

LKC
T
59.2
.C2
S74
1998
c.2

IC



Standards *Systems*

A Guide for Canadian Regulators



Government
of Canada

Gouvernement
du Canada

Canada

For more information, contact:

Regulatory Affairs and Standards Policy Directorate
Industry and Science Policy Sector
Industry Canada
5th Floor, West Tower
235 Queen Street
Ottawa ON K1A 0H5

Tel.: (613) 952-6450
Fax: (613) 952-1980
E-mail: carriere.paula@ic.gc.ca

This publication is also available electronically on the World Wide Web at the following address:
<http://strategis.ic.gc.ca/stdsguide>

This publication can be made available in alternative formats for persons with disabilities on request.
Contact the Information Distribution Centre at the numbers listed below.

For additional copies of this publication, please contact:

Information Distribution Centre
Communications Branch
Industry Canada
Room 205D, West Tower
235 Queen Street
Ottawa ON K1A 0H5

Tel.: (613) 947-7466
Fax: (613) 954-6436
E-mail: publications@ic.gc.ca

© Her Majesty the Queen in Right of Canada (Industry Canada) 1998
Cat. No. C2-361/1998E
ISBN 0-660-63787-9
52069B

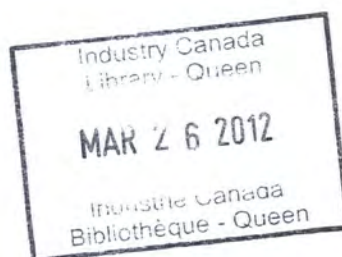


20% recycled
material



Standards *Systems*

A Guide for Canadian Regulators



Acknowledgments



The Regulatory Affairs and Standards Policy Directorate, Industry Canada, and the Regulatory Affairs Division, Treasury Board Secretariat, thank the many individuals and organizations who provided input to this guide and gave their advice and support. Particular gratitude goes to:

Mr. Robert Howse, Faculty of Law, University of Toronto

Dr. Bill Leiss, School of Public Studies, Queen's University

Dr. Peter Victor, Environmental Studies, York University

Mr. Bruce Doern, School of Public Administration, Carleton University

Mr. Tony Flood, Gould Shawmut Co.

as well as officials from Health Canada, Transport Canada, Environment Canada, the Canadian Food Inspection Agency, Industry Canada, the Standards Council of Canada, the Consumers' Association of Canada and the Canadian Standards Association who provided valuable insight into the issues discussed in the guide.

Contents



Introduction	4
Chapter 1: Overview of Standards	6
Standards Council of Canada	6
Standards Development Organizations	6
Conformity Assessment Bodies	7
International Standards Regime	7
Trends in the Use of Standards	8
Chapter 2: Using Standards Development Processes for Regulations	10
Options for Incorporating Standards into the Regulatory Regime	10
Standards Development Process	11
Considerations	13
Chapter 3: Using Standards-based Conformity Assessment Processes	24
Options and Current Experience	24
Considerations	27
Chapter 4: Using Voluntary Standards as an Alternative to Regulation	34
Considerations	35
Conclusion	38
Appendix A: Overview of Canada's National Standards System	40
National Standards System	40
Standards Council of Canada	41
Standards Development Organizations	41
Conformity Assessment Bodies	43
International Standards Organizations	43
Non-NSS Standards Development Regimes	45
Appendix B: Summary of International Trade Requirements	46
Appendix C: Glossary of Abbreviations	48
Figures	
Figure 1: Standards Development Process Prescribed by the Standards Council of Canada	12
Figure 2: International and National Standards Systems	40

Introduction



Governments may decide to intervene in the marketplace for a variety of reasons. When doing so, they can choose from a wide range of instruments, from regulations to educational programs. This guide introduces federal officials to the instruments and options available through the National Standards System.

The National Standards System (NSS) is the system for developing, promoting and implementing standards in Canada. The NSS is coordinated by the Standards Council of Canada (SCC). In turn, the SCC accredits both standards development organizations (SDOs) and conformity assessment bodies. Not all standards-related activity in Canada falls under the NSS.¹ This guide focusses primarily on SCC accredited organizations, although many of the concepts presented here apply to international standardization bodies, and some may also apply to non-accredited organizations.

This guide is not prescriptive: it does not propose that consensus standards or conformity assessment processes must be used to address a given policy issue. Numerous policy instruments are available to government decision makers. Some will be more appropriate or effective than others in a given situation; some will be more or less available, depending on the political climate and the priorities of the government of the day. In many cases, the most effective approach will include a combination of instruments. Decision makers will continue to have to choose and design instruments to meet different policy objectives; however, this guide does suggest that the government use the NSS to strengthen and add flexibility to the available policy instruments.

SDOs prepare standards according to the procedural guidelines prescribed by the SCC. (Note that the term *standard* can have numerous meanings when used in discussions and in legislation and regulations. This guide refers to standards developed by accredited standards development organizations.)

Conformity assessment bodies provide three types of services related to monitoring and verifying compliance with standards: certification, testing and management systems registration.

The international context within which the NSS operates is becoming increasingly significant. The domestic standards systems of other countries have grown tremendously in scope and importance in recent decades, as they have in Canada. Similarly, international standard setting by organizations such as the International Organization for Standardization and the International Electrotechnical Commission has helped open up global markets, allowing importers to meet local requirements and permitting the coordination and integration of parts and processes from different countries. As a result, Canadian firms must now consider the potential benefits of complying with standards established domestically, in other countries and internationally. The SCC coordinates Canadian participation in the activities of international standards organizations. Similarly, Canadian SDOs and conformity assessment bodies keep abreast of the activities of foreign and international bodies.

1. Appendix A discusses non-accredited organizations involved in standards activities.

The use of standards to gauge the design or performance of products and processes has become increasingly common and important in all industrial societies. The growth of international trade, concerns about technical compatibility, and consumer pressures for easily understandable information have combined to significantly increase the strategic and practical importance of standards. In recognition of this, the Agreement on Internal Trade calls for increased reliance by governments in Canada upon standards and conformity assessment bodies. International trade agreements, such as the North American Free Trade Agreement and the World Trade Organization Agreement on Technical Barriers to Trade, oblige Canadian governments to consider using international standards when developing domestic regulations. Similarly, the Government of Canada's *Regulatory Policy 1995* requires federal officials to determine whether an international standard exists upon which they can base a domestic regulation.

This guide is divided into four chapters and contains three appendices.

Chapter 1 provides an overview of domestic and international standards.

Chapter 2 discusses issues governments should consider when working with standards development organizations to develop standards that will be incorporated into regulations.

Chapter 3 discusses issues governments should consider when using standards-based conformity assessment processes to promote and monitor compliance with regulations.

Chapter 4 discusses issues governments should consider when promoting the development of voluntary standards to supplement regulatory regimes.

Appendix A provides descriptions of each of the main standards organizations.

Appendix B summarizes the provisions of Canada's most important international trade agreements that are relevant to the development and use of standards.

Appendix C contains a glossary of the abbreviations used in this guide.

Overview of Standards

Standards Council of Canada

The National Standards System (NSS) is the system for developing, promoting and implementing standards in Canada.² The Standards Council of Canada (SCC) coordinates the NSS. The SCC is a federal Crown corporation comprising representatives from the federal and provincial governments as well as from a wide range of public and private interests. It prescribes policies and procedures for developing National Standards of Canada, coordinates Canada's participation in the international standards system, and accredits more than 250 organizations involved in standards development, product or service certification, testing and management systems registration activities in Canada.



Key Attributes of Standards

- developed by a consensus-based multi-stakeholder process
- stipulate requirements that a product, process or service must meet
- prepared under the auspices of a recognized SDO

Standards Development Organizations

There are four SCC accredited standards development organizations (SDOs) in Canada: the Canadian Standards Association (CSA), the Underwriters' Laboratories of Canada (ULC), the Canadian General Standards Board, and the Bureau de normalisation du Québec. Appendix A provides more information on these SDOs.

Each SDO develops standards according to the procedures stipulated by the SCC, including the use of a multistakeholder committee, consensus-based decision making, and public notice and comment requirements. See Chapter 2 for a complete review of the standards development process.

Types of Standards

Standards development organizations develop four types of standards.

Performance standards: tests that simulate the performance of a product under actual service conditions form the basis of standards for, among other things, food safety, fuel economy, and the design of packaging for transporting hazardous goods.

Prescriptive standards: these identify product characteristics, such as material thickness, type and dimensions (e.g. CAN/ULC-S603-1992, Standard for Underground

Steel Storage Containers for Flammable and Combustible Liquids).

Design standards: these identify specific design or technical characteristics of a product (e.g. CSA Z183 Oil Pipeline Systems).

Management standards: these set out standards for quality management (e.g. International Organization for Standardization (ISO) 9000) and environmental management system (e.g. ISO 14000) processes.

² Appendix A discusses the various elements of the NSS in detail.

SDOs may submit standards they develop to the SCC to be recognized as National Standards of Canada. SDOs also develop other standards-related documents, such as codes and guidelines (non-mandatory guidance and information documents).

Conformity Assessment Bodies

The NSS also includes organizations that provide three conformity assessment services related to monitoring and verifying compliance with standards: certification, testing and management systems registration.

Certification organization (CO) marks attest that products or services conform to standards. COs regularly conduct on-site audits, and sample and test certified products and services. As of 1998, there are 14 COs in Canada.

Testing organizations determine whether a product or service meets the appropriate standard. There are currently more than 200 accredited testing organizations in Canada, including private research laboratories, government and industry facilities and most of the certification organizations. The SCC accredits them based on their ability to perform tests according to recognized standards and procedures, and to document their findings.

The process of demonstrating conformity to a management standard is known as management systems registration, a relatively recent addition to the NSS. Management systems registrars issue registration certificates to companies that meet one of the four International Organization for Standardization (ISO) standards for quality management (ISO 9000 series) or the ISO 14000 environmental management standard. By mid-1998, the SCC had accredited more than a dozen management systems registrars.

International Standards Regime

As noted above, the NSS operates within an international standards regime that includes both the domestic standards systems of other countries and the various international standards development and conformity assessment organizations. The latter includes the following groups: the ISO and the International Electrotechnical Commission, as well as many specialized bodies such as the International Telecommunication Union, the International Organization of Legal Metrology, the Codex Alimentarius Commission, the International Telegraph and Telephone Consultative Committee, 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 Organization. Appendix A provides a description of international standards organizations.

Trends in the Use of Standards

Implications for Competitiveness of the Effective Use of Standards

Standards play an increasingly important role in improving the operations of the marketplace and promoting growth and trade. There has been a rapid rise in the number of standards used by most of Canada's main trading partners. Many factors have contributed to this: mass production; labour specialization; a growing demand for interchangeable parts; globalization; manufacturers' concerns about product liability litigation; demands for cheaper goods; consumer pressure for easily understandable product information; public demand for product safety and quality control; concerns about technical compatibility between products; and demands for precision in product measurement.

Standards have become key determinants of economic competitiveness. The positive effects of standardization include the following:

- technical efficiency, by increasing the ease with which one firm's products can be substituted for, or combined with, those of another
- interchangeability and compatibility of products, contributing to higher levels of productivity through exploitation of economies of scale and scope
- efficiency of resource allocation (producing goods to meet recognized standards can reduce the amount of information customers need to make informed purchase decisions)
- improved information that can reduce the risk of product failure and consumer perception of such risk
- technical and product innovation through the use of leading-edge standards
- reduced translation costs (such as those for moving data between systems using different software).

