**Foundation Document
for the
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Stakeholders Advisory Council**

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1. Introduction

— *Standards have become strategically important.*

Voluntary standards are pervasive in our society. They help assure consumers that the appliances they purchase will be compatible with the electrical system in their homes. They help make the Internet function. They help ensure sound quality and environmental management systems. And they are now being developed for such issues as privacy and energy efficiency. In a time of globalization, rapid rates of technological change, shorter product lifespans, and government deregulation, standardization activities have assumed increasing strategic importance.

Recognizing these developments, the Standards Council of Canada (SCC) identified the need for a Canadian Standards Strategy (CSS) in its Strategic Plan, 1998-2001. The CSS will provide guidance to Canadian governments, industry, standardization organizations and consumers on the standardization measures and priorities necessary to enhance Canada's social, environmental and economic well-being.

— *A strategy is required to guide Canadian standardization activities and policies into the 21st Century.*

This paper provides background information for the SCC's Stakeholders' Advisory Council (SAC), which has been established to help develop the Strategy. The paper describes the international and domestic context for a CSS, presents a rationale for its development, and thematically identifies key issues that might form the subjects of SAC working groups. The paper is not intended to be exhaustive or authoritative but, rather, to provide a starting point for SAC discussions and help to identify possible work areas.

This paper has six sections. Following this introduction, Section 2 describes the main globalization trends impacting on standardization activities. Section 3 reviews Canada's place in the global economy. Section 4 summarizes relevant federal government trade and economic priorities. Section 5 summarizes federal regulatory reform policies. Finally, section 6 describes the main issues and challenges facing Canada in the area of standardization, organized thematically:

1. ***International trade*** —improving market access by harmonizing standards and pursuing the mutual recognition of conformity assessment requirements with key trading partners;

2. ***International standardization activities*** —
   enhancing Canadian interests through strategic
   participation;

3. ***Domestic standardization activities*** —responding
   to process concerns and re-organizing and renewing
   the infrastructure; and

4. ***The role of Canadian governments*** —developing a
   more strategic relationship.

Appendix A contains a glossary of the acronyms used in
this document.

Appendix B provides an overview of the standards
world, including descriptions of standards and
conformity assessment activities, the various
components of the Canadian National Standards System
(NSS), the international standards regime and various
foreign standards regimes.

To illustrate the type of processes relied on to develop
standards, Appendix C outlines the general process for
the development of standards in Canada, and the
process used by the International Organization for
Standardization (ISO) for the development of
international standards.

Appendix D summarizes the provisions of Canada's
most important trade agreements that are relevant to
standards.

Appendix E summarizes strategic directions with respect
to standardization being taken by the U.S., the
European Union, Great Britain and Japan.

2. The Impacts of Globalization

— *Globalization is an economic phenomenon with important governance dimensions.*

Over the last twenty years, national economies have become more integrated as cross-border flows of trade, investment and financial capital have increased. These trends are commonly referred to as globalization.

Globalization refers to the "rapid and pervasive diffusion around the globe of production, consumption and investment of goods, services, technology and capital."[1] It is emerging as the paramount economic issue for the 21st century.

While globalization is an economic phenomenon, it also includes important governance dimensions. The increase in the number and importance of international agreements and codes setting out rules on a wide range of subjects from trade to wildlife conservation and the creation of institutions to administer these rules (e.g., WTO, OECD) are also manifestations of globalization.

The fall of various currencies against the U.S. Dollar in the summer of 1998, largely in response to developments in the Asian financial markets, is another example of the interconnections of a global economy and the governance issues to which it gives rise.

Globalization has been made possible by a number of developments, the most important of which are the liberalization of trade throughout the world and rapid improvements in communications and information technology.

— *Globalization is significantly enhancing the importance of common international standards and conformity assessment requirements.*

As a result of the GATT/WTO (General Agreement on Tariffs and Trade / World Trade Organization) negotiations and unilateral decisions, almost all countries have recently lowered tariff barriers to foreign trade. Over the past decade, trade has increased twice as fast as domestic production, foreign direct investment three times as fast and cross-border trade in shares ten times as fast.

It is no coincidence that international standardization activity has also increased substantially in that period. As traditional barriers to trade and investment are eliminated, and as international technology transfers increase, there are increasing pressures to harmonize standards and conformity assessment requirements. Global trade requires global standardization practices.

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[1] Michael Hart, 1994, *What's Next: Canada, the Global Economy and the New Trade Policy* (Centre for Trade Law and Policy, Ottawa).

— Standards have facilitated the evolution of modern information technology.

With the costs of communication and computing falling rapidly, the barriers of time and space that separate national markets have been falling. Cheap and efficient communications and transportation networks allow firms to locate their production processes in different countries, while maintaining close communication and management direction from head office. Modern information technology also reduces the need for physical contact between producers and consumers. Standards have both facilitated these trends by ensuring the compatibility of communications and computing systems, and become more important as a result.

Not all industry sectors, of course, are affected equally by these trends. Sectors that participate extensively in export trade (e.g., the automotive and forestry sectors in Canada's case) can be expected to have a greater interest in the use of common international standards and conformity assessment practices than sectors that engage in a low level of trade activity. The nature of a product (e.g., undifferentiated commodity versus goods with unique attributes) and the basis upon which it competes (e.g., price versus quality or performance) also have important standards implications. For example, a sector characterized by strong price competition may be primarily interested in standards related to product efficiency and to quality management systems (such as ISO 9000). A sector that competes primarily on the basis of performance, however, may be more concerned with compatibility and diffusion of technology (cf. Table, Appendix B).

— The importance of standards varies from sector to sector.

In addition to globalization, the past two decades have seen the emergence of regional trade blocks, most notably the 15-country European Union (EU) and North America (*North American Free Trade Agreement* or NAFTA), but also including the Asia-Pacific Economic Cooperation (APEC), the European Free Trade Area (EFTA), the Mercosur Forum, etc. The pressure to adopt common standardization practices is particularly strong within these blocks. The EU, for example, is developing a Union-wide conformity assessment system. For their part, Canada, Mexico and the United States have been addressing common standards issues under Chapter 9 of NAFTA. They are also among the 34 countries that have agreed to address standards-related issues within the Free Trade Area of the Americas (FTAA).

Counterbalancing the trend towards regionalization has been the work of specialized international organizations mandated to promote internationalization in specific areas of standardization For example: ISO and IEC promote international standards development; the Bureau internationale des poids et mésures (BIPM) promotes common measurement (metrology) standards; the International Laboratory Accreditation Cooperation (ILAC) promotes common calibration and testing lab accreditation practices; and the International Accreditation Forum (IAF) works toward common quality and environmental management systems. Although these organizations are usually comprised of national member bodies, they provide an important coordinative function for work undertaken at the regional level.

Whether at the regional or international level, growing trade increases the need for open and transparent standards development and conformity assessment practices. As trade grows, standards are needed to ensure product compatibility and inter-changeability, as well as precision in measurement. Similarly, consumers and purchasers continue to demand assurances of reliability and safety in products regardless of where in the world they are made.

Standardization issues are thus becoming an integral component of trade negotiations. The World Trade Organization (WTO) *Agreements on Technical Barriers to Trade* (TBT) and on *Sanitary and Phytosanitary Standards* (SPS), the *North American Free Trade Agreement* (NAFTA) Chapter 9 "Standards-Related Measures," and the Canadian *Agreement on Internal Trade* (AIT) all require that domestic regulations and voluntary standards adhere to two core principles: *most-favoured-nation* (MFN) and *national treatment*. MFN requires that the measures applied to one trading partner should not be "less favourable" (i.e., more demanding) than the measures applied to any other member of the trade agreement. National treatment requires that imported products not be treated less favourably than domestic products (e.g. regarding internal taxes and standards).

In addition, both the TBT and SPS agreements encourage countries to base domestic regulations or standards on international standards, except when

— *Standards and conformity assessment procedures are becoming important features of trade agreements.*

international standards would be ineffective or inappropriate for fulfilling the "legitimate objectives" of the domestic regulation or standard.

The agreements place an onus on countries to provide scientific evidence to justify deviation from an international standard.

The latest edition of the SCC's requirements for accreditation of standards development organizations (SDOs) (CAN-P-1D) incorporates all of the relevant provisions of the *SPS Agreement*, of Annex 3 of the *TBT Agreement* (Code of Good Practice), and of Chapter 9 of NAFTA (as well as ISO Guide 59 on standards development). Standards developed by accredited SDOs will therefore satisfy relevant international trade agreement requirements.

Conformity assessment involves assessing whether a product or system meets the requirements of technical regulations, standards or specifications. The field is defined by the TBT agreement as including "…sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations". In Canada, the SCC ensures that accredited Canadian conformity assessment organizations follow, or base their operations on, internationally-agreed procedures and guidelines. Examples include the ISO/IEC Guide 25 for the operation and management of calibration and testing laboratories, Guide 58 for the operation of systems for the accreditation of testing, calibration and measurement laboratories, Guide 62 for the registration of suppliers' quality systems, and Guide 61 for the operation of systems for the accreditation of registration organizations.

3. Canada's Place in the Global Economy

— *Canada depends on trade more than almost any other major industrial country.*

Canada depends on trade to a greater extent than almost any other major industrial country. Over the past 20 years, the value of Canada's exports has grown from 18 to 41 percent of its gross domestic product (GDP). Continued access to foreign markets is therefore extremely important to Canada's economic performance. Access to trade opportunities also provides a valuable source of employment. Every $1 billion in exports supports on average 11,000 jobs.

The growing importance of trade to the Canadian economy is perhaps best illustrated by the fact that the value of international exports exceeds the value of internal trade for all provinces, except Prince Edward Island. Indeed, Canada now produces more for the American market than it does for its own.

— *Most of our trade is accounted for by a few large companies, many of which trade within their own organizations.*

Canadian companies participate in international trade at sharply different rates. Sales by large companies represent 90 percent of Canadian exports, with five firms (GMC, Ford, Chrysler, IBM and Noranda) accounting for approximately a quarter of this total.

Table 1

Canada's Exports of Goods—by Sector*

Automotive	$22.2
Machinery	$21.5
Industrial	$16.8
Forestry	$10.3
Agriculture	$ 7.4
Energy	$ 7.0
Consumer Goods	$ 3.3

Source: Department of Foreign Affairs and International Trade Canada, 1998. *Billions of dollars, First quarter of 1998.

— *Canada is primarily a "standards-taker."*

Canada's relatively small share of world trade (about 3%), as well as other factors including high foreign ownership and traditionally low investment in research and development, mean that Canada is a net technology importer, and hence a net standards-taker in most fields rather than a standards-maker (although there are some notable exceptions). Unlike the U.S., Canada must rely much more on harmonizing with standards developed by international consensus or by our major trading partners. Standardization practices adopted inter-nationally and in other countries are therefore of vital interest to

Canadians where these impact on the exportability of our products and services.

The significance of trade to Canada's economic well-being and the increasing emphasis on trade as a vehicle for growth make it important for Canadians to participate in international and regional standardization activities that affect exports and imports. Canada needs to ensure that foreign and international standards and conformity assessment procedures do not unjustifiably discriminate against Canadian products, particularly in the industry sectors that are most important to Canadian trade. Likewise, Canada is obliged to ensure that our standards and conformity assessment practices do not unjustifiably impede imports into Canada.

The following examples illustrate the potential adverse effects that foreign standards and standards processes can have on Canadian exporters:

- Japanese agricultural law prohibits foreign organizations from administering certification and quality control programs. This prohibition increases the cost to Canadian producers of complying with Japanese agricultural standards, thereby reducing their ability to compete in that market.

- China requires that manufacturing facilities of boilers and pressure vessels be inspected by officials from the Ministry of Labour before the product can be imported. This process requires that companies cover the costs of inspection, including travel for the Chinese inspectors. These costs can be onerous for small and medium enterprises (SMEs).

— It is important for Canada to develop MRAs and monitor and participate in international and regional standardization activities.

Canadians are active participants in organizations that develop international voluntary consensus and *de facto* standards. Canada is the 10th most active country in ISO, providing the international secretariats for numerous technical committees, including those developing the ISO 9000 and 14000 series of standards, and also for several important industries affecting Canada's industrial growth, such as for paper, board and pulp, nickel and nickel alloys, and timber structures. Canada's participation in the International Electrotechnical Commission (IEC) is comparable to that of ISO. Canadians also participate in many of the other organizations that develop standards used internationally. These include various prominent American SDOs, including the Institute of Electrical and

Electronic Engineers (IEEE), the American Society for Testing and Materials (ASTM), the American Society for Mechanical Engineers (ASME) and the Society of Automotive Engineers (SAE).

Canada is also placing considerable emphasis on negotiating mutual recognition agreements (MRAs), whereby two or more countries agree to recognize each others' test results, certification marks, laboratory accreditation, and quality / environmental management systems for a given trade sector or area of conformity assessment. Canada has signed several such agreements in recent years and is actively pursuing others at a multilateral level. MRAs are expected to become a major instrument to promote trade liberalization in the coming years.

