supports the need for the ORD, the ORD shall be withdrawn.

<u>Note 8:</u> The justification should describe the extent of use and application of the ORD and the progress made towards its incorporation into a standard. If insufficient progress is being made towards its incorporation, the justification should include the reasons.

**4.5.10** If a Regulatory Authority Advisory Body requests the cessation of certification to the requirements stated within the ORD, or if the appropriate Standards Development Committee formally rejects and ORD for technical reasons, the CB shall inform all its affected clients and other CBs, and will cease all certifications based on that ORD and remove the product listings from its product directory from that time forward.

**4.5.11** CBs that are SDOs may issue ORDs that are verbatim copies of balloted (i.e., approved by TC) revisions to standards for use in product certification while those standards are going through the SDO approval or editing stage step.

<u>Note 9:</u> Acknowledgement by the Regulatory Authority Advisory Body is not required if the documents have received positive ballot by a multi-stakeholder technical committee that included the regulators.

**4.5.11.1** The CB issuing the ORD shall inform all other accredited CBs that certify product under the scope of the ORD, prior to its use. The ORD must be made available to all CBs and they must be advised of the means by which it may be obtained.

**4.5.11.2** The ORD shall be withdrawn when the official standard revision is released and all subsequent certification shall reflect the revised standard.

#### 4.6 Participation in the National Standards System

- **4.6.1** CBs shall support the National Standards System and participate, when appropriate:
- a) in consultations, research and development, to enhance the system;
- b) on technical committees of Canadian Standards Development Organizations; and,
- c) in the development, interpretation, dissemination and application of standards related to their certification programs.

**4.6.2** CBs shall maintain a comprehensive knowledge of regional, national and international standards and certification programs in their areas of accreditation and shall participate, when appropriate, in the development of related standards and international certification programs.

**4.6.3** CBs shall maintain up-to-date knowledge of Canadian recognized standards in their areas of accreditation.

#### 4.7 Relationships with Canadian Regulatory Authorities

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**4.7.1** CBs shall establish working relationships with applicable Canadian Regulatory Authorities for each regulated area of accreditation. This liaison shall:

- a) provide Regulatory Authorities an opportunity to discuss certification issues and regulatory requirements with CBs. (To accomplish this, CBs shall agree to attend meetings with Regulatory Authorities as required.);
- b) enable CBs to confirm regulatory requirements such as the use of a Canadian identifier, processes for addressing corrective action and the need for dual official language safety warnings; and,
- c) enable CBs to process ORD development as required.

**4.7.2** CBs may establish such working relationships with a Regulatory Authority Advisory Body rather than with each provincial jurisdiction. CBs shall abide by the requirements of the Canadian Regulatory Authorities or their designated Advisory Bodies.

**4.7.3** CBs shall operate in accordance with federal, provincial and municipal laws and regulations as administered by the Regulatory Authorities.

**4.7.4** In unregulated certification areas, CBs shall develop an Advisory Council of appropriate concerned Canadian interests.

**4.7.5** CBs shall permit SCC and relevant Canadian Regulatory Authorities to examine any information used in making certification decisions, including test data. Such examination may be conducted at the supplier's premises or at the CB's premises.

**4.7.6** CBs shall advise the relevant Regulatory Authority Advisory Committee of any safety related product incidents or safety related recalls involving products that were certified for the Canadian marketplace. The notification shall be in writing and be provided in both of Canada's official languages. The CBs shall copy SCC on all such correspondence for inclusion in the SCC Product Advisory database.

#### 4.8 Language

**4.8.1** CBs shall make their certification services available to all parts of Canada and in both of Canada's official languages.

**4.8.2** Applicants shall demonstrate dual official language capability by providing:

- a) a description detailing how they will respond to both oral and written requests in each official language;
- b) a description outlining how they will conduct inspections in the official language of the supplier's choice;
- c) samples of an application form and a listing, labeling and follow-up service agreement in both official languages; and,
- d) a publicly available information document (e.g. simple brochure or fact sheet), in each official language, outlining the CB's services and providing an address and telephone number that can be accessed by suppliers using either official language.

**4.8.3** CBs shall include dual language safety labeling within their product certification requirements, if so required by the standard or by the authority having jurisdiction.

#### 4.9 Use of the SCC Accreditation Mark

**4.9.1** Product certification certificates issued by CBs to their suppliers may bear the SCC Accreditation Mark. A statement indicating that the CB is accredited by the SCC may also be used. The use of the SCC Mark or statement shall not imply that a product is endorsed by the SCC.

**4.9.2** Suppliers may use a statement adjacent to the CB's mark, on the product, on product packaging or on insert documentation, indicating that the CB is accredited by SCC. The SCC Mark shall not be used on the product or its packaging (see Annex B).

**4.9.3** To use the SCC Mark, the CB must sign the SCC License Agreement and follow the usage requirements specified therein.

#### Annex A -- Illustrations of Some Methods of Identifying the Scope of a Certification and Market Area

<u>Note 10:</u> In the following examples, "CB" is the certification mark of an SCC accredited certification body. In each case, the certification body has taken steps to clearly indicate the aspects and the market area for which the product is certified.

с <b>CB</b>	c <b>CB</b>	с <b>СВ</b>	<b>CB</b> <sub>US</sub>	<b>CB</b> <sub>US</sub>	c <b>CB</b> us	CB
Electrical Safety	CSA B352.2 1996	Gas & Electrical Safety	ANSI A 17.1	Food Safety	NSF 61	Toy Safety Certified for the EU

## <u>Annex B</u> -- An Illustration of a Method of Identifying the Accreditation Body Related to a <u>Certification Mark</u>

<u>Note 11:</u> In the following example, "CB" is the certification mark of an SCC accredited certification body.

CB is Accredited by the Standards Council of Canada