Organizations are applying standards to a wider range of products, procedures and services because standards no longer just pertain to measures directly protecting health, safety and consumers. Perhaps the best known example is the ISO 9000 series of quality management standards. In addition, more and more standards are based on objectives, rather than being prescriptive. This trend promotes innovation and minimizes the risk of a standard becoming a barrier to competition.

Increased Importance of International Standard Setting

While standardization provides important domestic benefits, it is becoming more and more important internationally, making a number of modern technologies and products possible. The Internet functions because of agreed-upon interconnection protocols. Standards also benefit users by providing reliable information on product quality, safety and performance. For example, standards ensure that electrical appliances plug into standard wall sockets. International standardization also helps open up global markets, allowing importers to meet local safety requirements and permitting the coordination and integration of parts from different countries.

International trade agreements, such as the World Trade Organization, and regional ones, such as the North American Free Trade Agreement, now require participating countries to consider the use of international standards when developing rules to guide industry. (Appendix B summarizes the relevant provisions of these agreements.) As a result, the rate at which international standards are set is growing. The ISO, for example, now publishes about 350 standards a year, more than twice as many as it did 20 years ago.

This increased reliance on international standards has significantly enhanced the strategic importance of linking domestic regulatory and standards development initiatives to international trends.³ Rarely now can governments develop national standards without closely assessing concerns about consistency with current or potential international standards.⁴

The growing importance of international standards has also increased the strategic importance of participating in international standard-setting activities, which can help ensure that international standards reflect Canadian interests. Such efforts can also reduce the time and money governments subsequently spend to develop or modify domestic standards and regulations on the same subject.

3. The timing of national and international standard setting is important to observe. There is risk associated with developing a national standard in advance of a scheduled international standard, because national efforts could be out of line with international directions. On the other hand, developing a national standard first can provide a strategic advantage in international discussions. For example, the CSAs experience developing its environmental management system standard helped greatly in international discussions about ISO 14000. The relevance of these strategic considerations will vary a great deal, and each case should be judged on its merits.

4. Governments must make an important decision when major export markets rely on different standards (e.g. when the United States relies on standards different from those of the European Union). These situations require judgments concerning the relative importance of the markets and the likely international trend of standards for the product or process.

Using Standards Development Processes for Regulations



Hybrids

- Governments develop some regulations themselves using standards-like consensus processes.
- Some standards are developed by a standards development organization, mandated by regulations, and enforced through the regulatory apparatus.
- Some regulations are enforced through standards-based conformity assessment processes.

Options for Incorporating Standards into the Regulatory Regime

In most cases, regulatory regimes comprise a complex structure of rules, guidelines, compliance policies, controls over the exercise of discretion, and historical practices and traditions. The rules are usually mandatory, and are based either on statutes or on regulations made under enabling powers found in statutes.

Governments can use the standards development process to create a number of the components of a regulatory structure, including both the mandatory rules found in statutes or regulations and the non-mandatory guidelines that are sometimes used to elaborate the rules.

There are several ways to use standards to create mandatory rules within a regulatory regime. A standard may include all of the requirements of the regulation. For example, section 4.7.1 of the *Canadian Environmental Protection Act's* Environmental Code of Practice for Underground Storage Tank Systems Containing Petroleum Products and Allied Petroleum Products requires that overfill protection devices be “designed, built and certified” in accordance with the relevant Underwriters’ Laboratories of Canada standard.

Alternatively, a regulation may include a standard that addresses part of the behaviour to be controlled with another, more comprehensive set of requirements. For example, Health Canada’s proposed medical devices regulations will require, among other things, that manufacturing processes for medical devices in specified risk categories be certified as complying with the International Organization for Standardization (ISO) manufacturing practice standards for medical devices.

Methods of Incorporating Standards into Law

Standards may be incorporated into law in several ways:

- incorporated directly into statutes (i.e. the statute reproduces the wording of the standard)
- incorporated by reference into statutes (i.e. the statute refers to a particular standard, but does not reproduce the wording of the standard; section 10 of the *Food and Drugs Act*, for example)
- reproduced directly in regulations (e.g. the Processing and Distribution of Semen for Assisted Conception Regulations)
- incorporated by reference into regulations (e.g. the Transportation of Dangerous Goods Regulations incorporate by reference numerous domestic and international standards)
- used as guidelines to elaborate rules found in statutes or regulations (e.g. s.B.01.056 (Sched. 923) of the Food and Drug Regulations).

Standards Development Process

Standards development organizations (SDOs) may develop a standard in response to a request from anyone concerned. 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. It then ensures that the various stakeholders can provide the necessary funding. The SDO 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 the standard may bring.



SDOs will avoid issues when they do not believe that they will be able to develop a technically sound standard, either due to the complexity of the issue or their lack of expertise in the particular subject matter.

In general, SDOs are less interested in developing a standard when funds are not available to cover development costs, or when it will be difficult to assemble a technical committee that meets the “balance” requirements of the Standards Council of Canada (SCC). SDOs may also be reluctant to develop a standard when they are concerned about potential liability flowing from claims related to damages incurred by activities or products that met the standard.

Standards development by accredited SDOs generally follows the SCC requirements for the preparation and approval of National Standards of Canada (CAN-P 2E) (see Figure 1, page 12). These guidelines reflect the standards community’s strong commitment to consensus and due process.

The central feature of this process is the reliance on volunteer technical committees to develop standards through consensus-based decision making. If an SDO decides to develop a standard, it will establish and support a technical committee, the members of which have relevant expertise and represent a balance both geographically and in terms of interests and perspectives. The precise composition of each committee depends on the nature of the standard to be developed, but generally includes consumer and general interest representatives (e.g. academics and safety associations), government officials and producers. In a number of subject areas, such as child safety, standing committees may be involved in the development of several standards at a time.

At the outset, the technical committee reviews existing standards for possible application. To meet the requirements to become National Standards of Canada, standards must be consistent with or incorporate appropriate international standards. The committee also initiates the necessary testing and data collection, and determines the breadth and scope of the standard.

Technical committees reach decisions by consensus, requiring substantial but not unanimous agreement among the parties involved. The process also calls for committee members to discuss and revise standards until they are agreed upon.

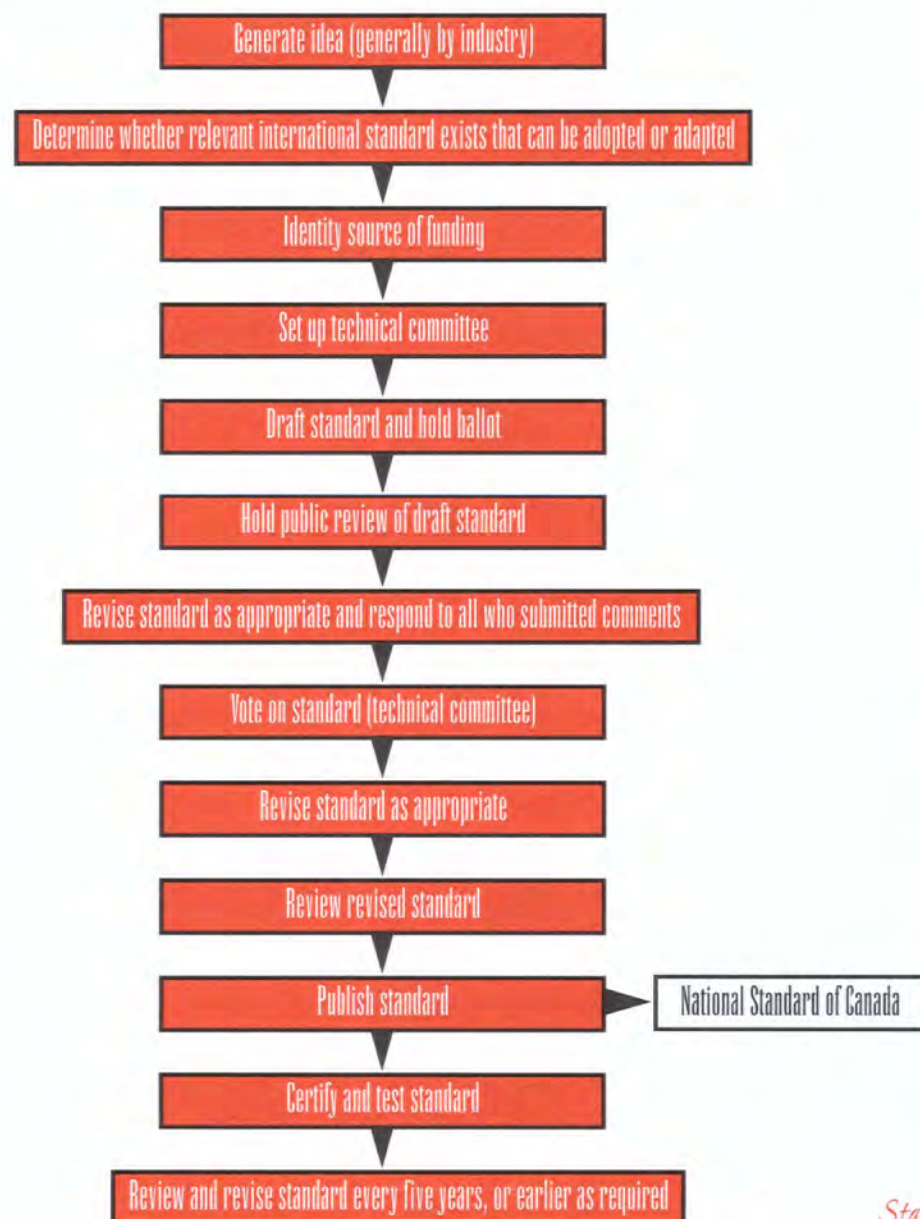
SDOs ensure that standards undergo a thorough review for technical as well as policy considerations. When the issue being addressed involves health or safety, the SDO will also conduct a thorough risk assessment.

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 it, the SDO may also distribute it 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 compliance with process requirements (e.g. balanced representation and consensus) rather than to re-evaluate technical or substantive content. Before adopting a standard, the SDO allows at least 60 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 then compiles all the comments and ensures that they are reviewed by the technical committee. The committee will either incorporate the comments in the standard or identify reasons for not doing so. If anyone who comments enquires about the status of his or her submission, the SDO will provide an explanation of how the committee incorporated the comment, or why it did not.

Standards development under this process takes an average of one to one-and-a-half years. Once finalized, the SDO publishes the standard and makes copies available on reasonable terms to any person who requests one, no matter where he or she is located. If the SDO puts the standard forward for designation as a National Standard of Canada, it must publish the standard in both official languages, maintain it and review and update it every five years. Upon completing these reviews, the SDO will reaffirm, revise or withdraw the standard. The SDO is also responsible for maintaining proper records of the standards development process.

Figure 1
Standards Development Process Prescribed by the Standards Council of Canada



Comparison of Standards and Regulations

Standards

Standards Development Process

- Standards development organizations (SDOs) facilitate the development of standards in response to requests from proponents.
- SDOs seek consensus on the content of standards.
- Government review and analysis requirements do not apply to standards developed by SDOs. However, SDOs send out proposed standards to experts for review.
- National Standards of Canada are automatically reviewed and updated at least once every five years.

Conformity Assessment

- Certification organizations, testing organizations and management systems registration organizations conduct conformity assessment.

Regulations

Regulatory Development Process

- Governments take the lead in developing regulations.
- Governments consult interested parties, but do not necessarily seek consensus.
- Federal regulations are subject to Regulatory Impact Analysis Statement requirements, and are subject to review by the Department of Justice Canada.
- Treasury Board requires regular reviews of regulations to ensure their ongoing relevance and currency.

Compliance Assurance

- Governments enforce their regulations themselves or, at least, remain accountable for enforcement when they rely on others to carry it out.