Trade is very important to our economy, yet Canada's ability to influence international negotiations on issues such as standards is, broadly speaking, limited. To be sure, Canada's participation rate and effectiveness in ISO and IEC technical committees is quite strong and in many key sectors Canadians have played leadership roles (e.g. ISO 9000 and 14000). The fact remains, however, that Canada's share of international trade, and thus our economic "weight" in the world, is much smaller than countries such as Germany, the U.S. and Japan. Canada therefore needs to be well prepared and focused if it wishes to influence the international trading regime in standards-related areas and issues.

More importantly, Canada must deploy its limited resources strategically within the vast world of international standardization activities. The costs of participating in international standards development can be very significant, even for multinational corporations. They are even more so, of course, for small and medium-sized enterprises and for non-governmental organizations (NGOs).

Canada's ability to influence international standards is largely a function of its economic strengths and weaknesses. Thus, the opportunity for Canada to influence a standard either domestically or internationally for a product developed largely outside the country (e.g., automobiles) is much lower than for one where Canada is a technological leader (e.g., telecommunications networks). It also depends, to a growing extent, on

— Canada should focus its international standardization participation as strategically as possible.

— Canadian standardization activities must account for the American market, which represents over 82% of Canadian exports.

sufficient domestic private sector interest and willingness to provide funding.

While the Canadian Standards Strategy should be outward looking in general, it will be particularly important for it to recognize the size and importance of the US market. Canada's trade and investment relationship with the United States is quantitatively and qualitatively different from that with any other country. Canada and the United States are each other's largest trading partners, with two-way trade in goods and services valued at approximately half a trillion dollars last year. In 1997, Canada exported $244.1 billion in goods to the United States, representing 82 percent of Canadian merchandising exports. A Canadian Standards Strategy will therefore have to take account of American standardization activities and trends.

Table 2

Canada's Exports of Goods—Major Destinations

United States	82.5%
European Union	5.6%
Japan	3.0%
Other OECD Countries	2.6%
Other Countries	6.3%

Source: Department of Foreign Affairs and International Trade Canada, 1998

Because of the inter-connectedness of our economies, Canadian and American agencies have been cooperating closely to reach mutual recognition agreements in metrology, testing and certification, and quality systems registrars. For example, the SCC and the US National Institute for Standards Technology (NIST) signed an agreement in 1994 for the mutual recognition of the accreditation of testing laboratories. And for the benefit of an industry that exports $1 billion in fasteners annually to the U.S., the SCC has finalized an agreement with the NIST Accreditation Body Evaluation Program to conduct tests in Canada on Canadian fasteners and fastener metals bound for U.S. markets. In 1997, the SCC also signed an MRA with ANSI and the U.S. Registrar Accreditation Board for accreditation of quality management systems registration organizations.

If common international standards are increasing in importance to Canada, harmonized provincial standards are becoming relatively less visible. This trend is largely the result of the growing scope of north-south trade between Canada and the United States. Nevertheless, inconsistent provincial standards and regulatory requirements increase costs to business and thus reduce the competitiveness of Canadian industry. These costs have been estimated at about $125 million (half of which are in the trucking industry), or less than 0.1 percent of the value of interprovincial trade.[2] It bears mentioning that hard economic estimates of the effect of differing standards, technical regulations, and conformity assessment practices are notoriously difficult to establish. This is particularly true in the case of differing occupational qualifications and profes-sional standards across the provinces in fields such as medicine, law, education, and construction (the focus of work under the *Agreement on Internal Trade*).

4. Canada's Economic and Trade Policy Objectives

— *Canada favours multilateral mechanisms for promoting compliance with international trade rules.*

Globalization makes it more difficult for national governments to pursue independent economic or social policies and to shelter selected industries. Canada's domestic policies —as much as its international policies— must take into account global conditions, including trading rules and barriers to trade.

As a country heavily dependent on external trade, Canada has a strong interest in effective trade rules to ensure stable economic growth and to prevent bigger and more powerful economies from operating outside these rules. As a small country neighbouring a super-power, Canada has traditionally championed multi-lateral solutions to international problems. This is why, among other things, Canada has consistently promoted the development of open and fair international and bilateral trading systems, and continues to participate in the entire range of WTO activities.

Canada's international trade policies and priorities include:

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[2] TCI Convergence Ltd. 1997: Standards Related Barriers and Constraints to an Open Internal Market.

- *Managing the Canada-U.S. economic relationship*. This is the top priority, reflecting the high trade dependence on the U.S. for the Canadian economy, the high rate of two-way foreign direct investment, the frequent movement of people across the border, and the costs —both real and potential— of non-harmonized standards and regulations. Officials consider this to be the most complex and substantial economic relationship between any two countries in the world.

- *Establishing an effective WTO*. Canada seeks to support the role of the WTO as a strong, credible and transparent multilateral rules-based institution. Canada will also be preparing for WTO negotiations in new market framework policy areas, such as investment and competition policy.

- *Improving international rules governing foreign direct investment and anti-competitive behaviour*. This strategy involves negotiating bilateral and regional foreign investment protection agreements with developing economies and economies in trans-ition. As well, Canada is concerned with establishing greater vigilance regarding the anti-competitive behaviour of large multinational corporations.

- *Widening Canada's network of free trade partners*. The Government seeks to widen its network of free trade partners to improve market access for Canadian exporters. In particular, this will be done within the context of NAFTA, the Free Trade Area of the Americas (FTAA), the Asia-Pacific Economic Cooperation (APEC), and the WTO. A longer-term objective is to seek free trade status with the European Union.

5. The Federal Government's Regulatory Reform Objectives

Regulatory reform is also an important priority for the Federal Government (and a priority that is growing in importance for many provincial governments). Regulatory reform essentially entails reducing the burden of regulation on the economy and finding new ways of "regulating smarter." The federal government's current regulatory reform strategy recognizes the important contribution standardization (i.e. both standards development and conformity assessment) can make to improving the efficiency of Canadian business and opening up new markets at home and abroad.

The Federal Regulatory Policy requires government policy makers and regulators to consider standard-ization as either an alternative to government action or as a means of developing and enforcing legislative requirements. Furthermore, regulatory reform objectives support efforts to encourage the private sector to develop standards and conformity assessment practices that allow for industry coordination and compatibility or that protect health, safety, and the environment.

— Federal regulatory policy supports the use of voluntary standards wherever possible and appropriate.

In December, 1994, the Treasury Board announced a package of measures on regulatory reform. At the same time, Industry Canada announced the government wide action plan, Building a More Innovative Economy (BMIE). The plan is designed to help Canadian companies increase sales and create jobs in the global marketplace. As part of those two related initiatives, the government then developed the Standards Initiatives Program (SIP).

Under the SIP, the Federal Government initiated a four-year program to promote economic growth through standardization. This $8 million program has funded initiatives to:

— Standardization could play an important role in supporting government efforts to promote "smart regulation," public-private partnerships, and self-management.

- promote Canadian intergovernmental co-operation to reconcile conflicting standards and regulations;
- increase the international recognition of Canadian conformity assessment activities;
- negotiate mutual recognition agreements in key markets;
- show how the National Standards System (NSS) can provide a framework of consistent, accepted international standards and make regulation more efficient through the use of voluntary standards; and
- introduce new technology in the system.

SIP has four main "policy pillars": internal trade, international trade, technology diffusion and regulatory reform. The Standards and Regulatory Reform Program (SARRP) is part of the final pillar. SARRP activities include: the identification of opportunities within government for more effective use of the NSS; increasing the buy-in of regulators (e.g. Health Canada, Ontario Ministry of Health) and the public to the advantages of using voluntary standards-based systems for regulation; the development of management systems to promote the effective use of these systems; and the

— SARRP is an important vehicle for the federal government's efforts to promote opportunities for regulators to use the NSS.

creation of a fund for projects that demonstrate and test the advantages of greater reliance on standards-based systems. One of the projects funded by SARRP was the development of a Guide that can be used by government officials to determine when to use a voluntary standard or a conformity assessment process as a complement or alternative to regulation and traditional regulatory compliance methods.

6. Current Issues and Challenges in Standardization

6.1 Rationale for a CSS:

Possible objectives:

- *strategic participation in international and regional standardization bodies;*

- *further integration of standards development efforts with trade agreements;*

- *timely and effective participation by all relevant stakeholders in domestic and international standardization activities;*

- *faster standards development processes and less onerous conformity assessment requirements;*

- *reform of the current standards infrastructure to support overall strategic directions and priorities;*

- *better integration of voluntary standards and regulatory systems.*

Development of a Canadian Standards Strategy requires the SAC to identify and address a number of issues and opportunities that are confronting the Canadian standardization community. Globalization, rapid technological change, trade agreements, and the importance of international standardization activities are placing new pressures on the National Standards System. These pressures are intensified by resource constraints in governments and in the private sector (both at the industry and NGO level).

A Canadian Standards Strategy will mobilize the capacity of Canada's standards system to respond more effectively to the demands of the emerging global economy. It will allow for an increased international orientation of Canadian standardization activities, providing an informed basis for deciding where best to focus participation in international standardization activities. It will provide guidance to the government's efforts to help open up foreign markets through the harmonization of standards and conformity assessment processes with our major trading partners. It will respond to the pressures from businesses to reduce the costs and time associated with standards development and with third party conformity assessment processes. It will also address concerns from consumer represent-atives, environmental groups and other public interest bodies about the time and cost required to participate effectively in standards development activities, particularly as more of these occur at the international level. And it will provide clear direction to the domestic standards community, help support government efforts to promote "smart" regulation, and enhance public-private partnerships in protecting Canada's social, environmental and economic well-being.

6.2 Four Key Areas for the SAC to Consider:

This section groups the various issues and opportunities introduced above into four broad and overlapping categories. A series of exploratory questions accompanies the discussion in each category. These categories and questions could form the basis of preliminary agendas for SAC working groups. If the SAC proceeds with such groups they may want to determine whether additional categories or questions should be added, and will need to prioritize the issues to be explored before the agendas can be fully developed.

The four categories are:

i. ***International trade*** —improving market access by harmonizing standards and conformity assessment requirements with key trading partners;

ii. ***International standardization activities*** — enhancing Canadian interests through strategic participation;

iii. ***Domestic standardization activities*** —responding to process concerns and re-organizing and renewing the infrastructure; and

iv. ***Role of Canadian governments*** —developing a more strategic relationship with standards activities.

i.   International Trade:
improving market access by harmonizing standards and conformity assessment requirements with key trading partners

Standardization has become a trade policy issue. At the international level, the progressive lowering of tariffs under the GATT/WTO and multilateral trade agreements has brought into focus the discriminatory trade effects of differing standards, technical regulations and conformity assessment requirements. These can impose additional and unjustifiable transaction costs on businesses wishing to export, and can serve to retard development of new markets abroad for Canadian products and services.

— *Should Canada use trade agreements to limit the potential for countries to use standards and conformity assessment requirements as non-tariff barriers? If so, how?*

In trade organizations such as the WTO, APEC and NAFTA, as well as standards and conformity assessment fora such as ISO, IEC, ILAC, and the IAF, Canada actively supports efforts to remove or otherwise limit the negative impact of these new non-tariff barriers by subjecting standards and conformity assessment practices to agreed-upon multilateral rules and arrangements. International agreements on standardization issues are expected to proliferate in the coming years.

The WTO *TBT Agreement* encourages members to accept other members' product tests and approvals as long as they provide equivalent guarantees in terms of quality, health, safety and other requirements. At the bilateral and multilateral levels, Canada is an active proponent of mutual recognition agreements (MRAs). Agreements can be negotiated between governments (e.g., the recently signed Canada-EU MRA), between accreditation bodies (e.g., the agreement between the SCC and the American National Standards Institute and the Registrar Accreditation Board on quality registration), and between testing and certification organizations (e.g. the agreements on electrical equipment testing with standards bodies from more than 30 countries under the IECEE CB Scheme).

MRAs confer various benefits. For the exporter, regulated products covered by a government-to-government MRA can be distributed in the importing country without additional testing or certification. Accordingly, exporters can avoid the additional costs and delays of duplicate testing. In addition, the risk of the importing country using reverse engineering to appropriate proprietary technology (on the basis of knowledge gained through testing for conformity with a domestic standard) is somewhat reduced.

— Canada should have a coherent strategy for the development of MRAs.

In the non-regulated products area, the benefits of an MRA are similar to the above; except that products complying with voluntary standards typically do so to assure purchasers and consumers rather than regulators.

Given the importance of these agreements, the SAC should consider the adequacy of Canada's overall strategy for the negotiation of MRAs —for determining which countries, which products or sectors, and which testing, certification, accreditation and registration processes should be targeted. A central issue in an MRA strategy will be how best to ensure and pay for appropriate input into negotiations.

— Should Canada be involved in the export of standards and codes, or provision of technical assistance to newly industrialized countries?

The SAC might also consider whether there are other standardization activities which could be pursued to enhance Canadian trade opportunities:

- The Canadian government could help Canadian exporters become more vigilant against potential standards-related trade barriers in other countries. The US Trade Representative, for example, annually publishes a list of foreign standards-related barriers that discriminate against US exports. Should Canada do the same?

- The Canadian government could also seek additional trade benefits from domestic standards. Some countries are actively exporting their standards and codes as a means to enhance trade opportunities (e.g., Germany to China). Should Canada do the same?