Considerations

When government officials are determining when and how to regulate, they should consider principles of good regulatory management. These have been set out in a number of documents, including the Government of Canada's *Regulatory Policy 1995* and the *Recommendations of the Council of the Organisation for Economic Cooperation and Development (OECD) on Improving the Quality of Government Regulation* and the *OECD Reference Checklist for Regulatory Decision-making*.

Among the common themes of good regulatory management are the following:

- the need for a clear definition of the problem to be addressed
- the provision of opportunities for interested stakeholders to present their views
- the identification of the benefits and costs of the proposed action
- the obligation to respect international and interprovincial agreements
- the need to conform with legal requirements
- the use of clear, comprehensible language
- the need for the resulting rules to be accessible.

In addition to respecting these considerations for regulatory development, government officials will also want to ensure that they meet broader regulatory management objectives when following the standards development process in order to maintain accountability. For example, agencies and departments must develop appropriate complaint-resolution processes, implement effective compliance and enforcement strategies, and allocate adequate resources to support their regulations,



Common Attributes of Standards and Regulations

- both represent structured rule-making processes
- both stipulate a desired condition or result
- both must meet similar criteria for their development (e.g. technical soundness, positive benefit and involvement of interested parties)
- both require compliance strategies to ensure that their objectives are met
- both are officially published

regardless of how they develop rules. The use of standards or the standards development process per se will not ensure that these requirements are satisfied. When standards are incorporated into federal regulations, the complaint-resolution processes of the federal department will deal with concerns about the standards. Similarly, departments proposing that standards be incorporated into regulations will have to manage the resulting regulatory program effectively.

The following subsection of the guide covers matters that officials should take into account regarding the capacity of SDOs to develop standards to be used in regulations. The next six subsections review the ways in which these processes address the regulatory development considerations identified above. The final five subsections address considerations related to the following: accountability, development and maintenance costs, timeliness, the nature of the commitments government can and should make concerning the use of a standard, and government participation on technical committees.

Capacity of SDOs to Develop Standards to be Used in Regulations

An important issue for government officials who consider relying on an SDO to develop a standard is whether the SDO and the committee drafting the standard have the appropriate subject area expertise. SDOs rely primarily on the expertise of their technical committees. In assembling these committees, SDOs seek to ensure that they have well-qualified experts while satisfying the representational criteria for a balanced group. It is also helpful if SDO staff members have experience and are familiar with the subject area, and are able to commission research from academics or consultants as required.

The SCC accreditation process requires that SDOs satisfy several criteria, including:

- the capacity to provide an assurance of continuing operations
- the ability to reflect major national interests at all stages of development of a standard
- the knowledge about standardization
- the ability to provide adequate secretariat support
- the existence of well-defined procedures for preparing, reviewing, publishing and distributing standards.

Effective Consultation

Observers and participants disagree about the degree to which the SCC standards development process provides, in practice, for effective consultation and reflects fairly the full range of interests on any given issue. It is important, therefore, to emphasize that government officials considering using an SDO should consult with the SDO to determine whether its process will satisfy the government's own process requirements.

The SCC rules for the development of a National Standard of Canada require the following⁵:

- that the technical committee includes balanced representation
- that SDOs provide for public input, both on an ad hoc basis and through public review processes
- that committee decisions are based on "consensus."

Each of these features is reviewed on the pages that follow.

5. Organizations operating outside the NSS will not necessarily conform to these process requirements. In particular, non-accredited organizations may not use multistakeholder processes, relying instead on industry-specific technical expertise.



The SCC defines balanced representation as follows: “no single category of interest representation can dominate the voting procedures of the committee.”

Accordingly, SDOs typically try to ensure that a technical committee features a balance of interests both geographically and with respect to substantive interests.⁶

Balanced Representation

The SCC rules on balanced representation require “a reasonable agreement among the views of a number of capable individuals whose collective interests provide a balance of representation of producers, consumers and others with relevant interests, as may be appropriate to the subject at hand.”

Notwithstanding these requirements, however, various public interest groups have observed that they have had difficulty participating on technical committees. In some cases, non-governmental organizations (NGOs) have complained that their requests to participate as voting members have been denied. In most cases, however, NGO participation problems relate to a lack of funding for preparation and travel.

Although government officials cannot dictate who may participate on a technical committee run by an SDO, they can influence the composition of a committee established to develop a standard that they have requested. While SDOs will normally be receptive to such requests or suggestions, they will not allow government to stipulate who is precluded from participating.⁷

Public Input

In addition to the formal committee process, SDOs provide for public input through a variety of means. Most SDOs make public announcements about their intention to develop a standard. If an interested party asks to attend a committee meeting, the committee may invite him or her to attend as an observer, or may ask for a formal presentation of his or her concern or proposal. In some cases, the committee may decide to address the issue raised by striking a subcommittee, which may include non-committee members.

Technical committees also circulate drafts of the standards for at least 60 days to interested persons and technical experts. Committees must consider and respond to all comments received.

SDOs that are also certification organizations (COs) may provide for additional public input by circulating drafts of new or revised standards to their clients.

The increasing importance of international standards may have significant implications for public participation in standards development. The SCC requirements for the preparation and approval of National Standards of Canada (CAN-P 2E) state that SDOs must examine whether international standards are available that can be adopted or adjusted to create a Canadian standard. The objective is to increase harmonization and reduce trade barriers. However, the resulting use of a growing number of international standards reduces the opportunity for most Canadians to be meaningfully consulted and involved in the standards development process. This problem applies to both standards and regulations since government policy and treaty obligations also require government officials to consider international standards prior to developing regulations. While this trend may

6. The SCC rules recognize that “there may be some circumstances where the subject matter... is specialized to the extent that it is not possible to form a balanced committee.” In such cases, the SCC requires the SDO to substantiate the reasons for the imbalance when it forwards the proposed standard to the SCC for approval as a National Standard of Canada.

7. It is important to note that an SDO, when creating a technical committee, must ensure that no one interest outweighs another in terms of voting membership. As a result, in some cases, voting membership cannot be provided to every interested party. This, however, does not preclude all interested parties from providing input to the technical committee.



The SCC defines consensus as follows: “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).

emphasize the need for Canadian SDOs and governments to be involved in international standards development, it limits opportunities for public consultation and input.

Consensus-based Decision Making

SDOs use a consensus process to develop standards. As defined by the SCC, *consensus* does not mean that the volunteers comprising the technical committee have to unanimously agree on the appropriate standard. Instead, it means that the group has reached substantial agreement and attempted to resolve all objections; in other words, it implies more than the concept of simple majority but less than unanimity.

The features of balanced representation, public input and consensus-based decision making are not unique to standards development processes. Government can duplicate them with such mechanisms as consultation and expert advisory groups. All government regulators consult to a greater or lesser degree in the development of new regulations and the adjustment of the existing regulatory regime. Indeed, many regulatory authorities are now using consensus-based regulatory negotiation processes to reach accommodation on regulatory action. For example, the Canadian Environmental Assessment Agency developed regulations under the *Canadian Environmental Assessment Act* through its Regulatory Advisory Committee, a multistakeholder body chaired by a professional facilitator, operating on the basis of consensus.

This type of government-sponsored regulatory negotiation is very similar to the consensus process run by SDOs. In theory, in both cases, a broad range of interests is represented. No one interest is allowed to dominate the process and the government is simply one player at the table. A facilitator helps the group to reach an agreement through consensus.

One of the most important benefits of either type of consensus-based process is that it can enhance support for, and compliance with, the resulting standard among those parties who participate in its development. Having been involved in its development, industry participants will be more likely to “buy in” to its implementation. A reduction in compliance costs for the government may more than offset any added cost resulting from government support of the process.

A consensus process, however, will not always be appropriate. They are often lengthy, not allowing a quick response to urgent situations. When there is an important political dimension to the regulatory decision or the credibility of the regulator is important, it may be necessary for the government to retain greater control than it would in a consensus process.

Consensus may also be impossible when the interests involved have such divergent views or fundamental beliefs that the government must step in to make the final decision. There may also be situations in which value judgments are such an important element of the regulatory development process that accountability demands that the decision maker be a responsible political representative.

In some cases, SDOs may have more in-house experience than government in developing consensus-based decisions in a given subject area. In some cases, it may also be valuable to be able to take advantage of the neutrality of SDOs, particularly when important prospective participants distrust government on the issue.

SDOs will not always be the appropriate body to run a consensus process, however. One factor to consider when deciding this may be the importance of ensuring the public’s perception of government involvement. Many observers view regulatory negotiation as a process that is directly sponsored by government and integrated into the development process. This can be an advantage in some situations, particularly when it is important that the public perceive that government is taking action.



Important Process Questions

- When is consensus — as opposed to consultation — appropriate?
- When is it appropriate to rely on an SDO-run consensus process?



When consensus is appropriate, when should government decision makers consider relying on an SDO?



Before relying on or participating in an SDO-run consensus process, it is important to ensure that the committee reflects the appropriate range of stakeholders and that all parties have adequate capacity to participate effectively.

In addition, SDO-run processes will not always provide for an appropriate balance of interests. Because they rely on voluntary input, SDO-run consensus processes can favour large business interests over those of small businesses or public interest groups who are less able to afford the resources necessary to participate effectively. Standards often focus on highly technical issues and many NGOs have minimal technical expertise and few resources. As such, they too may not be in a position to participate effectively in SDO-run processes.

One important consideration is whether it would be appropriate to cover some prospective participants' costs for preparing for and participating in a consensus-based process. In some cases, SDOs are willing to cover these costs for NGOs. In other cases, government may have to do so to ensure balanced input.

Government participation in the SDO consensus process can promote the consideration of public interest concerns. Information and alternatives developed by government can ensure that the interests of NGOs or stakeholders with limited resources are not ignored. Government, by its very participation, can thus help ensure that the appropriate range of interests is considered in the consensus process.

Benefits and Costs of Action

Before proposing regulations for enactment, federal proponent departments must complete a Regulatory Impact Analysis Statement (RIAS). This requires the proponent to demonstrate that it has assessed the benefits of regulatory action, as well as the costs. When developing regulations internally, government regulators must carry out this analysis early in the process and incorporate it into regulatory proposals. If a standard is being incorporated in a regulation, it is also subject to a RIAS.

SDO technical committees will not necessarily assess the costs and regulatory burdens of a standard with the same analytical depth and rigour as will a well-done RIAS. The consensus reached through a standards development process can generally be read as a good indicator that interested parties accept that the benefits of the standard outweigh its direct costs and that its application will be cost-effective. A technical committee, however, may not necessarily consider whether the social benefits outweigh the social costs.

The standards development process will address some relevant considerations at a pragmatic level:

- the business representatives on the technical committee will take into account economic considerations, in particular, the impact on business
- the mandatory public review will also allow for consideration of some economic and employment-related impacts
- because they can be amended more easily than regulations, standards can provide a flexible means of responding to rapidly evolving technology.

The SDO process is unlikely to systematically address concerns related to distributional effects and social costs; however, government officials could develop social cost-benefit analyses of various options under consideration by the committee.

International and Intergovernmental Agreements

Canada is a party to numerous bilateral and multilateral agreements addressing issues such as environmental protection, human rights and labour provisions. Federal government officials must, therefore, ensure that the standards they sponsor comply with these agreements.

In addition, various trade agreements also explicitly address the use of standards in regulations. These agreements include the World Trade Organization agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary Measures (SPS), the North American Free Trade Agreement (NAFTA) Articles on Technical Barriers to Trade, and the Canadian Agreement on Internal Trade.