International Trade: Areas for Possible Focus

International Trade Agreements:

- Is Canada adequately addressing standards issues in international agreements, such as the WTO TBT, NAFTA, and in other international fora, such as APEC and the Pan American Commission on Technology Standards (COPANT)

- What steps should Canada take to ensure that Canadian standardization interests are adequately addressed in future WTO negotiations and in other multilateral trade negotiations?

- Are Canadian governments adequately protecting Canadian exporters against foreign standards-based barriers to trade?

Mutual Recognition Agreements (MRAs)

- How is Canada deciding which MRAs to enter into? What changes to Canada's strategy towards MRAs, if any, are required?

Exporting Standards and Technical Assistance

- What should be Canada's role in the export of standards and the provision of technical assistance?

Participation and Coordination of Input

- What level of support should Canada provide to help relevant stakeholders participate in these decisions and processes?

Resources

- What are the resource implications of the SAC's recommendations on these issues?
- Who should support whatever increased resources are required?

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ii. International Standardization:

enhancing Canadian interests through strategic participation

— *International, regional and bilateral standardization activities are increasing rapidly in importance, frequency, and diversity.*

International standardization activities are increasing in importance and frequency for two related reasons. Globalization has created an unprecedented economic interest in common standards and conformity assessment procedures. At the same time, trade agreements such as the GATT/WTO and NAFTA now require participating countries to consider the use of international standards in developing rules to guide industry.

This increased reliance on international standards has significantly enhanced the strategic importance of linking domestic regulatory and standards development initiatives to international trends. Both the federal Regulatory Policy and the SCC criteria for the development of National Standards of Canada require consideration of international standards. Of the 556 National Standards of Canada developed between April 1994 and April 1997, 443 (78 percent) were based on international standards. Similarly, 100 of the 117 National Standards established in 1996-97 (85 percent) were based on international standards.

Just as international standards have become more important, so too have their number and source increased dramatically in the last decade. ISO, for example, is now publishing about 350 standards a year, more than twice as many as twenty years ago. As recently as 1957, there were only a few dozen ISO standards. In 1987 there were about 7000. By the end of 1997, there were almost 12,000.

Many international standards are developed by formal bodies with broad international representation, such as ISO and IEC. Some standards used internationally are developed by American SDOs which have achieved an internationally preeminent position in some areas (e.g., the American Society of Mechanical Engineers' internationally recognized Boiler and Pressure Vessel Code). Other international standards are developed by NGOs (e.g., the Forest Stewardship Council's certification program for sustainable forest management). Other standards are industry-driven, emerging through marketplace competition as the preferred *de facto* standard. In some cases, a group of companies with a shared interest in an issue will develop what is known as a "consortium standard."

— The internationalization of standards creates opportunities as well as challenges for a trade-oriented country like Canada.

The growing importance of international standards in a global economy (and for Canada's export-oriented economy in particular) has increased the importance of—and challenges associated with—participating in international standard-setting activities. Canadians must ensure that their interests (as a nation, as individuals and organizations concerned about specific public interest issues such as environmental protection and consumer choice, and as firms and industries) are reflected in international standards. Participation in standardization also often yields important intelligence that benefits Canadian industries, particularly those that are directly represented in the standards development process.

A recent ISO example illustrates the importance of international participation. A European member of an ISO subcommittee recently proposed changing the long-established industrial reference temperature for measuring length from 10 to 23 degrees Celsius, a change that would have cost Canadian industry more than $200 million. Canada's involvement on this subcommittee gave it early warning, however, and industry was able to mobilize and defeat the proposal.

— Failure to maintain an ongoing presence in international standardization activities could be very costly for Canada.

Just as Canadians must participate in international standards setting, they should also participate in bi-national standardization activities. Largely due to the growing importance of NAFTA trade, bi-national (primarily U.S. – Canada) and tri-national (North American) standardization activities are increasing in frequency and importance. The SCC has sponsored, together with its NAFTA counterpart bodies, an annual North American Trilateral Standardization Forum that provides an opportunity to open up trading channels by reconciling differences in the voluntary standards used in the three countries.

— International participation is resource intensive, and should be targeted strategically.

The growing importance of international standards raises particularly difficult questions about participation and resources. Transnational corporations (TNCs) play a large role in international standardization activities. They have a vested interest in the outcome. They account for three-quarters of world trade in manu-factured goods, and they can afford to participate in the process. Indeed in some cases, a single TNC will coordinate the input of several subsidiaries working

through different national standards bodies to increase its influence over the standard or conformity assessment requirement being developed. By contrast, however, smaller companies and organizations have significantly less ability to participate in, and influence, international standard setting.

— Canadians want training to enhance their ability to participate effectively in international standardization processes.

In addition to ensuring that Canadians participate in the appropriate international fora, it is important they be prepared to participate effectively. A recent survey conducted by the SCC found that participants in international standards development want the SCC to provide more training, financial support and access to information to support their participation. The current lack of training for Canadian participants should be contrasted to the active support provided to participants from some other countries, including the U.S.

— Recent arrangements between the EU's main standardization bodies and ISO and the IEC may affect the ability of Canadians to influence standards development decisions.

The agreements concluded between CEN and ISO and between CENELEC and the IEC raise an additional issue for Canadian participation in international standardization activities. These agreements provide for fast-tracked adoption of EU standards by the ISO and the IEC. There may be here a need for better understanding of these agreements and their impact on the part of Canadian ISO and IEC delegates.

— Concerns about the time required to develop standards are presenting fundamental challenges to the traditional requirements of consensus and balance.

The SAC should also consider addressing the recent challenges to the traditional requirements of consensus and balance that are now being debated at the international level. Globalization and the increasingly rapid rate of technology development and the resulting decline in many product life spans are creating pressure both to speed up the time required to develop standards and to reduce the costs associated with assessing conformity with them. These pressures, in turn, are calling into question many of the traditional approaches to standards development and conformity assessment, including the requirements for consensus and balance in the standards development process.

The speed of technological change presents new challenges for standardization bodies. Although in recent years, international standards organizations, such as ISO, have cut the time to develop a standard in half, this pace is still too slow for some industries, resulting in those industries establishing by themselves the standards

they need. As ISO and the IEC have noted, "this trend is splintering the global standards effort and eroding the democratic principles enshrined in the directives that govern ISO and IEC."[3]

The main impediment to a faster standards development process is the traditional requirement for consensus decision making, as the IEC noted in its 1994/95 annual report.

Some SDOs have sought to address these concerns by enhancing their internal capacity to develop standards and to respond to rapidly evolving technologies. IEC, for example, now uses Technology Trend Assessments and an Advisory Committee on Future Technology.

Recognizing that there may be limits to the degree to which they can streamline the process for developing a formal consensus standard, both ISO and the IEC are now also offering alternative products. The IEC recently approved industry use of technical agreements, which are minimum specifications for fast-moving technology. And ISO is considering ways to speed up the process by skipping steps or adopting industry documents as first drafts of standards.

— Concerns about the cost of obtaining third-party certification or registration are leading many companies to favour self-declaration.

Cost considerations are also leading some multinational companies to question the need for third party conformity assessment processes. Third party testing, certification or registration are often required by law or by large upstream purchasers. However, in some instances, this can be considerably more expensive than self-declaration, with no discernible reduction in risk or value-added improvement to the purchaser or customer. Where the market will permit, some sectors, notably information technology, have begun to demand self-declaration as a means of attesting conformity with a standard and to reduce delays in bringing products to market. In some cases, this trend has received some degree of government endorsement. For example, self-declaration has much broader acceptance by governments in Europe and the U.S. than in Canada.

Even large companies are finding the requirements of the international standards system onerous. In April of this year, fifty-eight multinational companies in the

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[3] CONSENSUS, SCC, Vol 25, No. 7, Nov. 1996, p. 4.

telecommunications, aerospace, automotive and high-tech sectors met in Munich under the auspices of the International Committee on Standards and Conformity Assessment, to protest the high costs of standards and testing practices and the proliferation of standards that require third party registration by purchasers. In the resulting 40-resolution "Munich manifesto", these multinationals called for suppliers to self-declare conformity to the ISO 9000 quality assurance standards by 2005.

<u>International Standardization</u>: Areas for Possible Focus

<u>Priority setting</u>

- How should Canadians set priorities regarding participation in international standardization?

- Should Canada set priorities by region? By sector? If so, how?

- How should Canada decide when to be a standards leader and when to be a standards-taker?

- Should specific industries or sectors be targeted for standards development or other attention (e.g., intelligence gathering, communication, coordination of input or feedback)?

- When should Canada align its standards with U.S. standards and when with international standards (e.g., ISO)?

Are Canadians gaining appropriate benefits from the information gained by participants in international standardization activities? If not, what measures should it put in place to access and disseminate standards intelligence derived from Canadian participation in international standardization work?

<u>Participation</u>

- How should Canadians ensure adequate input into relevant international and bi-national standards development processes from: industry associations? individual businesses? SMEs? consumers? labour? NGOs?

<u>Training</u>

- Should Canada consider establishing strategic standards training and education programs to support Canadian participation in international standards development processes?

<u>Challenges to the consensus requirement</u>
- What position should Canada take on the emerging pressures on international SDOs to develop standards more quickly, and to reduce or eliminate the requirement for consensus?

- What are the implications of a possible decline in the development and use of consensus standards for Canadian industry (e.g. the high tech sector, worth $16 billion/year in exports)?

- What are the liability and due diligence implications for manufacturers if SDOs move away from the consensus process to use a more streamlined process with narrower participation?

<u>Resources</u>

- What are the capacity implications of the SAC's recommendations on the above issues? Who should support whatever increased resources are required?

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iii. <u>Canadian Domestic Standardization Activities:</u>

a) *Responding to process concerns*

— *Any change to the consensus requirement should respect the need to ensure due process and input from affected parties within Canada.*

b) *Re-organizing and renewing the infrastructure*

— *How should priorities be set and participation encouraged with respect to Canadian standardization activities?*

The concerns described in the previous section about the time and cost associated with relying on the consensus process and with utilizing third party conformity assessment processes are primarily relevant to international standards. Some businesses in Canada are starting to articulate similar concerns, however. Similarly, one of the main impediments cited by government officials to the increased use of the NSS by government is the time required to develop a standard by the consensus process.

Simultaneous with these pressures for faster processes, the proliferation and increased significance of standards are leading to growing demands for enhanced transparency, participation opportunities and accountability. These demands are coming primarily from public interest advocates, but in some cases also come from smaller businesses concerned about anti-competitive behaviour.

The key challenge will be to respond to these pressures while ensuring that the national standards system continues to respect due process, provides Canadians with a measure of control over their standards, and safeguards environmental and human health protection objectives.

Over the past three decades, Canada's standardization regime has grown into a highly complex system of public and private sector institutional partnerships encompassing a broad array of standards development, testing, certification, and registration organizations at all levels of government and industry. Although this system is rightly perceived as one of the most effective and efficient in the world, one of the most important challenges facing the SAC will be to review and assess this system, and to provide recommendations for improving or strengthening it in response to the many changes brought about by globalization and other forces of change in recent years.

In addressing this issue, the SAC will have the benefit of the considerable amount of strategic thinking on this topic conducted in recent years. There have been a number of academic and government-sponsored

commentaries on the NSS. The SCC conducted a national survey and study in the mid-90s. That study led to a series of recommendations to government and, ultimately, to the amendment of the SCC Act and restructuring of the SCC. Following those reforms, the newly constituted Council developed a three-year Strategic Plan for 1998-2001.

Issues that might be appropriate for the SAC to consider under this topic, include:

- *Mechanisms for ensuring adequate input:*

As a rule, Canada establishes both domestic and international standardization priorities on the basis of informed and timely input from the full range of affected parties. The development of a new National Standard of Canada is typically supported by input from relevant experts and social perspectives. Similarly, Canada's contribution to international standardization activities should reflect relevant domestic expertise and perspectives.

Infrastructure issues confronting the NSS include:

- *coordinating input into standardization decisions;*
- *coordinating federal and provincial standards related activities;*
- *access to information;*
- *education and awareness;*
- *funding adequate participation among SMEs and NGOs.*

These objectives require considerable institutional support. The SAC could review the adequacy of the current mechanisms and processes in place to provide input to the SCC, the various SDOs and to Canada's international delegations, among others.

- *Coordination among governments:*

As is the case with numerous other types of inter-national agreements that Canada enters into, there is often a need to involve the provincial and territorial governments in the negotiation of international standards related agreements. The federal government recently completed the negotiation of a mutual recognition agreement with the EU addressing, among other things, electrical safety standards. Although this is an issue within provincial regulatory jurisdiction, the federal negotiators did not seek provincial and territorial input into the negotiations until very late in the process. The SAC could explore options for minimizing the likelihood of a similar problem arising in the future by seeking ways to improve federal-provincial coordination on standardization issues.

- *Information dissemination*:

The SCC spent considerable time, energy and money in developing its Internet-based Standards Information Service of Canada (SISC). This system has greatly enhanced the ability of all Canadians to access standards related information. It has also created the technological capacity to support electronic monitoring or even active participation in standards development processes. It would nonetheless be useful to ask what information support gaps exist, and how they should they be filled.

- *Education and awareness:*

Although most large exporters appreciate the strategic importance of standards, too few Canadian businesses and governments do. One of the main focuses of both the Federal Standards Initiatives Program and of the SCC is increased awareness of standards. A great deal needs to be done in this area, such as to provide standards briefings to participants involved in international trade trips, such as Team Canada, before they depart.