These agreements require that domestic regulations and voluntary standards adhere to two core principles: most favoured nation (MFN) and national treatment. MFN requires that the rules applied to one trading partner not be “less favourable” (i.e. more demanding) than those 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. In addition, both the TBT and SPS agreements encourage countries to base domestic regulations or standards on international standards, except when no applicable international standard exists, or when international standards would be an ineffective or inappropriate means to fulfil the legitimate objectives of the domestic regulation or standard. The agreements place the onus on countries to provide scientific evidence to justify deviation from an international standard. Appendix B summarizes relevant trade agreement requirements.

The latest edition of the SCC’s requirements for accreditation of SDOs (CAN-P 1D) incorporates all of the relevant provisions of the the General Agreement on Tariffs and Trade, TBT, SPS and NAFTA agreements. Standards developed by accredited SDOs will, therefore, satisfy relevant international trade agreement requirements.

Government officials will also have to ensure compliance with any other relevant agreements (e.g. those on labour, environmental and human rights). For standards developed by non-accredited organizations, officials will have to confirm that all international obligations are satisfied, either by the organization developing the standard or by government.

Legal Requirements

Regulators wishing to make a standard developed by an SDO part of a regulation can do so either by reproducing the text of the standard in the regulation or by incorporating the standard by reference. A variety of legal issues apply in either situation. This section summarizes three of these issues. In all cases, however, it is important to receive legal advice on a case-by-case basis.

Incorporation by reference is a technique in which a regulation refers to another document without setting out its contents. Some statutes explicitly authorize incorporation by reference. The courts have not yet determined the precise scope of opportunities for incorporating standards by reference when statutes do not address the issue.

Motor Vehicles for Disabled Persons

The Vehicles for the Transportation of Physically Disabled Passengers Regulations under the *Ontario Highway Traffic Act* incorporate by reference CSA Standard D409. This standard prescribes the structure and performance of such vehicles, and is used to regulate what equipment qualifies for this purpose in certain circumstances.

A second important legal issue has to do with the status of amendments to standards. The precise legal requirements for incorporating by reference standards that are “amended from time to time” are not clear.

Thirdly, regulators interested in incorporating a standard into a regulation should also be aware of the distinction between requiring that regulated products “comply with standard ABC” versus requiring that they “be certified as complying with standard ABC.” The former places the onus on the regulated company to ensure that it is in compliance. By contrast, the latter requires regulated companies to pay for an accredited certification organization to certify that their products are in compliance.

Clear, Comprehensible Language

As with regulations, standards are intended to be clear and comprehensible to their intended audience. The SCC *Criteria and Procedures for the Preparation and Approval of National Standards of Canada* (CAN-P 2E) require, among other things, that standards:

- include statements identifying the intended coverage of the subject and use of the standard
- be based on requirements that are stated as far as possible in measurable terms
- be formulated in terms of performance to avoid inhibition of design or innovation and, at the same time, to facilitate objective measurement of conformity.

Accessibility

Regulators must ensure that the public has easy access to the standards to which regulations refer. In theory, regulations can incorporate the complete text of standards. In such cases, they will be available to the public through the *Canada Gazette* and any other vehicle the department or agency relies on to disseminate its regulations. It is very rare, however, for regulations to reproduce the text of a domestic standard since such standards can be quite detailed and are readily available. This technique can be very helpful, however, when using a foreign standard that might not be easy to consult in Canada.

In other cases, a regulation will incorporate a standard by reference (i.e. refer to the title of the standard, but not reproduce its text). In this case, the public will have to obtain a copy of the standard to understand the relevant regulatory requirements.

In general, this should not be a problem, since the SCC requires accredited SDOs to publish their standards promptly and to make copies available under reasonable terms to any person, wherever he or she is located. Moreover, all National Standards of Canada are available in both French and English.

It is important, however, to avoid situations in which a regulation refers to one standard that, in turn, refers to one or more others. In such cases, it can be very difficult for a regulated party (or any interested member of the public) to understand the relevant requirements, particularly if the referenced standards are subject to revision.

Accountability

The government is accountable for all of its regulations, regardless of how they are developed. Accordingly, when the government uses a standard in a regulation, whether by incorporation by reference or by reproducing the standard in the text of the regulation, the government is accountable for the contents of the regulation. The use of the standards development process to develop the standard does not relieve the government of responsibility for the regulation.

Furthermore, when the government uses the standards development process rather than drafting a regulation internally, it must continue to ensure that the public participation process is acceptable from a regulatory perspective. Thus, while the SCC is responsible for ensuring that the standard is developed according to its rules for a National Standard of Canada, government officials may still want to request process modifications or to support broader consultation or publication efforts.

The government is also accountable for implementing the regulatory regime and establishing adequate compliance and enforcement systems.

Development and Maintenance Costs

In general, an SDO will develop a standard only if a proponent is willing to pay for the development process or if the SDO can cover those costs by selling the standard and through conformity assessment services. In some cases, interested businesses will be willing to cover the costs of developing a standard. However, when revenues from conformity assessment services are not likely to be high and when there are no other interested sponsors, the government agency wishing to sponsor the development of a standard must pay for it.

Most SDOs are non-profit organizations, and therefore seek only to recover their costs. These will vary depending on the complexity of the subject matter, but can be as high as hundreds of thousands of dollars. These costs do *not* include most expert and multistakeholder input, which is voluntary, but do cover the organization's time and resources engaged in the following activities:

- recruiting and training staff (if necessary) to develop the standard
- conducting a feasibility analysis
- coordinating and administering the consensus process
- providing lab and testing equipment, as required
- distributing the draft standard for public review and receiving comments
- publishing and marketing the standard.

The potential cost to government of using an SDO relative to that when developing a regulation internally can be estimated on a case-by-case basis only; however, they are often comparable. For example, the consensus-based standards development process may reduce the government's consultation costs for the adoption of the standard as a regulation. One important factor to consider, however, is that internal development by government typically uses considerable personnel time. By contrast, the government will have to pay for the bulk of the costs of using an SDO to develop a standard out of its operations and management budget, and assign fewer people to the file.

The cost of standards development does not end with the creation of the standard, however, because regular review and revision is an inherent part of the standards system. When the government has sponsored the development of a standard, or used a standard in a regulation, it may be necessary for the government to support the review and revision process by the relevant SDO.

Although SDOs traditionally carry out all steps in the development of a standard, in some circumstances they may be willing to adopt government-sponsored work to satisfy some of their preliminary requirements. When government contemplates using an SDO, or when it is undecided, it is



Government agencies can reduce the cost of using SDOs by undertaking some of the preliminary steps internally.

advisable for it to ensure that any preliminary work (e.g. background research, preliminary consultations and expert advice) is conducted so it will satisfy the procedural requirements of the NSS.⁸ This will eliminate the need to repeat early steps in order to satisfy a process-related requirement of an SDO. The feasibility of this approach should be checked early on with the SDOs with whom the agency contemplates partnering.

Health Canada's Organ and Skin Grafting Standard

Before asking the Canadian Standards Association (CSA) to develop a standard addressing organs and tissues, Health Canada conducted considerable preliminary research. This work included asking Health Canada experts as well as a multistakeholder expert advisory committee to recommend the appropriate scope of the standard. Because this process replicated the CSA's normal practice, the CSA agreed to forego some of its usual steps, thereby reducing the cost to Health Canada for sponsoring the standard's development.



The development of standards also imposes costs on industry and other participants.

As governments use SDOs more frequently to develop regulations, the capacity and willingness of both industry and NGOs to participate in regulation development will have to increase. Participation in the consensus process to develop standards can be prohibitively costly for small businesses and NGOs, more expensive, in fact, than for most consultations on government regulations. In some sectors, even large businesses have opposed regulators' increased reliance on SDOs due to concerns about the high cost of participating in the regulatory development process.

As the use of international standards increases, participation in all of the relevant standards development bodies may become a significant financial and logistical challenge, even to Canada's largest businesses and the government. As noted previously, however, this participation is becoming increasingly important both to promote and protect Canadian economic interests and to preserve Canada's capacity to develop domestic regulations as it chooses.

Timeliness

The speed with which regulators address an issue may be important, particularly when a rapid response to a new risk is required and when economic competitiveness depends on quick adaptation to changing circumstances.

Government and business officials have expressed concerns about the length of time required to complete the consensus process relied upon by SDOs. Although these take, on average, one to one-and-a-half years, SDOs have some flexibility to arrange for a much quicker process. As with development costs, it is necessary to compare on a case-by-case basis the likely time required for an SDO to develop a standard versus the time it would take government. Regulatory negotiations by government can be equally time-consuming. On the other hand, faced with an emergency, government can significantly reduce its usual negotiation or consultation process and issue regulations very quickly.

8. This work must be adequately documented, both to satisfy the NSS requirements and to ensure accountability.

An important factor to consider when estimating the likely time requirements is that government can help reduce the SDO's research time by providing money and expertise to support the technical work required by the committee preparing the standard. In particular, the government can support the type of analysis that might otherwise be required by a Regulatory Impact Analysis Statement.

Government Commitments to the Use of a Standard

One of the most important issues confronting government officials who wish to rely on an SDO to develop a standard is the commitment the government should provide to the SDO with respect to the use of the standard. In many cases, government officials will want to reserve the right to modify or reject altogether a standard when drafting a regulation. The dilemma, however, is that officials may have to provide some reassurance that a standard will be adopted in order to encourage appropriate stakeholders to invest voluntarily the time and resources required to use the SDO process.

Ultimately, Cabinet (and Parliament) will always retain the right to decide on the content of a regulation. In practice, however, if the government asks an SDO to develop a standard for use in a regulation, it should make good faith efforts to adopt the standard as developed.

Instead of relying on its right to modify the standard after the fact, government should seek to influence the content of the standard as it is being developed. It can do so in three ways:

- by influencing the composition of the technical committee
- by undertaking some of the preliminary steps internally
- by playing an active role on the technical committee.

Government Participation on Technical Committees

One of the most effective ways to monitor and, if appropriate, influence the content of a standard is to participate on the technical committee. All SCC accredited SDOs consider the participation of government officials. Although government participation does not entail veto power, the government may have considerable resources and expertise with which to support participation on a committee, if it desires. A well-informed participant can have considerable influence over decisions and play an important role in informing and persuading fellow committee members.

Finally, it should be noted that SDOs have the flexibility to establish bodies and mechanisms through which regulators can advise standards committees on regulatory needs and review standards for their acceptability for regulatory purposes before they are finalized.


Canadian Advisory Committee on Electrical Safety (CACES)

The committee comprises provincial and territorial regulators that advise the Canadian Standards Association and the Standards Council of Canada on the content and the need for electrical safety standards in Canada.

Considerations for Using Standards Development Organizations to Develop Standards for Use in Regulations

1. Does a problem or risk exist? Is federal government intervention justified?
2. Is there an international standard, or is an international standard being developed, that will address the domestic requirement?
3. Does the standards development organization (SDO) have the necessary experience and capacity to develop a standard for the issue in question?
4. Will the SDO ensure an adequate consultation process that accounts fairly for the full range of relevant interests?
 - Should government support the participation of any non-governmental organizations?
 - Should government provide other opportunities for public input?
5. To what extent will the SDO ensure that the benefits of the resulting standard outweigh its costs to industry, government and society?
 - What additional analysis will government have to undertake?
6. To what extent will the SDO ensure that the resulting standard does not unnecessarily impede wealth generation and employment opportunities?
 - What additional analysis will government have to undertake?
7. Will the SDO ensure that the resulting standard respects relevant international trade, human rights, labour or environmental agreements?
8. Will the SDO ensure that the standard is written in clear, comprehensible language?
9. Will the SDO ensure that the resulting standard is easily accessible by the public in both official languages?
10. Can the SDO develop the standard in a timely manner?
11. How will the standard be incorporated into regulation? By reference or by reproducing the text of the standard in the regulation? Is there adequate legal authority to do so?
12. Has the government established appropriate accountability mechanisms with respect to the development and implementation of the resulting standard?
13. Can government afford the costs necessary to develop and revise the standard?
14. What commitment is the government able to provide to prospective voluntary participants on the SDO technical committee concerning the use of the resulting standard?
15. What role should government play on the technical committee?
 - initial development work
 - social cost-benefit analysis
 - risk analysis
 - representation of the interests of non-participants.