- *Participation and cost:*

For Canadian standards to continue to be effective and credible, it will be necessary to support their development with the appropriate expertise and representation of interests. The transition from a primarily domestic focus in standardization to a dominantly international focus, however, has important resource and logistical implications. The negotiation and implementation of international agreements adds costs over and above those required to operate the domestic system.

Canadian Domestic Standardization Activities: Areas for Possible Focus

Demands for New Products and Processes:

- How should the NSS respond to the demands from the marketplace for faster standard setting processes and new products while continuing to fulfill the objectives in s. 4 of the *Standards Council of Canada Act* (promote sustainable development, protect the health, safety and welfare of workers and the public, and assist and protect consumers*)*?

- How should the NSS balance the demands for faster standard setting with the requests for enhanced transparency, participation opportunities and accountability? Are any changes required in current processes to address these tensions?

- In what circumstances (if any) should the SCC and SDOs change or relax the traditional emphasis on consensus and balance?

Institutional arrangements

- Is the NSS structured appropriately to coordinate Canadian input into domestic standardization decisions? Into international activities?
- Is the NSS structured appropriately to coordinate federal and provincial standards related activities?

Education and awareness

- What measures should be taken, and by whom, to enhance public and private-sector awareness and understanding of domestic and international standardization activities?

Access to information

- Is the SCC's Standards Information Service of Canada fulfilling its objectives?
- What, if any, additional measures should be taken to enhance the dissemination of information to Canadians on standards and conformity assessment practices?

Participation

- Are standards development and conformity assessment activities supported by adequate levels of participation by SMEs, labour, consumer organizations, and NGOs?
- If not, what should be done to ensure effective input into Canadian standardization decisions from all affected parties?

Resources

- What are the capacity implications of whatever recommendations the SAC makes on the above issues?
- Who should support whatever increased resources are required?

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iv. **Role of Canadian Governments:**

Developing a more strategic relationship

— *At the same time as government support for standardization activities is declining, governments and regulators are making greater use of voluntary standards and standards processes.*

The relationship between Canadian governments and the NSS is characterized by two somewhat inconsistent trends. On the one hand, the federal government has reduced its financial support for NSS activities. Its contributions to the SCC have declined from 80 percent of operating costs to about 50 percent over the last decade. Similarly, it has significantly curtailed the attendance of government officials at international standardization meetings. On the other hand, there has been an expansion in reliance on voluntary standardization activities as supplements or alternatives to direct government regulation and control, particularly at the provincial and municipal levels. There has also been a dramatic increase in the number of government laboratories seeking specialized accreditation under the SCC PALCAN program. These trends, together with the increased pressure being placed on the standards

— How can governments most effectively support both domestic and international voluntary standards-related activities?

system as a result of the dynamics described in the previous parts of this paper, suggest that it will also be important for the SAC to review the relationship between Canadian governments, both federal and provincial, and the NSS.

Ideally, the Strategy articulated by the SAC will iden-tify how Canadian governments can most effectively support the basic objectives of the Strategy. At a minimum, this will require determining how both the Federal and provincial governments can best support the previous three issue themes (i.e., trade agreements, international standardization and the NSS).

— In what circumstances should governments seek to incorporate voluntary standards or standards-based conformity assessment processes into their regulatory regimes?

Articulating a more effective government role will also entail addressing various issues related to the way in which Canadian governments make use of standards and conformity assessment processes. At the same time as standards are becoming increasingly important determinants of economic competitiveness for Canada's businesses, Canadian governments are starting to make greater use of the NSS and of international standards for regulatory purposes. The federal government, for example, frequently incorporates voluntary standards into legislation as mandatory standards. Similarly, it is increasingly relying on the private sector to ensure that some public interest is met. In some cases, for example, it relies on industry to inspect specified products or services. In other cases, it relies on industry to maintain management and production processes that reduce the risk of harm to the public.

The following examples illustrate some of the ways in which governments are increasing their reliance on standards processes to achieve their policy objectives:

* *standards development*: Health Canada has asked the CSA to develop a standard addressing organ and tissue transplant. The new standard will likely be incorporated into a regulation once it has been approved as a National Standard of Canada.

* *accreditation:* In 1989 Environment Canada helped establish the Canadian Association of Environ-mental Analytical Laboratories (CAEAL) to act as the partner accreditation body for environmental testing laboratories and to provide quality assurance and quality control for laboratory tests in the fields of chemistry, radiochemistry, microbiology and toxicology. In 1994, CAEAL and the SCC signed a

partnership agreement that formed the basis for an operational program in which the assessments of environmental laboratories are performed by CAEAL that lead to accreditation of these labs by the SCC.

- *third-party registration*: Health Canada is proposing to require the use of an international standard to ensure consistent quality of their medical device products. The proposed regulation would require manufacturers of specified classes of medical devices to undergo third party registration to the standard by accredited registrars. The role the SCC will play in this new activity has yet to be determined.

There are essentially three categories of questions related to the role of government. First, how can government most effectively support both domestic and international voluntary standards-related activities? Second, in what circumstances should government seek to incorporate voluntary standards or standards-based conformity assessment processes into its regulatory regime? Thirdly, to what extent can government departments partner with the SCC and the NSS for the delivery of voluntary services in a regulatory environment.

Role of Canadian Governments: Areas for Possible Focus

Government's role within the NSS

- What is the appropriate relationship between the federal and provincial governments and domestic, regional and international standardization activities?

Government incentives

- Should the federal and provincial governments play a role in encouraging standards development participation by providing incentives (e.g., tax incentives for participation costs)?

Standards and regulation

- Should the Strategy comment on the use of standards and conformity assessment processes in regulatory regimes or as alternatives to government regulation?
- What is the potential for standardization to create a national approach to issues where regulatory authority is shared among jurisdictions (e.g., food protection, environment, etc.)?

Appendix A: Glossary

AIT	Agreement on Internal Trade
ANSI	American National Standards Institute: a private sector body that coordinates the standards work of approximately 30 percent of the US SDOs
APEC	Asia-Pacific Economic Cooperation
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
APLMF	Asia-Pacific Legal Metrology Forum
APMP	Asia-Pacific Metrology Programme
ARSO	African Regional Organization for Standardization
BIPM	Bureau internationale des poids et mésures
BNQ	Bureau de normalisation du Quebec
CAEAL	Canadian Association of Environmental Analytical Laboratories
CAN-P-1	Standards Council of Canada, *Accreditation of Standards-Development Organizations*, CAN-P-1E, (Draft, 1998)
CAN-P-2	Standards Council of Canada, *Criteria and Procedures for the Preparation and Approval of National Standards of Canada*, CAN-P-2E, January, 1992
CCMSC	Caribbean Common Market Standards Council
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CGSB	Canadian General Standards Board
CO	Certification Organization: an organization accredited by the Standards Council of Canada (or equivalent foreign accrediting body) to certify products or services as meeting a particular standard
Conformity assessment	The determination of whether a product, process or service conforms to particular standards or specifications; including conformity assessment services such as: certification, testing and quality management or environmental management systems registration
Consensus	"substantial agreement reached by concerned interests involved in the preparation of a standard. Consensus includes an attempt to resolve all objections and implies much more than the concept of a simple majority, but not necessarily unanimity." (CAN-P-2E)
COPANT	Pan American Commission on Technical Standards
COPOLCO	ISO Committee on Consumer Policy
CSA	Canadian Standards Association
EA	European cooperation for Accreditation
EOTC	European Organization for Testing and Certification
ETSI	European Telecommunications Standards Institute
GATT	General Agreement on Tariffs and Trade
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation

ISO	International Organization for Standardization
ISONET	An information exchange network for members of ISO
ITU	International Telecommunications Union
JTC 1	ISO/IEC Joint Technical Committee on Information Technology
JESI	Joint European Standards Institute (comprised of CEN and CENELEC)
MFN	Most favoured nation: a trade principle that requires that the rules applying to one trading partner should not be "less favourable" (i.e., more demanding) than the measures applied to any other member of the trade agreement
MRA	Mutual recognition agreement: an agreement between or among standardization bodies or countries to accept some or all aspects of the other's work, e.g., accreditation, testing, certification
NACC	North American Calibration Cooperation
NAFTA	North American Free Trade Agreement
NORAMET	North American Metrology Cooperation
NIST	National Institute of Standards and Technology
NGO	Non-governmental organization, such as a consumer or environmental group
NSC(s)	National Standard(s) of Canada
NSS	National Standards System
OECD	Organisation for Economic Co-operation and Development
OIML	International Organisation for Legal Metrology
ORD	Other Recognized Document: a requirement that is submitted to regulatory councils for approval and used for certification by COs.
PAC	Pacific Accreditation Cooperation
PASC	Pacific Area Standards Congress
Responsible Care	An environmental and occupational health and safety program run by the Canadian Chemical Producers Association
SARRP	Standards and Regulatory Reform Program
SCC	Standards Council of Canada
SDO	Standards development organization
SPS	*Sanitary and Phytosanitary Standards Agreement:* a sub-agreement under the GATT focused on food and health standards that may affect international trade
Standard	"a published document which contains requirements, procedures or definitions for a specific activity" (CAN-P-2E).
TBT	*Technical Barriers to Trade Agreement*: a sub-agreement under the GATT focused on both mandatory "technical" regulations and voluntary standards, applying to all products, including industrial and agricultural products. Also known as the "Standards Code"
ULC	Underwriters' Laboratories of Canada
WTO	World Trade Organization: the international trade regime that succeeded the GATT

Appendix B: Overview of the Canadian and International Standards Systems

B.1 Standardization

Standardization is a broad term that denotes both standards development and standards implementation (including conformity assessment). This Appendix is intended to provide the SAC with an overview of domestic and international standardization organizations and activities.

B.1.1 Standards

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purpose.

For example, the format of the credit cards, phone cards, and "smart" cards that have become commonplace is derived from an ISO International Standard. Adhering to the standard, which defines such features as an optimal thickness (0.76 mm) means that the cards can be used worldwide. Standards thus contribute to making life simpler, and to increasing the reliability and effectiveness of the goods and services we use.

Traditionally, standards were primarily technical and were aimed at establishing measures to promote commerce or protect health, safety and consumers or provide for technical compatibility. They were often design standards that specified the characteristics of a product in order to ensure its fitness for purpose. More often today standards are being developed that specify performance characteristics with which the product must comply. Standards are now also being applied to a range of procedures and services that are "horizontal," covering multiple industries. Perhaps the best known examples of these horizontal standards are the ISO 9000 series of quality management standards and the ISO 14000 environmental management standards.

Standards may be classified into three categories: voluntary consensus standards, mandatory standards and *de facto* standards. **Voluntary consensus standards** are developed using a formal coordinated process in which participants seek consensus. Appendix B describes the standards development process used within the National Standards System (NSS). Appendix B also describes the international standards development process used by ISO. The use of the resulting standard is voluntary. An example of a voluntary standard is the one used for photographic film speed, ISO 100, 200, 400, etc.

Mandatory standards are set by government and are often found in a regulation. A voluntary consensus standard developed for private use may become mandatory when referenced in legislation, even across borders. An example is the U.S. Consumer Products Safety Commission performance standard for the Flammability of Children's Sleepwear (FF5-74) referenced by Canadian *Hazardous Products (Children's Sleepwear)* Regulations (SOR/87-443).

De facto **standards** arise from uncoordinated processes in the competitive marketplace. When a particular set of product or process specifications gains market share such that it acquires authority or influence, it is considered to be a *de facto* standard. Examples include some standards that allow for software and computer compatibility.

Standards fulfill a range of **functions** as described in the following table:

FUNCTIONS OF PROCESS AND PRODUCT STANDARDS

CATEGORY	EXAMPLES
COMMERCIAL COMMUNICATION: Standards convey information about a product to a buyer in a consistent, understandable manner.	**Construction materials**: standard dimensions, strength, and durability make it easier for the builder to select materials for specific purposes. **Film speed**: standard ratings (ISO 100, 200, etc.) simplify matching film to photographic needs.
TECHNOLOGY DIFFUSION: A technological advance incorporated into a standard is more readily adopted and used by others.	**Personal computing architecture**: the use of PCs expanded rapidly once IBM-compatibility standards came into being. **Advanced materials** (e.g., composites, ceramics): standards that describe processing and test methods allow duplication and improvement upon state of the art.
PRODUCTION EFFICIENCY: Standardization of parts, processes and products enables economies of scale in production.	**Automotive assembly line**: efficient mass production pioneered with Model T Ford. **Fast food chains** (e.g., McDonald's): food, restaurant style and architecture, equipment and procedures standardized for efficiency.
ENHANCED COMPETITION: When some or all of the features of different manufacturers' products conform to one standard, comparison is easier and competition sharper.	**Direct-dial long-distance telephone service**: competing carriers offer a standardized basic service; competition centers on price and extra services. **Gasoline**: octane ratings allow consumers to compare similar products on the basis of price.
COMPATIBILITY: Standards defining interfaces enable products to work together or communicate with each other.	**Internet**: standard format for sending and receiving data enables communication among computers worldwide. **Stereo system components**: various components can be connected with standard cables and jacks.
PROCESS MANAGEMENT: Manufacturers not only design products to conform to standards, they also organize the manufacturing process itself in accordance with standards.	**Numerically controlled machine tools**: standard computing languages allow rapid reconfiguration of product line. **Quality assurance**: ISO 9000 series of standards guides firms in setting up and maintaining a quality assurance management system.
PUBLIC WELFARE: Standards are an important mechanism for promoting societal goals, such as protection of health, safety, and the environment.	**Health codes**: restaurants conform to sanitary standards that are backed by inspection. **Automobile air bags, seat restraints and bumpers**: government-mandated crash protection.

Source: Standards, Conformity Assessment, and Trade Into the 21st Century, US National Research Council, Department of Commerce, National Institute of Standards and Technology (National Academy Press, Washington, D.C.: 1995), page 12.

B.1.2 Conformity Assessment

Conformity assessment is the comprehensive term for procedures by which products and processes are evaluated and determined to conform to particular standards. Conformity assessment activities essentially provide for third party recognition of some sort related to the activities of the body being accredited. The accreditation body will accredit calibration and testing laboratories,

management systems registration organizations, product certification organizations, auditor certifiers and auditor course providers. These bodies in their turn provide third party services for their clients.

Distinct from standards development, conformity assessment is a central aspect of the use of standards. Measures to evaluate and ensure conformity to standards can be as significant, or more so, than the standards themselves. Conformity assessment allows purchasers of products, whether they be individual consumers of industrial purchasers of material for production, to have assurances regarding the reliability, suitability for purpose or quality of the product. This helps increase consumer confidence. In turn, manufacturers benefit from potentially reduced liability and improved productivity. Governments are increasingly using conformity assessment processes to substitute for or complement government monitoring and enforcement. This often reduces the cost of regulation for the government (and taxpayers), but it may impose significant costs on industry. Such costs, in fact, exist whenever the processes are used.

In addition, large NGOs such as the power utilities and larger corporations have chosen to require their suppliers to be registered to one of the two primary ISO 9000 models, ISO 9001 or 9002.

Conformity assessment services related to monitoring and verifying compliance with standards include: certification, testing and management systems registration. **Certification organizations** (COs) attest that products or services conform to a standard by authorizing the display of their certification mark. They regularly conduct on-site audits and sampling and testing of certified products and services. There are 18 SCC-accredited COs in Canada today (9 Canadian, 9 American). These COs are required by the terms of the SCC accreditation to establish working relationships with the Regulatory Authorities appropriate to the products they certify as a means of demonstrating compliance with regulatory requirements.

Calibration and Testing laboratories (TOs) determine whether a product or service meets the appropriate standard. There are over 250 SCC-accredited calibration and testing organizations in Canada. They include private research laboratories, government and industry facilities, and most of the certification organizations.

The process of demonstrating conformity to a management standard is known as management systems registration. Management systems registration is a relatively recent arrival to the NSS with the first three Quality Management Systems (QMS) registration organizations being accredited by the SCC in February of 1993. **Management systems registrars** issue registration certificates to companies that meet one of the three ISO 9000 registration models for quality management or the ISO 14000 environmental management standard. At mid-1998, there were seventeen accredited management systems registration organizations in Canada, 15 QMS and 2 EMS.

The SCC also operates an accreditation program for those organizations certifying management systems auditors and auditor course providers, both QMS and Environmental auditors. This program began to accept applications late in 1997; no organizations had been accredited by the third quarter of 1998.

The SCC accredits the conformity assessment organizations and establishes the rules under which they operate. These organizations are also monitored by the SCC to ensure that they themselves conform with the SCC requirements.

There is growing interest by large multinational companies and manufacturers in **self-declaration of conformity assessment**, based on internal testing and quality assurance mechanisms. It is particularly popular in Europe, even within some regulatory regimes. Issues such as risk assessment and the ability of the purchaser to identify poor quality or risks are elements in determining what areas might be suitable for self-declaration. In many countries, incentives for the accuracy of self-declarations are found in stringent laws dealing with false declarations and product liability.

The benefits of conformity assessment are leveraged through the negotiation and implementation of **mutual recognition agreements** (MRAs). MRAs allow members of the agreement to reciprocally accept product tests and approvals, generally as long as they provide the equivalent guarantees in terms of quality, health, safety and other requirements. Products can therefore be distributed in the importing country without additional testing or certification. They also promote cooperation among countries and conformity assessment bodies by enhancing transparency and promoting long-term harmonization. An example of an MRA is the one recently concluded between Canada and the European Union dealing with telecommunications equipment, electromagnetic compatibility, recreational boats, medical devices, pharmaceutical goods manufacturing practices, and electrical safety. The EU itself has taken a global approach to conformity assessment by adopting the rule that goods manufactured according to the EU's requirements will be permitted to display the CEN mark and circulate freely within the EU without additional requirements for conformity assessment.

B.2　Canada's National Standards System

The National Standards System (NSS) is the system for developing, promoting and implementing standards in Canada. The NSS includes more than two hundred and fifty organizations accredited by the Standards Council of Canada and involves 14,000 Canadians. The organizations in the NSS participate in conformity assessment as well as standards development. The NSS is coordinated by the Standards Council of Canada (SCC).

The NSS operates within the context of an international standards regime, which includes both the domestic standards systems of other countries and the international standards development and conformity assessment organizations that operate with voluntary consensus processes. For standards development, these include the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). For conformity assessment laboratories and accreditation systems, these include the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). The International Auditor Training and Certification Organization (IATCA) addresses auditor certification and training criteria requirements. There are, as well, numerous other specialized bodies, such as the International Telecommunications Union, Codex Alimentarius, the International Organization for Legal Metrology, the International Institute of Refrigeration, the International Bureau of Weights and Measures, the International Air Transport Association, the World Health Organization, the Organization for Economic Co-operation and Development and the International Labour Organization.

On a regional basis, these specialized bodies would include, among many others, the Asia-Pacific Laboratory Accreditation Cooperation; the Pacific Area Standards Congress, the Pacific Accreditation Cooperation, the North American Calibration Cooperation, the African Regional Standards Organization, the European Organization for Testing and Accreditation, and the Pan-

American Commission on Technical Standards -- all organizations in or with which Canada maintains an active presence or dialogue.

The National Standards System does not include all the standardization activity in Canada; though the SCC is seen by many both nationally and internationally as Canada's national accreditation body. There are organizations performing each of these services that are not accredited by the SCC and that operate outside the NSS. Nor is the system static; organizations can and do join and leave the system.

The NSS is a dynamic and complex structure with explicit formal processes to govern the relationships and the rule-setting and rule-enforcing activities of its many organizations. These processes are designed to ensure the effectiveness and credibility of the NSS. The following sections review briefly each of the main components of the NSS.

B.3   The Standards Council of Canada

The SCC is a federal Crown corporation created by an Act of Parliament to coordinate standardization activities in Canada. As mandated by its enabling legislation, the goals of the SCC are to promote efficient and effective 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 members of the Council are appointed by the Governor in Council with the objective of including a wide range of interests and ensuring that no one interest dominates the policy directions of the Council. The SCC includes representatives from the federal and provincial governments, as well as public and private interests. The SCC is partly financed by public funds.

The main responsibilities of the SCC are to:

- accredit organizations involved in standardization services (standards development, certification, testing registration, and auditor certifiers and course providers) in Canada;
- promote the coordination of the activities of these organizations;
- approve standards developed by these organizations as National Standards of Canada. The SCC has formulated 16 criteria that these standards must meet and maintains an official directory of all National Standards of Canada; and
- accredit Canadian representatives for the major international standardization bodies (e.g., ISO and the IEC). The SCC also works towards formal agreements with accreditation bodies in other countries to provide mutual recognition of each others' accredited organizations.

The Standards Council of Canada has established detailed criteria and procedures, including provisions for appeal, that the organizations it accredits must follow. These procedures include rules for developing standards, conducting certification activities and management system

registrations, and for conducting calibration and testing by accredited laboratories along with the certification of auditors and auditor training course provider accreditation.

The SCC audits on a regular basis the operations of the organizations it accredits to ensure that they maintain the capability to carry out the activities for which they are accredited. Where they do not meet the criteria, the SCC may withdraw accreditation following a prescribed process. While the SCC sets the rules for standardization activities in Canada within the NSS, it is in turn bound by the due process guidelines established by the international organizations to which it belongs, such as the ISO.

B.4   Standards Development Organizations

There are four accredited Standards Development Organizations (SDOs) in Canada: the Canadian Standards Association (CSA); the Canadian General Standards Board (CGSB); Underwriters' Laboratories of Canada (ULC); and the Bureau de normalisation du Quebec (BNQ). Each of these organizations develops standards through committees representing various interests and using a consensus process. Once developed, these standards may be submitted to the SCC to be recognized as National Standards of Canada (NSC). SDOs also develop standards-related documents such as codes and guidelines (non-mandatory guidance and information documents).

The CSA and ULC are private, not-for-profit organizations. They are market-driven to the extent that their activities are governed by the willingness of interested parties to pay and participate in standardization activities. Although funded primarily through the sale of conformity assessment services, their standards development activities are not restricted to areas with conformity assessment programs. For example, only approximately one-third of CSA's 2000 standards have related conformity assessment service offerings.

BNQ and CGSB, by contrast, are both public sector, cost-recovery organizations. Like the CSA and ULC, they offer conformity assessment services in addition to standards-development services. Like the private sector organizations, they do not restrict their standards development activities to cases where they have or could have conformity assessment programs. Unlike their private sector counterparts, however, their standards development activities are not subsidized by the sales of conformity assessment services. Funding for each standards development project is sought from stakeholders and interested parties.

Although the SCC provides administrative services to all of the Canadian Advisory Committees and Sub-Committees (CACs/CSCs) that support Canadian representatives on ISO and IEC standards development committees, in some cases, individual SDOs administer the CACs/CSCs. Under the auspices of the SCC, Canadian SDOs also provide the secretariat and funding for some ISO and IEC committees.

B.4.1 Canadian Standards Association (CSA)

Founded in 1919, the CSA is Canada's largest and oldest SDO and offers a full range of services (standards development, testing, certification and management systems registration) for a number of industries. CSA standards are often incorporated into government regulations, particularly in the fields of health, safety, building construction and the environment.

B.4.2 Canadian General Standards Board (CGSB)

Established in 1934 by the federal government, the Canadian General Standards Board offers a full range of services (standards development, certification, quality and environmental management system registration) for a number of industries. CGSB standards are also incorporated into provincial and federal legislation. CGSB provides services that are of common interest to both the private and public sector with emphasis on the public sector interests.

B.4.3 Bureau de normalisation du Quebec (BNQ)

The Quebec government established le Bureau de normalisation du Quebec in 1961 to serve the procurement needs of the Quebec government. BNQ now offers a full range of standardization services, including standards development, certification, management system registration and laboratory accreditation. BNQ is reaching beyond its traditional market in Quebec to offer its services in English in other regions of Canada and in the United States. Since 1990, BNQ has been part of the Centre de recherche industrielle du Quebec.

B.4.4 Underwriters' Laboratories of Canada (ULC)

Established in 1920 as a not-for-profit organization, Underwriters' Laboratories of Canada offers a full range of services, including standards development, certification, testing and management systems registration in a wide range of areas.

B.5 Conformity Assessment Bodies

Conformity assessment is defined as "as any activity concerned with determining directly or indirectly that relevant requirements are fulfilled". (ISO/IEC Guide 2:1996). Establishing good standards and standards development processes are only half the NSS story. It is important also to have a reliable means to determine that products, services and systems conform to standards. To this end, the Standards Council accredits conformity assessment organizations. These organizations, also part of the National Standards System, indicate that a product or service conforms to an applicable standard, usually through a report, a certificate or a mark applied to a product.

More than 250 conformity assessment organizations have been accredited. They include:

- certification organizations that certify, on an ongoing basis, that a product or service meets an applicable standard;
- testing and calibration laboratories that conduct the tests specified in certain standards or provide calibration services;
- quality systems registration organizations that examine and register ISO 9000 quality management systems;
- environmental management systems registration organizations that examine and register ISO 14000 environmental management systems; and
- Management systems auditor certifiers and auditor course providers who respectively certify auditors and perform auditor training. This applies both to quality system and environmental auditors.

The Standards Council's accreditation programs for these organizations operate according to internationally accepted guidelines where they exist. For programs where international standards or guides do not yet exist, Canadian criteria are developed by bodies of experts working within the SCC's advisory committee structure.

B.5.1 Certification Organizations

Certification organizations (COs) attest by authorizing display of their certification mark or logo that products or services conform to a standard. They regularly inspect and audit processes and products. In the summer of 1998 there were 18 COs accredited by the SCC.

Certification organizations accredited by the SCC may also certify products where no standard exists using Other Recognized Documents (ORDs). ORDs are developed by the certification organization and submitted to regulatory councils in Canada (which are authorities having jurisdiction for the product or service to be certified) for approval prior to being used for certification. The development process for an ORD is usually faster (typically 3 to 6 months) than the development of a National Standard of Canada and is used to get certified products to the market quickly. Government is consulted throughout the process and certification of the product will not go forward until all the concerns of the regulators and others are addressed. The cost of development of an ORD is borne by the manufacturer or regulator requesting the ORD. For COs that are also SDOs, the ORD is usually then submitted to the responsible committee for development as a National Standard of Canada.