Using Standards-based Conformity Assessment Processes



The National Standards System (NSS), like other standards regimes, offers a wide range of conformity assessment processes. These include testing for conformity with the standard by accredited labs, designating third parties to certify conformity, and management systems registration by accredited registrars. This chapter describes the opportunities to integrate these mechanisms into the compliance program of a regulatory regime. The first section describes these options in detail and provides examples of the different ways in which existing regulatory regimes use them. Following that is a discussion of the considerations regulators should address when determining whether and how to use these options.

Options and Current Experience

Conformity assessment is the determination of whether a product, service or process conforms to particular standards or specifications. Standards-based conformity assessment processes include testing, certification and management systems registration.

Regulators can include some or all of these processes as part of the enforcement regime both for regulations that incorporate standards developed by standards development organizations (SDOs), and for regulations that make no reference to such standards. For example, a regulation requiring compliance with a National Standard of Canada could specify that conformity be determined by a conformity assessment body accredited by the Standards Council of Canada (SCC). Similarly, a regulation requiring compliance with a rule developed by government could also specify that conformity be demonstrated through certification by an accredited conformity assessment body.

The following subsections summarize the different types of conformity assessment processes, and some of the ways in which existing regulatory enforcement regimes can use these processes.

SCC Accreditation Processes

The SCC accredits organizations to perform each of the types of conformity assessment processes on a fee-for-service basis. Accreditation requires the conformity assessment body to demonstrate its ability to satisfy SCC requirements. The process also involves regular reviews by the SCC to ensure ongoing competence. Failure to satisfy SCC requirements leads to withdrawal of SCC accreditation. In this way, the SCC provides for an “audit the auditors” regime.

Accreditation of Calibration and Testing Laboratories

The SCC accredits labs on the basis of their ability to perform tests in accordance with recognized standards and to adequately document their findings. Accredited labs are an independent source of testing; they provide test results, but do not interpret data. In the case of calibration laboratories, the technical part of the accreditation process is carried out by, or on behalf of, the Calibration Laboratory Assessment Service of the National Research Council. The labs may publicize their competence based on the SCC’s nationally recognized accreditation program. The SCC publishes a *Directory of Accredited Testing Organizations* that lists the testing or calibration activities for which each lab is accredited.

Some government laboratories, such as that of the Canadian Food Inspection Agency's Centre for Veterinary Drug Residues, are accredited. Various government programs, as well as private businesses, also make use of labs certified in the private sector. For example, Environment Canada's Environmental Technology Centre contracts some of its testing to private laboratories certified by the Canadian Association of Environmental Analytical Laboratories, which, in turn, is accredited by the SCC.

Canadian Association of Environmental Analytical Laboratories

In 1989, Environment Canada helped establish the Canadian Association of Environmental Analytical Laboratories (CAEAL) to act as the certification body for environmental analytical laboratories. CAEAL is a non-profit organization with a board comprising representatives of the public and private sectors, as well as regional interests. CAEAL applies a Canadian standard that is based on ISO Guide 25 when certifying laboratories. In 1994, CAEAL and the Standards Council of Canada signed a partnership agreement forming the basis for the certification of environmental laboratories in the fields of chemistry, radiochemistry, microbiology and toxicology. As the only certified organization of its kind in the world, CAEAL has helped export Canadian laboratory practices and standards to many countries.

Some regulatory programs also work with SDOs to develop test methods to support regulatory initiatives. In some cases, the resulting test methods are referenced in regulations.

Product or Service Certification

Certification organizations (COs), which are themselves accredited by the SCC, carry out tests to verify that a product, product component or process meets the requirements of the relevant standard. The CO then certifies products or services as conforming to the standard and authorizes the manufacturer to use the CO's logo. The manufacturer or service provider may use the logo for publicity or to assure the public of adherence to a standard denoting quality or accuracy.

The CO audits the manufacturer or service provider from time to time and verifies through quality control record review and sample testing that the product or service continues to meet the standard against which it was tested and certified. The CO may withdraw permission for the manufacturer or service provider to use the logo if the product or service fails to meet the specified standard. In turn, the SCC audits each accredited CO every two years.

The SCC requires each CO to provide ways for members of the public to complain about certified products or services. The SCC also requires accredited COs to allow companies to appeal a refusal to certify or a withdrawal of certification.

Elevator Safety Code

The Safety Code for Elevators (CAN3-B44-M85) describes the requirements for the design, installation and maintenance of elevating devices in Canada. There is a certification program associated with the code. The Canada Labour Code references this standard in a variety of places, in particular in the Canada Occupational Safety and Health Regulations in Part 4 of the Code. In addition to referring to this standard, these regulations require that inspection and testing of elevating devices comply with the testing and certification requirements set out in the standard.

Ice Hockey Helmets

CAN/CSA-Z262.1 describes the requirements for, and testing of, ice hockey helmets. The standard has an associated certification program. The *Hazardous Products Act* and its regulations require that hockey helmets comply with the standard before they can be imported, advertised or sold in Canada, and that the manufacturers/suppliers show compliance with the terms by a certification mark.

Management Systems Registration

The SCC accredits management systems registrars such as the Quality Management Institute, which is accredited both as an environmental management systems registrar (International Organization for Standardization (ISO) 14000 standards) and a quality management systems registrar (ISO 9000 standards).⁹ Registrars must demonstrate that they have qualified staff and proper record keeping, and are free from conflicts of interests. The SCC regularly audits each accredited registrar.

Management systems registrars inspect firms to determine whether they may be registered for a management systems standard. Meeting the standard indicates that firms follow accepted procedures, processes and administrative mechanisms. A registrar carries out an on-site assessment of the firm to determine whether its management systems, information systems, and quality control systems meet the appropriate ISO 9000 or ISO 14000 standard. The certificate of registration issued to the firm is valid for a specified period and follow-up audits are conducted at least annually. Management systems registration assesses only a firm's quality or its environmental management system, and is not a certification of the products or services themselves or an indicator of performance.

9. There are also specialized quality management systems, such as Z809, the Sustainable Forest Management System and QS-9000, which is the quality management system for Tier 1 suppliers to the automotive industry.

Medical Devices

Health Canada is proposing to use international standards (DIS13485) that require medical device manufacturers to implement ISO 9001 to ensure consistent quality of their products. The proposed regulation would require manufacturers of specified classes of medical devices to undergo third-party registration for the standards using accredited registrars.

First-, Second- and Third-party Conformity Assessment Processes

Conformity assessment services can be provided in various forms.

First-party conformity assessment occurs when a company operates an SCC accredited laboratory that tests the company's own products.

Second-party conformity assessment occurs when company A pays accredited lab B to test its products. Company A then uses the test results to declare that it is in conformity, and the test results remain the property of company A.

Third-party conformity assessment occurs when a company pays an accredited certification organization to certify its products. In this case, the CO may use an accredited lab to test the products, but all test results are available to the public.

Emerging International Competition Among Conformity Assessment Bodies

As with most commercial activities, conformity assessment is being affected by market globalization. The increasing amount of international activity is raising the pressure for domestic recognition of conformity assessments performed in other countries. Similarly, it is resulting in a growing interest on the part of foreign conformity assessment bodies in becoming accredited and competing in the Canadian marketplace.

Considerations

Rationale

Using standards-based conformity assessment processes to promote or monitor compliance with a regulation can provide a number of benefits. It can reduce government (but not necessarily industry) costs by requiring regulated parties to pay SCC accredited labs, registrars and COs for their services. In some cases, use of third-party certification and registration bodies can also ensure that individuals with greater expertise or familiarity with industry processes than government oversee the compliance process.

Both of these benefits apply regardless of whether the rule with which compliance is required is a standard developed by an SDO or a regulation developed by government. There are, however, a number of additional potential benefits from using standards-based conformity assessment processes in conjunction with a standard that was developed and is maintained by an SDO. The most important

of these is the flexibility that is retained by the SDO to modify the standard, in response to either technological change or learning that a revision might enhance compliance and overall performance. In some cases it may be easier for the conformity assessment organization to communicate the need for such changes to the appropriate SDO than it would be for government enforcement officials to argue for a modification to a regulation.

Notwithstanding these potential benefits, there are a number of important factors to be considered when determining whether and how to integrate standards-based conformity assessment processes into a regulatory regime. The remainder of this section reviews the following considerations: compliance levels, capacity, consistency, accountability, regulatory negligence, credibility and cost.

Compliance Levels

Regulators have considerable flexibility in the way they use standards-based conformity assessment processes. The degree to which regulators choose to rely on these options, and the particular design of the overall compliance assurance program, should reflect both the degree of risk associated with non-compliance and the likelihood that contextual factors will promote compliance.

Government decision makers must identify the pressures for and against compliance on a case-by-case basis in order to determine whether a given compliance assurance model will be effective. A firm's compliance decisions depend on a complex mix of factors, including:

- awareness, understanding and acceptance of the objectives and rules of the regulatory program
- capacity to comply (e.g. expertise and sophistication of the industry, know-how about compliance and resources available to invest in compliance)
- the existence of incentives for compliance, including:
 - the threat of official sanctions
 - market pressure
 - consumer pressure and concern about public image
 - pressure from other industry members
 - opportunities and incentives for the public to identify and expose non-compliance
 - opportunities and incentives for competitors to identify and expose non-compliance
 - potential cost savings or other advantages resulting from compliance (e.g. improved reputation and increased sales)
 - reduction in potential liability (e.g. adequate due diligence defence).

Standards-based conformity assessment processes tend to be the most effective — and politically acceptable — means to promote compliance with a regulation when an environment of compliance incentives is in place (e.g. when quality products and reliable manufacturing processes are important to the firm or when customers or competitors can see compliance with product certification). Regulating against a background of an existing product liability regime can also be a strong incentive for compliance.

Capacity

Before relying on a standards-based conformity assessment body, it will be necessary to ensure it currently has, or has the capacity to develop, the skills and resources to carry out its responsibilities.

A challenge arises when the domestic capacity for conformity assessment in the required area is low. Experience indicates that it is possible for organizations to which responsibilities are delegated to

develop the requisite expertise in a new subject area, provided they have adequate resources and experience in related work. At a minimum, government agencies intending to rely on private conformity assessment bodies must allow sufficient lead time for the market to develop the required capacity. Government intervention may be required to ensure that the private sector can respond to the demand for certification, registration or testing services created by a new regulation. In some circumstances, government should consider helping create the necessary capacity (e.g. by offering training to COs).

Consistency

Consistent application of regulatory rules is essential. Consistency is an important element of fairness and minimizes the possibility of anti-competitive impacts. Consistency is also important to the regulated businesses because it allows them to plan with certainty. In addition to the availability of adequate resources and expertise, three important factors can contribute to consistency within a compliance assurance program:

- standards should be clear and objective
- oversight bodies should have sufficient independence to avoid conflict of interest and capture by industry
- decision making should be transparent and follow the principles of fairness.

Clear and Objective Rules

Rules, whether in the form of a regulation or a standard, must be sufficiently clear and specific to limit ambiguity and reduce uncertainty about behavioural expectations, both on the part of those to whom the rule applies and on the part of those responsible for compliance assurance. In general, it is also preferable to ensure that the rule is output- or results-oriented. This will allow for discretion in terms of how to comply, and focus on the desired end result.