B.5.2 Calibration and Testing Organizations

Testing organizations test a product or service to a given standard and report on the result. Calibration labs verify the accuracy of measuring instruments used for production and trade. There are over 250 accredited testing organizations in Canada. They include private research laboratories, university laboratories, government and industry facilities, and most of the certification organizations. The SCC accredits them based on their ability to perform tests in accordance with recognized standards and procedures and to document their findings. The SCC has partnerships with several groups to facilitate delivery of services and to minimize client costs. These partnerships may take two fundamental forms. The first represent full partnerships where the organization meets ISO/IEC Guide 58 requirements - the same requirements met by the SCC. The bulk of the accreditation work is carried out by these partners and recommendations for accreditation are sent to the SCC for approval. The SCC performs regular assessments of the partner to ensure the international criteria are being met. The second form of partnership represents agreements between the SCC and regulatory authorities. The typical approach for accreditation services is for the SCC to provide the quality assessors for an accreditation service while the regulator partner provides the technical expert who is part of the accreditation team.
When calibration labs want to make sure that their own measurements measure up, they turn to an accreditation program run jointly by the Standards Council of Canada and the National Research Council of Canada (NRC). The program allows clients of accredited calibration labs to measure with accuracy and confidence. It covers the full gamut of metrology – the system of weights and measures – from mass, length and time to thermometry, photometry, electricity and ionizing radiation.

Calibration labs seeking accreditation must demonstrate that their administration and operations meet the requirements of ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories, the international guidelines document that is the basis for

assessments conducted by the Standards Council's lab accreditation program. They must also demonstrate their technical competence by obtaining certification from the Calibration Laboratory Assessment Service (CLAS), part of the NRC's Institute for National Measurement Standards (INMS). During the summer of 1998, the SCC signed a collaborative agreement with the NRC that permits the CLAS group to carry out both the quality and technical assessments that lead to the SCC accreditation of a calibration laboratory. The effect of this agreement is that the laboratory is able to deal with only one agency (NRC) while still obtaining an SCC accreditation. Lab accreditation is voluntary in Canada, with about 15 of an estimated 55 accreditable Canadian calibration labs having sought accreditation, and more on the way in the coming years.

The globalization of trade is forcing manufacturers to ensure that their products will be compatible with those produced elsewhere. The main aim of calibration lab accreditation is to convince purchasers that Canadian products have the properties or dimensions they claim to have. Securing that confidence globally eliminates the costs associated with having the product retested in every market where it is sold.

B.5.3 Management Systems Registrars

The process of demonstrating conformity to a management system standard is known as management systems registration. Management systems registrars issue registration certificates to companies that meet one of the three ISO 9000 series of standards for quality management systems or the ISO 14001 standard for environmental management systems. Although management systems registration is a relatively recent arrival to the NSS, by mid-1998, there were seventeen accredited management systems registration organizations in Canada.

B.5.4 National Systems of Accreditation

Accreditation is formal recognition that an organization is competent to carry out specific types of testing, measurement and calibration. It enables people who want a product, material or instrument to be checked or calibrated to find a reliable testing or calibration service able to meet their needs. Accreditation also allows a laboratory to determine whether it is performing its work correctly and to appropriate standards. Manufacturing organizations may also use laboratory accreditation to ensure that the testing of their products by their own in-house laboratories is being done correctly. Formal accreditation of competent laboratories through a recognized national program thus provides a ready means for customers to access reliable testing and calibration services.

The Standards Council of Canada operates the Program for the Accreditation of Laboratories - Canada (PALCAN), a national program for accrediting calibration and testing. PALCAN meets the requirements of ISO/IEC Guide 58, General Criteria for the Operation and Mutual Recognition of Laboratory Accreditation Systems, and is based on ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories, which forms the basis of accreditation programs around the world. This fact has made it possible for the Standards Council to negotiate mutual recognition agreements with accreditation bodies in other countries.

In essence, signatories of MRAs accept the equivalency of each other's accreditation programs. MRAs have already been concluded by the SCC with two key U.S. accreditation bodies — the National Institute of Standards and Technology (NIST) and the American Association of Laboratory Accreditation (A2LA). On a multilateral level, the SCC is participating in developing a number of regional agreements covering North America, the Western hemisphere, Europe and the Pacific Rim.

For example, the Standards Council and the NRC are participating in activities intended to align the national measurement systems of Canada, the U.S. and Mexico. The North American Calibration Cooperation (NACC) and its sister committee NORAMET (North American Metrology Cooperation) promote cooperation in calibration laboratory accreditation, and are in the process of developing an MRA.

Accreditation of testing facilities is a key element in Canada's participation in the IEC System for Conformity Testing to Standards for Safety of Electrical Equipment (IECEE). Under this system, a certification organization in one country can accept an electrical product based on test results prepared by a similar organization in another.

The Standards Council is a member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and is actively pursuing an agreement with the European cooperation for Accreditation. The APLAC peer review assessment of the SCC is expected in 1999.

In January, 1998, the SCC was part of the first group to sign agreements with the International Accreditation Forum (IAF) and the Pacific Accreditation Cooperation (PAC).

The ultimate goal would be to produce a global conformity assessment framework in which every lab would meet the same operating criteria, regardless of where in the world it is located. Test results would be universally accepted, no matter where they originate.

In the area of quality systems registrations, the SCC accredits management systems registrars in accordance with ISO Guide 62 for the registration of suppliers' quality systems, and auditor certification program accreditation according to Guide 61 for the operation of systems for the accreditation of registration organizations. The SCC is an active participant in mutual recognition agreements in these areas.

Continued PALCAN growth in the face of declining government appropriation led to a decision to have all accreditation programs recover their costs of providing services. In 1995 the then Executive Committee of the Standards Council called upon all conformity assessment programs to become fully self-sufficient with respect to revenue and to recover both direct and indirect costs. In the last six years, there have been a number of changes in PALCAN including the formation of Program Specialty Areas (PSAs) for specific program activities such as pesticide residues, drug abuse, environmental, fasteners, food, forensic and mineral analysis. These PSAs are developed and implemented in partnership with the relevant government department or regulatory agency.

B.5.6 International Electrotechnical Commission (IEC) System for the Conformity Testing and Certification of Electrical Equipment (IECEE)

As a complementary activity to standards development, the IEC runs 4 inter-related certification schemes for electrical equipment. The IECEE is composed of two schemes. First is the CB Scheme - exchange of test reports. Members of the CB Scheme accept test reports from applicant manufacturers issued by other members of the scheme, thereby avoiding duplicate testing. The second scheme is called the Full Certification Scheme (FCS) - each member of that scheme will fully accept assessment of manufacturer's product (initial tests, as well as ongoing surveillance) by another member against the importing country's own requirements. The FCS is currently being

implemented. The third scheme is the IECEx scheme - the first manifestation of the "one standard, one test, one mark" objective. When operational (in perhaps 4-5 years), manufacturers will then be able to go to the certifier of their choice, and obtain certification. The mark will be a common mark used and accepted by all other partners in the scheme. Canada does not participate in the fourth scheme, IECQ(uality), which applies to electronic components included into products by original equipment manufacturers (OEMs).

B.6   *International Standards Organizations*

Both domestic and international polices and agreements require Canada to consider the use of voluntary standards, and in particular international standards, in the development of rules to guide industry. The Federal *Regulatory Policy* requires federal officials to determine whether an international standard exists that can provide the basis for domestic regulation. The *Agreement on Internal Trade* calls on federal and provincial governments to use: i) the National Standards System of Canada or international standards, and ii) the conformity assessment services of the NSS. Similarly, the GATT *Agreement on Technical Barriers to Trade* states that "with a view to harmonizing technical regulations and standards on as wide a basis as possible, Parties shall play a full part...in the preparation by appropriate standardizing bodies of international standards for products...."

There are a number of international organizations involved in standardization activities. The major ones are described below.

B.6.1   International Organization for Standardization (ISO)

ISO is a federation of national standards bodies with some 130 members. It is a non-governmental organization established in 1947 to promote the development of standardization to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity. It covers all areas of standardization, except the electrical and electronic fields, which the International Electrotechnical Commission (see below) addresses. ISO includes all the major trading nations, as well as various international organizations such as the United Nations Environment Programme and the World Wildlife Fund. The SCC represents Canada in ISO.

ISO's work results in published international standards (see Appendix C). Any group of five member countries can begin this process by suggesting the need for a standard to the ISO Secretariat in Geneva. The Secretariat will review the proposal and the opinions of member countries to determine if support exists for work to begin on the proposed standard. The technical work of ISO is carried out by a hierarchy of some 2,850 technical committees, subcommittees and working groups. Over 30,000 experts participate in meetings each year. National standards bodies that are members of ISO (such as the SCC) are given the responsibility for administering a standards committee. The committee chairman assists committee members in reaching a consensus. The Secretariat ensures that the documents approved by technical committees are submitted as Draft International Standards to ISO member bodies for voting. Acceptance criteria stipulate approval by two-thirds of the members that have participated actively in the standard development process and approval by 75 percent of all members that vote.

At present, Canada holds two extremely important ISO secretariats for standards development: ISO 9000 and 14000 series. It also holds secretariats related to its most important industries representing paper, board and pulp, nickel and nickel alloys, thermal insulation and timber structures. Canada is also active in the ISO Committee on Consumer Policy (COPOLCO) and is heading the ISO TMB Advisory Group that will make recommendations to TMB on the desirability of developing an international standard on privacy and the protection of personal information.

B.6.2   International Electrotechnical Commission (IEC)

The IEC consists of more than 50 participating countries, which account for more than 80 percent of the world's population and over 95 percent of its electrical energy production. Members are drawn from the principal standardization bodies at the national level. The IEC's mission is to promote, through its members, international cooperation on all questions of electrotechnical standardization. The IEC's charter embraces electronics, magnetics and electromagnetics, electroacoustics, telecommunications, and energy production and distribution. It also includes associated disciplines, such as terminology and symbols, measurement and performance, dependability, design and development, and safety and the environment. The IEC maintains advisory committees on electromagnetic compatibility, electronics and telecommunications, and safety. The Joint Technical Committee on Information Technology (JTC-1) allows both the IEC and ISO to work cooperatively on the preparation of international standards in the information technology area. The International Telecommunications Union (see below) has an official liaison role with JTC-1.

B.6.3   International Telecommunications Union (ITU)

The ITU is a treaty organization of approximately 160 members run by the United Nations. Governments administer and enforce the regulatory telecommunications standards that are developed by the ITU. The ITU maintains five permanent activities: the General Secretariat, the organization of World Conferences on International Telecommunications, the Radiocommunication Sector, the Telecommunications Standardization Sector and the Telecommunications Development Sector. The ITU typically develops recommendations that are implemented as national standards or regulations by national telecommunications authorities (e.g., Industry Canada and the Canadian Radio-television and Telecommunications Commission). Industry Canada is responsible for coordinating Canada's participation in the ITU. A committee of SCC, the Canadian National Committee of the IEC, is the member for Canada.

B.6.4   *Codex Alimentarius*

The *Codex Alimentarius* is a collection of internationally adopted food safety and quality standards, supplemented by various advisory documents in the form of codes of practice, guidelines and other recommended measures intended to facilitate achievement of its purposes. The *Codex* was developed in 1962 by the Codex Alimentarius Commission, which was founded to facilitate trade in food. The Commission, a 150-member intergovernmental organization, is the food standards body of the United Nations.

There are three types of *Codex* standards: General Standards, Worldwide Food Standards and Codex Regional Food Standards. General Standards encompass standards such as maximum pesticide residue limits for foods, food labeling and food additives. Worldwide Food Standards are

standards for individual food commodities and products. Codex Regional Food Standards apply only to foods traded exclusively or almost exclusively intra-regionally.

When the Commission accepts a standard, national governments are encouraged to adopt the standard as a national law. Full acceptance of a standard ensures that a product complying with the standard will be distributed freely within the country where the standard has been accepted, and that any product not complying "will not be permitted to be distributed under the name and description laid down in the standard." *Codex* standards only have binding authority once they have been adopted as domestic standards within individual nations.

B.6.5 Other International Standards Organizations

There are also a number of specialized organizations that have been established to coordinate standards internationally. These include the International Organization for Legal Metrology, the International Institute of Refrigeration, the International Bureau of Weights and Measures, the International Air Transport Association, the World Health Organization and the International Labour Organisation. These organizations have liaison status with ISO and IEC, and participate in the presentation and drafting of international standards (or ISO adopts their standards as international standards).

B.6.5.1   International Accreditation Forum (IAF)

The IAF, created in January, 1993, is a group of international accreditation bodies which have joined together to promote international recognition of accreditation for quality systems (ISO 9000) registrars. A multilateral recognition agreement (MLA) was signed in 1998 by thirteen accreditation body members, including Canada (SCC), in the area of quality systems registration. The long-term objective of IAF is to include other areas, such as certification and testing. The signatories of the IAF Memorandum of Understanding (MOU) have committed themselves to:

- establish confidence in the members and bodies accredited by them
- support development and use of ISO/IC documents
- establish the equivalence of the members' programs based on a multilateral agreement among them
- promote regional multilateral agreement

B.6.5.2   International Laboratory Accreditation Cooperation (ILAC)

ILAC is an international cooperation between the various laboratory accreditation schemes operated throughout the world. Founded twenty years ago, ILAC was formalised as a cooperation in 1996 when 44 national bodies signed a Memorandum of Understanding (MOU) in Amsterdam. This MOU provides the basis for the further development of the Cooperation and the eventual establishment of a multilateral recognition agreement between ILAC member bodies. Such an agreement will further enhance and facilitate the international acceptance of test data, and the elimination of technical barriers to trade.

As part of its global approach, ILAC also provides advice and assistance to countries that are in the process of developing their own laboratory accreditation systems. These developing systems are able to participate in ILAC as associate members, and access the resources of ILAC's more established members.

In conjunction with ILAC, specific regions have also established their own accreditation co-operations, notably in Europe (EAL) and the Asia-Pacific (APLAC). These regional co-operations work in harmony with ILAC and are represented on ILAC's board of management. ILAC is encouraging the development of such regional co-operations in other parts of the globe.

Hence ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test facilities around the globe.

B.6.5.3 International Auditor Training and Certification Association (IATCA)

The International Auditor and Training Certification Association was formed in 1995 by organizations which certify/register auditors of quality systems and/or approve the provision of training courses for such auditors, in order to provide a mechanism for international recognition of these certifications/ registrations and approvals.

The principle of recognition, however, also applies to the certification/ registration of auditors for other management systems, such as environment or occupational safety and health. The principal objective of IATCA is to facilitate the recognition of the certification/registration of auditors of management systems.

As an accreditor of auditor training course providers, the SCC is a member of IATCA.

B.7   Regional Organizations

Much of the emphasis on international standardization activities has been placed on participation in such organizations as ISO (see above). Regional fora, however, are becoming important venues for discussion, cooperation and harmonization of standards related activities.

B.7.1 NAFTA

Chapter Nine of the *North American Free Trade Agreement* (NAFTA) sets out the obligations of parties concerning standards, and promotes the harmonization of the parties' standards-related measures, conformity assessment procedures and technical regulations. The Chapter promotes the mutual acceptance of test and certification procedures and results, as well as mutual recognition by signatories of each others' certification and accreditation bodies. The NAFTA Committee on Standards-Related Measures is responsible for the implementation of Chapter Nine. There is a parallel committee dealing with the harmonization of voluntary standards, the Tri-Lateral Standardization Forum, comprised of members of the three national standards organizations. The SCC represents Canada.

B.7.2 Western Hemisphere

B.7.2.1   Pan-American Standards Commission (COPANT)

The Pan-American Standards Commission (COPANT) is an umbrella organization for American countries to promote the development of technical standardization and related activities. It also develops certification systems based on international criteria and promotes the harmonization of these systems. COPANT has cooperation agreements with other regional standards organizations, such as the African Regional Organization for Standardization (ARSO) and the Caribbean Common Market Standards Council (CCMSC). Canada is an active COPANT member through the SCC.

B.7.2.2 Inter American Accreditation Cooperation (IAAC)

The SCC attends meetings of the Inter American Accreditation Cooperation (IAAC) but has not yet joined this group, formed in 1996. The IAAC is a regional body similar to the EA, i.e. to facilitate the accreditation of conformity assessment bodies of countries of the Western hemisphere, and to harmonize the procedures of existing accreditation bodies on the basis of ISO/IEC Guides in order to facilitate the realization of mutual recognition agreements. As of mid-1997, 12 Accreditation Bodies have joined the IAAC as full members and 6 organizations have signed on as associated members. The work of the IAAC is carried out through five working groups, including one on conformity assessment and one on mutual recognition agreements. The IAAC is based in Brazil.

B.7.2.3 North American Calibration Cooperation (NACC) and North American Metrology Cooperation (NORAMET)

In 1994, two committees were established to coordinate North American cooperation in the field of metrology. One was the North American Calibration Cooperation (NACC). This committee was formed to:

- Provide the regional infrastructure to facilitate harmonization of the programs within Canada, Mexico and the U.S.A. and the implementation of bilateral or multilateral agreements recognizing the equivalence of national calibration laboratory accreditation programs,

- Provide the regional infrastructure to negotiate calibration agreements with other regions of the world,

- Represent the members in liaison with similar organizations in other regions, and

- Promote the international acceptance of Certificates of Accreditation issued by the accreditation programs of its members.

Canada currently holds the chair of this committee.

The other committee that was formed was the North American Metrology Cooperation (NORAMET), with membership from the three national metrology institutes, to establish and document the degree of equivalence of the calibration services offered by its members. One of the most important roles of national metrology institutes (NMIs) is to supply the primary source of measurement traceability for the accreditation bodies in other countries. It follows that an important role for NORAMET is to support the North American Calibration Cooperation by ensuring and documenting the degree of equivalence of the calibration services of the NMIs of other countries. Canada is represented by the National Research Council in NORAMET, which is in turn a partner organization to the Inter American System of Metrology (SIM). SIM's objectives are to:

- Raise standards of basic metrology in each country in the hemisphere,

- Contribute to the measurement infrastructure required to promote equity in commercial transactions,

- Foster competitiveness and quality in the manufacturing sector in order to promote commercial transactions,

- Identify sectors and institutions that can conduct specific multinational activities in metrology support,

- Contribute to the metrological infrastructure required to protect the environment, to control the accelerated use of resources and to promote the general well-being of the population, including its health and safety.

B.7.3   Asia Pacific Region

B.7.3.1   Asia Pacific Economic Cooperation (APEC)

The Asia-Pacific Economic Cooperation forum (APEC), whose 18 members comprise half the world's economy, adopted the Osaka Action Agenda in 1995 to create a framework for regional cooperation in international standardization activities. The objectives of the Sub-Committee include alignment with international standards in priority areas, enhanced transparency, and the negotiation of MRAs in most regulated sectors in which there are mandatory standards, as well as in areas of voluntary standards. The APEC SCSC carries out its work with the active cooperation of a number of specialized regional bodies, including APLAC, APLMF, APMP, PAC, and PASC. Canada chaired the APEC Sub-Committee on Standards and Conformance in 1997 through the SCC.

B.7.3.2   Specialist Regional Bodies

B.7.3.2.1   Asia Pacific Laboratory Accreditation Cooperation (APLAC)

The Asia Pacific Laboratory Accreditation Cooperation was initiated in 1992 to provide a forum to enable laboratory and inspection body accreditation organizations in the region to meet, discuss issues and develop procedures for the establishment of mutual recognition arrangements such that laboratory test data and inspection reports produced in one country in the region could be accepted throughout the region and internationally through agreements with other regions. Canada joined in November 1997.

APLAC's principal objectives are to foster the development of competent laboratories and inspection bodies in member economies, harmonize accreditation practices in the region, and thereby facilitate the recognition of laboratories and inspection bodies and the acceptance of test data and inspection reports across national borders.

B.7.3.2.2   Asia-Pacific Legal Metrology Forum (APLMF)

The Asia-Pacific Legal Metrology Forum was established in Sydney in November, 1994. The Forum is attended by legal metrology authorities in fourteen of the eighteen APEC economies, including Canada.

Consistent with the principles of the APEC Heads of Economies declaration of a Free Trade Zone in the region it was agreed that the principal objectives of the Forum should be to: (1) develop and maintain mutual confidence between legal metrology authorities in the Asia-Pacific region; (2) identify and promote the removal of technical and administrative barriers to trade in the field of legal metrology; (3) promote mutual recognition arrangements between members and with other regional groups and individual nations; (4) cooperate with the International Organisation of Legal Metrology (OIML) and promote the use and acceptance of OIML International Recommendations and the OIML Certification Scheme.

B.7.3.2.3 Asia Pacific Metrology Programme (APMP)

The Asia Pacific Metrology Programme, with a membership of some 25 countries and territories within the region, has been identified by APEC as a Specialist Regional Body playing a key role in developing the standards and conformance infrastructure in the region for the purpose of eliminating technical barriers to trade. The APMP Secretariat is being funded from Australian APEC funds through the Department of Industry, Science and Tourism (DIST).

B.7.3.2.4 Pacific Accreditation Cooperation (PAC)

The Pacific Accreditation Cooperation (PAC) is an association of approximately 16 accreditation bodies and other interested parties whose objective is to facilitate trade and commerce among economies in the Asia Pacific region.

Its ultimate objective is the creation of a global system that grants international recognition of certification or registration of management systems, products, services, personnel and other programs of conformity assessment.

The PAC promotes the international acceptance of accreditations granted by its accreditation body members, based on the equivalence of their accreditation programs. The PAC operates within the framework of the International Accreditation Forum (IAF) and in cooperation with other regional groups of accreditation bodies around the world.

B.7.3.2.5 Pacific Area Standards Congress (PASC)

The Pacific Area Standards Congress (PASC) is comprised of 20 standards bodies in Asia and the Pacific Rim. PASC is a forum for consultation on matters of common interest relating to the development and adoption of international standards. The SCC is a member.

B.7.4 Europe

The European Commission has given responsibility for developing standards to three regional standards organizations: the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). As a result of the work of these bodies and a series of directives issued by the European Commission, harmonized European-wide standards are now replacing thousands of national standards. Under the Vienna Agreement, ISO and CEN technical committees share information and draft documents and give observer status to representatives of the other organization. Similar arrangements exist between CENELEC and the

IEC. ISO members from outside the European Union are permitted to have observer status on CEN when invited; ANSI in the United States currently has status as a CEN Corresponding Organization.

The European Telecommunications Standards Institute (ETSI) was established in 1988 to fast-track critical technical standards in coordination with CEN, CENELEC and the European Broadcasting Union. Its processes are different from most standards development organizations, with voting procedures being weighted in favour of those with technical competence. When a standard is given high priority, a full-time expert Project Team is set up. Companies in the United States and Canada can join ETSI as Associate Members; European subsidiaries can participate directly.

B.7.4.1   European cooperation for Accreditation (EA)

This body recently formed by the marriage of EAC (European Accreditation of Certification) and EAL (European cooperation for Accreditation of Laboratories), the bodies concerned with management systems and calibration and testing laboratories respectively. This regional body has an active peer review process designed to provide MRA services to the European accreditation bodies. In addition, some non-European accreditors such as NVLAP and A2LA in the U.S. and NATA in Australia have or are working on joining the EA MRA.

B.7.4.2   European Organization for Testing and Certification (EOTC)

The European Organization for Testing and Certification was established in 1990 by the Commission of the European Union, the European Free Trade Association (EFTA), and the European Committee for Standardization (CENELEC) to serve as the focal point in Europe for all issues relating to conformity assessment. The EOTC is mandated to provide the appropriate framework for the non-regulatory sphere with regard to conformity assessment issues, while giving technical support to legislation of the Commission of the European Communities and the EFTA countries regarding conformity assessment in the regulatory sphere. The EOTC has 32 members, including 16 representatives of national conformity assessment communities and 16 European organizations.

B.8   The Standards System in the United States

The American standards system is of particular relevance to Canada because of the importance of trade between the two countries. In contrast to the systems in most other industrial countries, the American standards system is highly decentralized. The hundreds of existing standardization bodies have tended historically to develop uniquely American standards with little reference to, or compatibility with, international standards. As is the case throughout the world, American companies are, however, becoming increasingly concerned about the need for the international harmonization of standards and conformity assessment requirements. In some cases, this concern is leading Americans to advocate the international adoption of US standards. In other cases, Americans are adopting (either de facto or formally) international standards.

From a bilateral perspective, it is important to note that Canadians participate in some American standards development committees, that U.S. standards have been referenced into Canadian regulations, and that in an increasing number of cases, standards are being developed jointly.

There is no U.S. equivalent to the Standards Council of Canada. The American National Standards Institute (ANSI), a private body, coordinates the activities of its member standards organizations, represents the U.S. on international standards bodies, and is a source of information on U.S. standards. ANSI's diverse membership includes companies, government agencies, institutions, professions, technologies, trade, labour and consumer organizations. The National Institute of Standard and Technology (NIST), a government agency within the U.S. Department of Commerce, has the mission to assist U.S. industry to advance its performance in the development and application of technology. NIST staff are involved in domestic and international standards development and the organization is the U.S. contact point for ISONET, an information exchange network for ISO members (although ANSI is the U.S. member of ISO). NIST has placed standards experts in key embassies around the world in order to promote U.S. trade interests.

B.9   Non-NSS Standards Development

Many standards used in Canada are not National Standards of Canada (NSC). In some cases, these standards may have been developed by Canadian SDOs and not put forward as a National Standard (see Appendix B). Client preferences, and the nature of the document itself, are normally the basis for a draft not being advanced for NSS status. Interested readers may wish to review the requirements and 16 criteria established by the SCC that need to be met for a document to be approved (page C-2). In addition, standards may be developed by organizations that are not accredited by the SCC.

It may not be always appropriate or necessary for a body serving a very specialized market niche to operate under the standards development procedures stipulated by the SCC (e.g., requirement for multi-stakeholder consensus building). The consensus requirement for an open process may be seen in some sectors as compromising the confidentiality of new products. In sectors like electronics, where technology changes rapidly, *de facto* standards may emerge, developed by a leading company or consortium more quickly than an SDO could develop a consensus standard by using a "balanced" committee. It should be noted that, in some cases, these standards may inhibit trade and broad acceptance because of the imbalance of stakeholders involved in the development of a standard. Having said this, the need has been identified to take into account standards writing activities "outside" the NSS, and all the implications these activities imply.