Independence

In general, favouritism can occur if the individuals and organizations responsible for compliance assurance are not sufficiently independent from the regulated party. As such, second- and third-party conformity assessment processes offer more assurances of independence and objectivity than first-party approaches.

In some cases, however, first-party approaches can be very effective. Various Canadian steel companies maintain SCC accredited labs to assure customers that their products meet specified standards. When relying on inspectors or auditors who are employees of the regulated companies to fulfil certain conformity assessment functions, their responsibilities and reporting relationships should be sufficiently clear to ensure that they are able to act autonomously and responsibly.

Transparent Decision Making

In order to allow for effective oversight, the decisions made by conformity assessment bodies that have an effect on a firm's compliance record or that impose sanctions should be recorded and available to government.

In addition, the use of standards-based conformity assessment processes should not deprive a firm of the procedural protections it might have when subject to direct government oversight. Thus, for example, before government or the conformity assessment body responds to a perceived violation, the firm should be notified of any intention to take action and have an opportunity to provide an explanation.

As with government enforcement agencies, conformity assessment bodies must address confidentiality issues concerning the interests of a firm wishing to maintain confidentiality regarding trade secrets and proprietary processes. When assessing conformity with standards, SCC accredited conformity assessment bodies have some discretion to address confidentiality issues. When asked to assess compliance with a regulatory requirement, they should be provided with clear authority and guidance as to how to balance confidentiality considerations against the government's interest in oversight, as well as the public's interest in the enforcement of the law.

Transport Canada's Airworthiness Regulations

Transport Canada uses employees of some regulated aeronautics companies to fulfil certain monitoring and certification activities required by its airworthiness regulations. The department has found that this reduces government enforcement costs and ensures that regulated companies identify and respond to problems more quickly than if it relied exclusively on government inspectors.

This arrangement works well with aeronautics companies because the cost of non-compliance to regulated companies in this area is very high. Accordingly, they have an interest in ensuring that the employees who are designated to carry out conformity assessment functions can do so independently and effectively.

In addition to a need for consistency, a certain amount of discretion is essential to the effective implementation of any regulation. Discretion is required to ensure that the punishment fits the offence; to allow the law to remain abreast of new conditions and understanding; and to allow laws to be applied to unforeseen circumstances. The objective should be to limit and review the discretion that conformity assessment bodies may exercise and to encourage consistency, but not to eliminate their discretion altogether.

Accountability

Regardless of how a government chooses to implement and enforce a regulation, it must remain accountable for the effectiveness of that regulation. The use of standards-based conformity assessment processes places considerable discretion in the hands of the CO. Effective accountability requires that the government retains the capacity to oversee the exercise of that discretion. To do so, the government must:

- retain independent residual enforcement and rule-making authority
- retain enough expertise in the subject area to allow it to perform an adequate oversight role
- have access to timely and adequate information.

Residual Enforcement and Rule-making Authority

The government must retain enough enforcement capacity to ensure effective oversight and accountability for the regime. In doing so, the government should tailor its level of oversight to the issue; in general, higher risk activities warrant a higher level of government involvement. The government should also focus its oversight at points of maximum leverage.

Retention of Expertise

Government agencies must also not allow the delegation of enforcement activities to erode their knowledge of the regulated sector. It is important to be familiar enough with the sector to be able to evaluate the efficacy of the regulatory regime and to engage in future policy development. This may require that government personnel remain actively involved in the oversight of the sector.

Ongoing expertise may also be required when government is heavily involved in export activities or international negotiations. For example, Transport Canada officials play an important role in dealing with foreign regulators concerning aviation manufacturing exports. Complete delegation of inspection and related activities could erode government's understanding of the industry and reduce its effectiveness in helping the industry demonstrate to foreign customers and regulators that it meets relevant requirements.

Timely and Adequate Information

In order for government to oversee a regime that relies on an accredited conformity assessment body, it requires access to timely information. This is a particularly important consideration with respect to the use of accredited labs. It will be important, for example, to ensure that the labs on which a regulator intends to rely for evaluating evidence collected during an investigation or for the purposes of a prosecution, can respond in a timely manner, notwithstanding pre-existing commitments to other clients.

There is also the difficult question of how much of the information generated by conformity assessment activities should be disclosed to government. In many cases, standards-based conformity assessment regimes require regulated parties either to conduct audits of their operations themselves or to arrange for third-party audits. Both cases present the issue of whether the results of those audits should be revealed to government.

The argument in favour of disclosure is that evidence of a violation of a regulatory regime uncovered in an audit must be disclosed. The argument against is that the threat of disclosure reduces the effectiveness of audits as a management tool. If it is known that audits will be available to government (and, by extension, to the public through access to information proceedings), companies will be less keen for auditors to search out and reveal violations and to make recommendations. In short, companies will be less likely to make these reports an integral part of their management processes.

Increasingly, regulators relying on audit processes are developing formal policies indicating how and under what circumstances they will use audits. One possible compromise is to indicate that routine reports of internal compliance groups and of external auditors will not be available to government agencies as long as the regulated party seeks to remedy problems identified in the reports. If the company fails to do so, the auditor would be obliged to reveal the report to the government. Moreover, if the government agency identifies the violation by means other than the audit report, it would be entitled to the report that discussed the violation.

Regulatory Negligence

In recent years, the courts have tended to find that regulators owe members of the public — the very people a regulatory regime was intended to protect — a duty of care; negligence in carrying out operational regulatory responsibilities can leave the regulator open to liability. There is no general liability, however, for “policy” decisions.

The general trend in liability indicates that government bodies must take their regulatory responsibilities seriously to avoid liability. The degree to which the government might be held liable for inadequate or negligent operation of an SCC accredited conformity assessment body on which it relied is uncertain.

Credibility

A compliance assurance regime must be credible to regulated firms in order to be effective. It must also be credible to the public in order to ensure political acceptability of the program. When exports are a significant component of the regulated activity, the regime must be credible in foreign markets and, in some cases, with foreign regulators.

Using an NSS conformity assessment process will generally provide the required credibility from the perspective of participants and markets. In some cases, however, the public and public interest groups may have less confidence in the process. For some, this may be due to a lack of awareness of the way in which the particular process operates. Concern may also arise due to a belief that the process fails certain interests and that only government can address certain high-risk issues. In other cases, foreign governments may require Canadian government involvement in a regulatory regime. This need may range from standard setting, to implementation and enforcement, to oversight of the regime through an auditing and reporting process.

Transport Canada's Airworthiness Regime

Transport Canada's regime for ensuring airworthiness provides an interesting example of a mix of regulatory requirements and conformity assessment processes.

Significant public concerns and export market demands require government regulation; however, the department also uses third-party certification processes to enhance the reach and efficiency of its regulatory compliance assurance regime.

Cost

The use of standards-based conformity assessment processes by government regulators will change the distribution of costs relative to those for an entirely government-run enforcement process.

Requiring regulated parties to pay for the services of an accredited lab, certification organization or registrar can increase the costs of regulatory compliance borne by the regulated parties themselves.

Regulatory requirements for the use of COs can also affect the SCC. When a regulation requires the use of an accredited CO to perform a new function (i.e. a function for which there are no accredited COs), the regulation may have the effect of requiring the SCC to develop a new accreditation program.

Finally, the use of COs can reduce government enforcement costs. As well, governments are now starting to experiment with user-pay models, in which regulated parties pay for government administration and enforcement. In addition, although the use of conformity assessment processes may reduce the need for government enforcement activities, it will not eliminate the need for effective oversight mechanisms and the retention of an effective residual enforcement capacity.

Considerations for Applying Standards-based Conformity Assessment Processes

1. Will the conformity assessment process be credible to the marketplace, foreign governments and the public?
2. Are sufficient factors present to ensure high compliance levels? These include:
 - awareness, understanding and acceptance of the objectives and rules of the regulatory program
 - capacity to comply (e.g. expertise and sophistication of the industry, know-how about compliance and resources available to invest in compliance)
 - the existence of incentives for compliance, including:
 - the threat of official sanctions
 - market pressure
 - consumer pressure and concern about public image
 - pressure from other industry members
 - opportunities and incentives for the public to identify and expose non-compliance
 - opportunities and incentives for competitors to identify and expose non-compliance
 - potential cost savings or other advantages resulting from compliance (e.g. improved reputation and increased sales)
 - reduction in potential liability (e.g. adequate due diligence defence).
3. Do the conformity assessment bodies have adequate monitoring and enforcement capacity?
4. Will the conformity assessment program be applied consistently?
 - Are the standards clear and objective?
 - Are the conformity assessment bodies sufficiently independent to avoid conflict of interest and capture by industry?
 - Is the decision-making process transparent and based on the principles of fairness?
5. Can the government be held accountable for results?
 - Will it retain independent residual enforcement and rule-making authority?
 - Will it retain enough expertise to perform an adequate oversight role?
 - Will it have timely access to sufficient information?
6. Is the conformity assessment process likely to respond to the needs of regulators?
 - Will government have access to enough information to continue to fulfil its policy-development activities?
 - Will it provide timely results?
7. Will the use of standards-based conformity assessment processes impose costs that are acceptable to all parties concerned?

Using Voluntary Standards as an Alternative to Regulation

Governments might be interested in promoting the development or use of a standard for reasons other than wanting to incorporate it into regulation. In some cases, of course, industry will support the development of a standard for economic or trade reasons. There may be situations, however, in which governments will be able to promote the development of a standard as an alternative or supplement to regulation.

For example, governments can use voluntary standards to elaborate or complement existing regulations.

Care Labelling of Textiles

Industry Canada administers the Care Labelling Program to promote the use by garment manufacturers of the CAN/CGSB-86.1-M91, Care Labelling of Textiles, standard. This standard specifies the type of information about cleaning and safety, for example, that manufacturers should include on garment and textile labels. This standard is not referenced in regulation, but helps supplement Industry Canada's consumer protection legislation.

In some cases, voluntary standards can help overcome some of the issues related to shared regulatory authority.

Canadian Food Inspection System Model Codes

Canada's food inspection system operates in a complex jurisdictional context. Federal authorities regulate food packaging, labelling and advertising. They also establish and enforce health and safety standards for imports, exports and interprovincial trade. The provinces and territories regulate health, safety and quality within their boundaries. Recently, Canada moved toward a more integrated regime. The 1994 *Blueprint for the Canadian Food Inspection System* called for harmonized standards and integrated inspection systems. The Canadian Food Inspection System Implementation Group, which is implementing this plan, has focussed on developing harmonized standards. In 1997, it approved the National Dairy Code, and is now developing similar codes for the meat and retail service sectors. The objective is to develop a model for legislation at all levels of government, and to promote outcome-based regulations supported by voluntary codes that describe best practices in detail.

Considerations

The federal government has published guides on the use and design of the wide range of non-regulatory instruments and options that are available. This chapter supplements that material by describing some of the considerations relevant to the promotion of standards.

When assessing the potential for a voluntary standard to serve a policy objective, and when comparing standards to other non-regulatory measures, government officials should keep in mind the process requirements stipulated by the Standards Council of Canada (SCC) for developing a National Standard of Canada. As is described in more detail on page 11, the SCC document CAN-P 2E requires accredited standards development organizations (SDOs) to rely on volunteer technical committees to develop standards based on a consensus approach. These committees must have adequate expertise and be balanced, both geographically and in terms of representation of interests and perspectives. Once a technical committee has developed a draft standard, the SDO must follow a prescribed process of public notice and comment. SDOs must publish National Standards of Canada in both official languages, and must review them at least every five years.