Consortia standards are developed by firms that are developing products that need to inter-relate with one another (e.g., the different parts of a computer). Members of consortia may sometimes also be competitors, in the sense that they are producing competing product lines. Interested firms set up an organization to develop a standard collectively. They operate according to a wide variety of process rules. This approach works best when no one company is dominant or where the standard can provide stability in a particular technical market that lacks coordination. Consortia standards encourage complementary products and the consortia guarantee continued use of the standard (e.g. the widespread adoption by various competing food manufacturers and retailers of bar codes for groceries). They can, however, create a form of monopolistic control over technology, and the closed nature of the development process differs from the multi-stakeholder approach used by others. When consortia operate within the committees of standards organizations, their influence on the results can be considerable.

In some cases, the reason why a standards development organization may exist outside the NSS relates more to the difficulty of defining the term "standard." Self-management and self-regulatory regimes occupy the gray area between government regulation and the standards system and their rules are sometimes difficult to classify as belonging to one or the other. Industrial groups that develop voluntary codes to govern their conduct, for example, can be said to be abiding by standards. Some of these codes are very detailed and specific and represent an industry consensus on best practices; they may also rely in part on compliance assurance mechanisms (e.g., third-party audits) similar to those used in the NSS. The Responsible Care program of the Canadian Chemicals Producers' Association is an example. The Environmental Technology Verification (ETV) program for innovative environmental products is another.

Appendix C: The Standards-Development and Laboratory Accreditation Process

C.1 Principles of Developing a Voluntary Standard in Canada

Standards development in Canada is guided by two SCC documents: (1) CAN-P-2, for developing National Standards of Canada (NSCs), and; (2) CAN-P-1, which lays out the criteria and requirements for Standards Development Organizations (SDOs) in Canada.

The development of a standard is triggered by a request to an SDO by anyone concerned (often from industry). In deciding whether to develop a standard, the SDO first determines whether an international standard exists or is being developed that can satisfy the domestic need. The SDO will then ensure that the necessary funding will be forthcoming from the various stakeholders. It may also weigh other factors, including the practicality of the proposal, the likelihood that the standard will generate a supporting product certification program, the availability of the necessary expertise, and the societal benefit to be achieved by the standard.

In general, SDOs will be less interested in developing a standard where funds are not available to cover development costs, or where it will be difficult to assemble a technical committee that meets the SCC requirements for balance in membership representation.

Standards development by accredited SDOs follows the SCC requirements (CAN-P2) for the preparation and approval of National Standards of Canada (NSC) (See Figure 1). These criteria reflect the standards community's broad commitment to consensus and due process.

Key Attributes of Standards

- developed by a consensus-based multi-stakeholder process;
- stipulate requirements that a product, process or service must meet;
- reflect the best judgment of experts in the topic; and
- prepared under the auspices of a recognized SDO.

The central feature of this process is the reliance on volunteer technical committees to develop standards by means of consensus-based decision making. If an SDO undertakes to develop a standard, it will establish and administer a technical committee, whose members have relevant expertise and represent a balance both nationally and in terms of interests and perspectives. The precise composition of each committee is based on the nature of the standard to be developed. The committees generally include consumer and general interest (e.g., academics, safety associations) representatives, regulators, and producers. In a number of subject areas, such as child safety, technical committees may be developing several standards at a time.

At the outset, the technical committee reviews existing standards from several sources for possible application. In order to meet the requirements to become National Standards of Canada, standards must be consistent with or should incorporate appropriate international standards to the extent suitable for the Canadian market. The committee also initiates the necessary testing and data collection, and determines the breadth and scope of the standard.

The consensus requirement means that committee members must reach substantial but not unanimous agreement. The decision-making process also calls for discussion and iterative revisions until agreement is reached.

SDOs ensure that standards undergo a thorough review for technical as well as policy considerations. Where the issue being addressed involves health or safety, the SDO will also conduct a thorough risk assessment.

The World Trade Organization (WTO) rules require that a public notice be issued when a decision is made to develop the standard. Additionally, once a committee has developed a draft standard, the SDO will publish a notice to the public inviting review and comments. In addition to sending the draft standard to any member of the public who requests a copy, the SDO may also distribute the draft standard to selected reviewers identified by the committee and the SDO staff. These reviewers may have particular expertise or interest in the standard. This step is designed to ensure that parties affected by the standard (but not involved in the development) have access to information that may affect their business and are given a chance to intervene. Before adopting a standard, the SDO allows at least sixty days for the submission of comments by interested parties within and outside Canada. This period may be shortened for urgent matters involving health or safety.

The committee administrator will then compile all comments and ensure that the committee reviews them. The technical committee will either incorporate the comments in the standard or identify reasons not to do so. If any commentator requests notification of the status of his or her comment, the SDO will provide an explanation of how the comment was incorporated, or why not.

Standards development under this process takes an average of one to one and a half years. Once finalized, the SDO publishes the standard. Copies are available on reasonable terms and conditions to any person, wherever located. If the SDO puts the standard forward for designation as an NSC, it will be responsible for publishing the standard in both official languages, and will be responsible for maintaining and updating the standard through reviews in a five-year cycle. Upon completing these reviews, the SDO will either reaffirm, revise or withdraw the standard. The SDO is also responsible for maintaining proper records of the standards-development process.

C.2 ISO Process

The process requirements imposed on Canadian SDOs are based on the processes of the international voluntary consensus bodies, such as ISO. As in Canada, the ISO process of standards development is triggered by a request, usually from an industry sector, that is communicated to a national ISO member body. ISO investigates whether there is interest among members in developing the particular standard. Once the need has been recognized and formally agreed upon, attention is given to the definition of the technical scope of the proposed standard. Working groups of technical experts from the countries interested in the matter carry out this task. The next phase is consensus building by negotiation on the detailed specifications within the standard. The committee will distribute a draft standard that has been based on their consensus work. Formal approval of the draft by two-thirds of the ISO members who have participated actively in the standards development process and 75 percent of all members is required before the draft is published as an ISO International Standard.

ISO also has developed some fast-track processes that are available for rapidly advancing areas, especially high technology.

C.3 PALCAN Laboratory Accreditation Process

All PALCAN programs use accreditation guidelines that are based on criteria developed by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Laboratory Accreditation Cooperation, specifically ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories. Compatibility with this internationally accepted guideline ensures that accredited Canadian labs meet the same criteria as labs in other countries.

The accreditation process involves several steps. In the first stage, the lab provides documented evidence of its compliance with criteria dealing with such issues as staff competence and quality systems.

The Standards Council notifies the lab of any shortcomings, asking that the appropriate changes be made. Next comes an on-site visit which includes a thorough review of the lab's human and physical resources as well as its administrative procedures.

A crucial part of accreditation is assessment of a lab's technical capabilities. An assessment team, which includes technical specialists often from one of the Standards Council's partner organizations (e.g. Canadian Association of Environmental Analytical Laboratories; Canadian Food Inspection Agency; Department of National Defence; Industry Canada; International Dairy Federation; National Research Council of Canada; Pest Management Regulatory Agency; Telecommunications Standards Advisory Council of Canada), carries out a detailed examination of the applicant's files and observations of a range of tests and measurements. Before the Standards Council approves the application and grants accreditation, one or more advisory committees may review the application and request that the lab modify its procedures or facilities. Even after accreditation has been granted, the Standards Council conducts maintenance visits to ensure that a facility continues to conform to PALCAN requirements.

In addition to the overall PALCAN criteria, each program specialty area has its own specific guidelines developed by working groups made up of experts in the field.

Appendix D: Summary of International Trade Requirements Relevant to Standards

Several trade agreements address the use of standards in government regulations. These include the World Trade Organization (WTO) agreements on *Technical Barriers to Trade* (TBT) and on *Sanitary and Phytosanitary Standards* (SPS), the *North American Free Trade Agreement* (NAFTA) Articles on Technical Barriers to Trade, and the Canadian *Agreement on Internal Trade* (AIT).

In many cases, a standard that is incorporated into a regulation will be a technical regulation as defined in the WTO *TBT Agreement* and in NAFTA.[4] These agreements require that, for technical regulations affecting trade, federal regulatory authorities must:

- prepublish proposals for new or changed technical regulations in the *Canada Gazette*, Part I, at least 75 days prior to implementation, except in urgent circumstances, and take into account comments received;
- specify, where possible, technical regulatory requirements in terms of performance rather than design or descriptive characteristics;
- give positive consideration to accepting as equivalent other forms of technical requirements if satisfied that they adequately fulfill the objectives of the existing regulations;
- ensure that technical regulations treat products from one jurisdiction no less favourably than like products from another;
- ensure that sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate when identical or similar conditions prevail;
- use available international standards, guidelines and recommendations where those standards achieve the regulatory objective;
- treat regulatees and products from one jurisdiction no less favourably than those from other jurisdictions when assessing conformity to technical regulatory requirements, providing they are in comparable situations; and
- have in place a process to review complaints concerning conformity assessment procedures and to take corrective action when justified.

The trade rules in these agreements are essentially based on two core principles: *most-favoured-nation* (MFN) and *national treatment*. MFN requires that the rules applied to one trading partner should not be "less favourable" (i.e., more demanding) than the measures applied to any other member of the trade agreement. National treatment requires that imported products not be treated less favourably than domestic products regarding internal taxes and standards.

Article XX of the General Agreement on Tariffs and Trade (GATT) allows Parties to the WTO to adopt measures that are inconsistent with these principles in certain circumstances. These exceptions are subject to two disciplines. First, the measure must not be a disguised restriction on trade. Second, it must not involve arbitrary or unjustifiable discrimination between countries where

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[4] Article 915 of NAFTA, for example, defines a technical regulation as "a document which lays down goods' characteristics or their related processes and production methods, or services' characteristics or their related operating methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a good, process, or production or operating method."

the same conditions prevail. Similar exceptions are present in NAFTA and other regional trade liberalization agreements.

The *TBT* and *SPS Agreements* of the WTO provide more detail about how standards should be designed and implemented regarding their effects on trade. The *TBT Agreement* addresses both mandatory technical regulations and voluntary standards applying to all products, including industrial and agriculture products. The *SPS Agreement* applies to all food and health standards that may affect international trade. These agreements essentially extend MFN and national treatment principles to regulations and standards.

The *Code of Good Practice for the Preparation, Adoption and Application of Standards* (Annex 3 of the *TBT Agreement*) further extends these principles to apply to voluntary standards. Voluntary standards supported by national governments must comply with the *Code*, and national governments must take reasonable steps to ensure compliance by sub-central governments and non-governmental standardizing bodies within their territories.

Both the *TBT and SPS Agreements* include an additional obligation that has attracted considerable attention. They encourage countries to base domestic regulations or standards on international standards except where no applicable international standard exists, or when international standards would be an ineffective or inappropriate means to fulfill the "legitimate" objectives of the domestic regulation or standard. The agreements place an onus on countries to provide scientific evidence to justify deviation from an international standard.

The latest edition of the SCC's requirements for accreditation of SDOs (CAN-P-1D) incorporates all of the relevant provisions of the *TBT, SPS and NAFTA Agreements*. Standards developed by accredited SDOs are therefore required to satisfy relevant international trade agreement requirements.

Appendix E: Examples of Other Standardization Strategies

E.1   Introduction

Canada is not alone in seeking to develop a more strategic approach to its standardization activities. This Appendix summarizes the strategies developed by the United States of America, the United Kingdom, and Japan.

E.2   United States of America

The U.S. does not yet have a formal standards strategy. International standards for products, processes and services are increasingly important to the U.S. economy due to the quickening pace of technological innovation and the globalization of trade. The U.S. Commerce Department estimates that standards serve as barriers to trade for $20 billion to $40 billion in exports. In the interest of developing a standards strategy, the National Institute of Standards and Technology (NIST) and the American National Standards Institute (ANSI) hosted a summit in September of 1998. This summit provided a forum for the discussion of issues in developing, supporting, and using national and international standards.

E.3   United Kingdom

The *British Standards Institution's (BSI) Strategic Plan* was developed in 1996. Strategies included in the *Plan* encompass:
- increasing the impact and influence of *BSI* in international fora;
- obtaining key secretariats/chairs;
- streamlining standardization processes;
- enhancing BSI's reputation as a facilitator;
- promoting change in international standards bodies such as CEN and ISO;
- developing the capabilities of Sector Boards (these Boards were established to provide better links between *BSI*, industry and the committee structure that performs technical work); and
- investing in new technology and developing a customer focus.

Each of these strategies will become programs of action under the *BSI*'s Operating Plan.

E.4   Japan

The Japan Industrial Standards Committee (JISC) published its standards strategy, the *Eighth Long-Term Standardization Plan,* in 1996. The Plan commits the government to support the development of Japanese Industrial Standards (JIS) in fields of consumer protection, welfare for the aged and environmental protection. The Plan also calls for the JISC to establish a system for developing Japanese industrial standards which respond to these current socioeconomic conditions as a priority.