To determine whether voluntary standards will change behaviour sufficiently to satisfy policy objectives, government officials might also consider the factors detailed below.



➤ Would non-compliance with the standard present an unacceptable risk to health or safety?

➤ Is there a high degree of political sensitivity or strong public opinion regarding the behaviour that is to be controlled?

➤ How often do consumers purchase the product or service?

➤ What value do consumers place on high-quality products or services?

➤ Is it easy for consumers to send market signals?

Risks to Health or Safety

When the risks to health or safety from non-compliance are high, the government may decide that it should back standards with the force of law and the possibility of legal sanctions.

Political Sensitivity

Even when a voluntary standards regime can achieve the government's objectives, there may be political or public policy reasons for invoking the power of the government to regulate behaviour.

Consumer Behaviour

Consumers who care about compliance, and whose purchasing behaviour reflects their approval of compliance, create strong incentives for companies to comply with voluntary standards.



- Is poor quality or high quality easily observable?
- Is the price relatively low?
- Can consumers correct purchasing errors without high penalties?
- Can consumers or other industry members detect non-compliance with the voluntary standard?
- Are there many importers who would not consider themselves bound by Canadian voluntary standards?
- Do independent legal liability regimes exist that could enforce incentives for compliance with a voluntary standard?
- Does the government have the constitutional legal capacity to regulate effectively in the area?
- Is it an area of shared jurisdiction?
- Would multijurisdictional cooperation be necessary to deal with a regulatory issue?
- Do international standards exist?
- Are there complementary standards in the same area?

Attributes of the Product or Service

When consumers can easily observe non-compliance with a standard and can change their purchasing behaviour rapidly and at low cost, an industry will have a greater incentive to comply with the standard.

Existence of Import or Export Markets

When there are a number of importers, voluntary compliance with a standard by domestic industry may not be sufficient to achieve government policy objectives, such as consumer protection.

Liability Regimes

The potential for independent legal liability, through product liability or workers' compensation regimes, for example, can induce industry to meet standards without government having to enact the standards as law.

Jurisdictional Issues

Industries operating across jurisdictions, even internationally, can meet voluntary standards without the limitations imposed by governments. When multiple jurisdictions rely on a common international voluntary standard, for example, industries can operate according to harmonized standards, achieve economies of scale in their operations and still meet the policy objectives of different governments without being subject to multiple (and possibly conflicting) regulations.

Existing Standards

When a voluntary standards regime exists, governments may find it worthwhile to encourage the further adoption or elaboration of the existing regime rather than to impose distinct regulatory requirements.

Design Requirements for Handicapped Access

CAN/CSA-B651 supplements the existing building code by focussing on how accessible buildings are for people with physical disabilities. Although this standard is not referenced in legislation, Public Works and Government Services Canada requires that buildings under its jurisdiction, such as post offices, comply with it.



- How many firms are in the industry?
- How sophisticated are the firms?
- Do they have compliance expertise?
- Are management systems in place that allow for compliance monitoring and accountability?
- Is there an established industry association that can be used as a focus for peer review and compliance enhancement?
- Is there an imbalance of power among the industry members that might make it difficult to achieve consensus or to avoid favouring certain interests?
- Are there irreconcilable differences of opinion about the need for change among the industry members?

Industry Structure

Sophisticated industries with a history of cooperation and compliance with government requirements are good candidates for self-regulation. The existence of an industry organization, or the ability to organize one, can be an advantage in developing and implementing a self-regulatory regime. An industry with relatively few members, most of whom agree on the need for change and who can monitor each other's compliance, is often one that can regulate itself successfully.

Testing Bio-containment Equipment

CSA Standard Z316.3, Biological Containment Cabinets (Class I and II): Installation and Field Testing, provides testing criteria and procedures for conducting field tests of bio-containment equipment. While this document is not referenced in any piece of legislation, the *Health Canada Laboratory Biosafety Guidelines*, 2nd Ed. require labs owning and using such equipment to demonstrate they comply with the standard, particularly in support of applications for research grants from the Medical Research Council and the Natural Sciences and Engineering Research Council.

Voluntary standards are likely to work in an industry with a relatively small number of firms that are sufficiently mature to take a long-term view of their interests and not be constrained by short-term considerations that inhibit investment in monitoring and compliance with standards.¹⁰

Firms with relatively high exit costs from the market may be more likely to comply with industry-wide standards. Firms with rapidly changing or advanced technology may be able to comply more effectively with standards in such areas as environmental quality, in which investment in new technology may be required for compliance. Sophisticated firms with established internal compliance systems are well placed to conform to voluntary codes or standards.

Firms are most likely to achieve consensus on a standard when they have sufficiently common interests to be able to agree and be willing to enforce the standard; ideally, the views of peers should be important to industry members and they should be sensitive to consumer or public opinion. Expertise must be available within the industry for standard development and for adherence to the standard. Low import activity and a situation in which all or most industry members will use the standard are also desirable.¹¹ When there are high levels of imports from countries not interested in or able to develop and promote similar standards, it may not be feasible to attempt to control an activity or product through voluntary domestic action.

Finally, economic incentives, such as product compatibility, access to markets, and legal liability, can be sufficient incentives to allow for standards development and compliance.

10. Standards are likely to be effective in circumstances similar to those in which effective codes work. For more information on codes, see *Voluntary Codes: A Guide for Their Development and Use*, Office of Consumer Affairs, Industry Canada and Regulatory Affairs Division, Treasury Board Secretariat, 1998.

11. When the imports are primarily from a country with a compatible standard, however, there are likely to be few problems enforcing the standard.

Conclusion



Standards and standards-based conformity assessment processes are important tools that government regulators can use in various ways, as alternatives to regulations, to supplement or provide guidance to regulatory requirements, or as part of regulations. Similarly, regulatory compliance assurance regimes can rely on all or some of the standards-based conformity assessment processes: using accredited laboratories for testing and calibration, accredited certification organizations, and management systems registrars.

This guide has identified some of the main considerations related to the selection, design and implementation of standards and standards-based conformity assessment processes. It is important to emphasize, however, that these options represent only some of the many regulatory and non-regulatory tools available to government. As such, the potential benefits and disadvantages offered by standards must be assessed and compared to other options on a case-by-case basis. It is also important not to rely on the factors identified in this guide as prescriptive criteria. In any given situation there may be circumstances that preclude the use of standards even though many of the considerations identified here may support their use.

This guide presents standards and standards-based conformity assessment processes as part of a suite of policy instruments available to government, a suite that also includes the following:

- statutes and regulations
- policies and guidelines
- memoranda of understanding and agreements with industry
- economic instruments such as taxes and subsidies
- education and moral suasion.

Depending on the circumstances, these instruments can complement, or be a substitute for, each other. Decision makers will consider a variety of factors when deciding which instrument or combination of instruments is most likely to be effective and efficient.

As with any of these instruments, standards are often best used in combination with other measures. Indeed, the decision to regulate or to apply a standard is unlikely to prove a mutually exclusive choice for a variety of reasons. Standards are almost always developed within a pre-existing regulatory context. In fact, they may be developed in anticipation of government regulation.

An activity the government wishes to control may also lend itself to having some aspects regulated while others are addressed through the use of a standard. Government may rely wholly or in part on the standards development process to write standards that become regulations. Similarly, it may also rely on standards-based conformity assessment processes to ensure compliance with a regulation developed within government. Thus, a system is developing in which both standards and regulations exist, but in which the government is also making use of hybrids that integrate aspects of each system.

Overview of Canada's National Standards System

National Standards System

The National Standards System (NSS) is the system for developing, promoting and implementing standards in Canada (see Figure 2, below). The NSS includes more than 250 organizations accredited by the Standards Council of Canada. These organizations are involved in several activities: standards development, product or service certification, product testing and quality and environmental management systems registration.

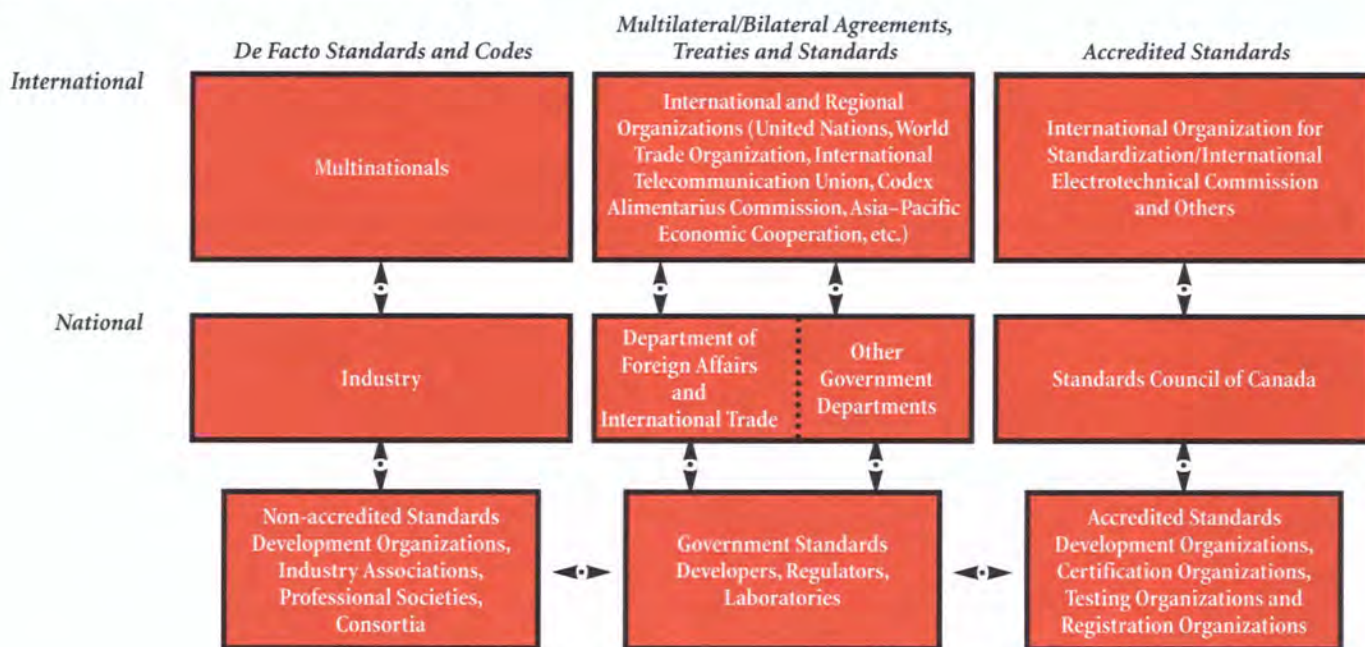
The NSS does not include all such activity in Canada: there are organizations performing each of these services that are not accredited by the Standards Council of Canada and that operate outside the NSS. Nor is the system static: organizations can and do join and leave the system.

The NSS is a dynamic and complex rule-setting and rule-enforcing system with explicit formal processes to govern the relationships among its many member organizations. These processes are designed to ensure the effectiveness and credibility of the NSS. As a result of the increasing importance of standards, Canadian standards development organizations (SDOs) are broadening their services to offer "one-stop shopping" to their customers, and are reaching out to the international market by seeking accreditation in foreign countries and offering services to international clients.

The following sections review briefly each of the main components of the NSS.

Figure 2

International and National Standards Systems



Standards Council of Canada

A federal Crown corporation, the Standards Council of Canada (SCC), coordinates standardization activities in Canada, including the designation of National Standards of Canada. The SCC is independent of government, although it remains partially financed by public funds. SCC members are appointed by the Governor in Council and include a wide range of interests so that no one party dominates policy directions.

The SCC was created by an Act of Parliament in 1970 (amended in 1996). Its main responsibilities are as follows:

- to accredit organizations involved in standards services in Canada (i.e. development, certification, testing and registration)
- to promote the coordination of the activities of these organizations
- to approve standards developed by these organizations as National Standards of Canada using the 16 criteria it has formulated, and to maintain an official directory of all National Standards of Canada
- to designate Canadian representatives for the major international standardization bodies (e.g. the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)), and to work to develop formal agreements with accreditation bodies in other countries to provide mutual recognition of each other's accredited organizations.

The SCC 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 systems registrations, and for conducting calibration and testing by accredited laboratories.

The SCC regularly audits the operations of the organizations it accredits to ensure they maintain the capability to operate the program for which they are accredited. When they do not, 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, such as the ISO, to which it belongs.

Standards Development Organizations

There are four accredited SDOs in Canada: the Canadian Standards Association (CSA), the Underwriters' Laboratories of Canada (ULC), the Canadian General Standards Board (CGSB), and the Bureau de normalisation du Québec (BNQ). Each of these organizations develops standards through committees representing various interests. SDOs may submit standards to the SCC to be recognized as National Standards of Canada. They can 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 affected 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 the areas in which they have conformity assessment programs. For example, only about one third of the CSA's 1800 standards have related conformity assessment service offerings.

The BNQ and CGSB, by contrast, are both public sector organizations that run on cost recovery. As with the CSA and ULC, they offer standards development services in addition to conformity assessment services. Like the private sector organizations, they do not restrict their standards development activities to cases for which they have or could have conformity assessment programs. However, unlike their private sector counterparts, their standards development activities are not subsidized by the sales of conformity assessment services; rather, they seek funding for each standards development project from stakeholders and interested parties.

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

Canadian Standards Association

Founded in 1919, the Canadian Standards Association is Canada's largest and oldest SDO and offers standards development, testing, certification and management systems registration services in a wide range of areas. A private, not-for-profit organization, it has published more than 1800 consensus standards and guidelines in 37 technology areas.

Underwriters' Laboratories of Canada

Established in 1920 as a not-for-profit organization, the 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. The ULC has published more than 240 standards and other recognized documents (see page 43 for more information on other recognized documents (ORDs)), many of which are referenced in codes and government regulations.

Canadian General Standards Board

Established in 1934 by the federal government, the Canadian General Standards Board offers a range of standardization services on a cost-recovery basis to both the public and private sectors. These services include standards development, certification and qualification listing, and management systems registration in a broad range of subject areas. Part of the federal department of Public Works and Government Services Canada, the CGSB focusses on providing services in support of government mandates and their related programs.

Bureau de normalisation du Québec

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

Conformity Assessment Bodies

Certification Organizations

Certification organizations (COs) attest, by authorizing the display of their certification mark, that products or services conform to a standard. They regularly inspect and audit processes and products. As of 1998, there are 14 COs in Canada. These organizations have registered trademarks or logos giving a visible indication that products or services comply with a standard.

Certification organizations accredited by the SCC may develop requirements to certify products when no standard exists. These requirements are called other recognized documents (ORDs) and are developed by the CO and submitted to regulatory councils in Canada (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 (typically three to six months) is usually faster 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 ORD development is borne by the manufacturer or regulator requesting it. For COs that are also SDOs, the ORD is usually then submitted to the committee responsible for developing it as a National Standard of Canada.

Testing Organizations

Testing organizations determine whether a product or service meets the appropriate standard. There are more than 200 accredited testing organizations in Canada, including private research laboratories, government and industry facilities, and most of the certification organizations. The SCC accredits them based on their ability to perform tests according to recognized standards and procedures and to document their findings.

Management Systems Registrars

The process of demonstrating conformity to a management systems standard is known as management systems registration, which is a relatively recent addition to the NSS. Management systems registrars issue registration certificates to companies that meet one of the four ISO 9000 series standards for quality management. The SCC has developed a similar system for ISO 14000 registration for environmental management. By mid-1998, there were more than a dozen accredited management systems registrars in Canada.

International Standards Organizations

In recognition of the importance of standards, various international agreements oblige Canada to consider using standards when developing regulations to guide industry (see Figure 2, page 40). The Agreement on Internal Trade requires that the federal and provincial governments use the National Standards System of Canada or international standards, and the conformity assessment services of the NSS. Similarly, the World Trade Organization 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..." SDOs, themselves, will look to international standards to see if a standard exists that can be adopted rather than independently developing a national standard.

International Organization for Standardization

The International Organization for Standardization is a non-governmental organization established in 1947 to promote international collaboration and trade. It covers all areas of standardization, except the electrical and electronic fields, which are the purview of the International Electrotechnical Commission (see below). With representation from the standards bodies of almost 100 countries, the ISO includes all the major trading nations, as well as various international organizations, such as United Nations Environment Programme and the World Wildlife Fund. The SCC represents Canada on the ISO.

The ISO's work results in international agreements that are published as international standards. Any group of five member countries can begin this process by suggesting the need for a standard to the ISO secretariat in Geneva.

International Electrotechnical Commission

The International Electrotechnical Commission consists of representatives from 42 countries that account for 80 percent of the world's population and 95 percent of its electrical energy production. Members are drawn from the countries' principal national standardization bodies. The IEC maintains advisory committees on electromagnetic compatibility, electronics and telecommunications, and safety.

Other International Standards Bodies

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

There are also a number of specialized organizations that coordinate standards internationally, including the International Telecommunication Union and the International Organization of Legal Metrology. These organizations have liaison status with the ISO and participate in the presentation and drafting of international standards (or the ISO adopts their standards as international standards). Other bodies working with the ISO include the International Telegraph and Telephone Consultative Committee, 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 Organization.

Standards Bodies in Other Countries

Japan, the United States and the major European countries each have their own national standardization organizations. The European Union has attached a high priority to the harmonization of the standards of its members. It promotes the mutual recognition of its members' approaches as the basis for Union-wide standards.

Of particular relevance to Canada, because of the importance of trade between the two countries, is the American standards system. In contrast to those in most other industrial countries, the American standards system is highly decentralized. U.S. private standards development, testing and certification bodies compete intensely with each other for both revenue and jurisdiction. There is no public sector equivalent in the U.S. to the Standards Council of Canada, and standardization bodies in the U.S. have strongly resisted the creation of such a body. The American National Standards Institute, a private organization, 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. The hundreds of existing standardization bodies have tended to develop uniquely American standards, with little reference to or compatibility with international standards.

Chapter Nine of the North American Free Trade Agreement sets out the obligations of parties concerning standards and promotes the harmonization of the parties' standards-related measures, conformity assessment processes and technical regulations. It promotes the mutual acceptance of testing and certification procedures and results, as well as mutual recognition by signatories of each others' certification and accreditation bodies.

Non-NSS Standards Development Regimes

Many standards used in Canada are not National Standards of Canada. In some cases, these standards may have been developed by Canadian SDOs and not put forward as a National Standard of Canada, often because of the cost of translating the standard into both official languages. In other cases, international, regional or foreign SDOs, such as the ISO, may have developed the standards. In addition, organizations not accredited by the SCC develop some standards. Important non-NSS standards include the Building Code, developed by the National Research Council.

In some cases, it may not be appropriate or necessary for a body serving a very specialized market niche to operate under the standards development processes stipulated by the SCC (e.g. requirement for multi-stakeholder consensus). The consensus requirement for an open process may be seen in some sectors as compromising the confidentiality of new products. In sectors such as electronics, in which technology changes rapidly, *de facto* standards may emerge, developed by a leading company or consortium, more quickly than may those an SDO could develop through consensus.

In other 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 or self-regulatory regimes occupy the grey area between government regulation and standards regimes and are, therefore, 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, an environmental and occupational health and safety program run by the Canadian Chemicals Producers' Association, is a case in point.

From a public policy perspective, therefore, the issue with using standards in a regulatory regime is not so much whether a standard was developed within the NSS or outside it, but whether it is effective and credible. The NSS ensures effectiveness and credibility through its requirements for consensus, accreditation, audits and appeal processes. To the extent that non-NSS standards meet tests similar to those used to develop NSS standards, they, too, should be effective and credible. Government regulators, however, may have to assume some of the responsibilities of the SCC (e.g. public consultation and the provision of review processes) in order to satisfy themselves that non-NSS standards meet their policy objectives and government requirements for regulatory action.

Summary of International Trade Requirements

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

In many cases, a standard that is incorporated into a regulation will be a “technical regulation” as defined in the WTO TBT agreement and NAFTA.¹² These agreements require that, for technical regulations affecting trade, federal regulatory authorities do the following:

- prepublish proposals for new or changed technical regulations in the *Canada Gazette*, Part I, for at least 75 days, except in urgent circumstances, and take into account any comments they receive
- specify, when 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 fulfil the objectives of the existing regulations
- ensure that technical regulations treat products from one jurisdiction no less favourably than similar 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 when those standards achieve the regulatory objective
- treat organizations being regulated and their 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
- have in place a process to review complaints about conformity assessment processes and to take corrective action when justified.

These trade rules are essentially based on two core principles: most favoured nation (MFN) and national treatment. MFN requires that the rules applied to one trading partner not be “less favourable” (i.e. more demanding) than those 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.

12. 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.” A technical regulation may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a good, process, or production or operating method.

Article XX of the General Agreement on Tariffs and Trade allows parties to the WTO to adopt measures that are inconsistent with these principles in certain circumstances. These exceptions are subject to two rules. First, the measure must not be a disguised restriction on trade. Second, it must not involve arbitrary or unjustifiable discrimination between countries where the same conditions prevail. Similar exceptions are present in NAFTA and other regional trade liberalization agreements.


The WTO's TBT and SPS agreements provide more detail about how standards should be designed and implemented considering 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 affect international trade. These agreements essentially extend the MFN and national treatment principles to regulations and standards.

In turn, the Code of Good Practice for the Preparation, Adoption and Application of Standards (Annex 3 of the TBT agreement) further extends these principles 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 other 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 when no applicable international standard exists, or when international standards would be an ineffective or inappropriate means to fulfil the "legitimate" objectives of the domestic regulation or standard. The agreements place the onus on countries to provide scientific evidence to justify deviation from an international standard.

The latest edition of the Standards Council of Canada's requirements for accreditation of standards development organizations (CAN-P 1D) incorporates all of the relevant provisions of the TBT, SPS and NAFTA agreements. Standards developed by accredited standards development organizations will, therefore, satisfy relevant international trade agreement requirements.

Glossary of Abbreviations



AIT	Agreement on Internal Trade
BNQ	Bureau de normalisation du Québec
CAEAL	Canadian Association of Environmental Analytical Laboratories
CAN-P 1	Standards Council of Canada, <i>Accreditation of Standards Development Organizations</i> , CAN-P 1D (Draft, 1998)
CAN-P 2	Standards Council of Canada, <i>Criteria and Procedures for the Preparation and Approval of National Standards of Canada</i> , CAN-P 2E (January 1992)
CGSB	Canadian General Standards Board
CO	Certification organization: an organization accredited by the Standards Council of Canada to certify products or services as meeting a particular standard
CSA	Canadian Standards Association
GATT	General Agreement on Tariffs and Trade
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NAFTA	North American Free Trade Agreement
NSS	National Standards System (Canada)
RIAS	Regulatory Impact Analysis Statement: an analysis of benefits and costs that must be prepared for each proposed regulation
SCC	Standards Council of Canada
SDO	A standards development organization accredited by the Standards Council of Canada
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures: a subagreement of the World Trade Organization focussing on food and health standards that affect international trade
TBT	Technical Barriers to Trade Agreement: a subagreement under the World Trade Organization focussing on both mandatory technical regulations and voluntary standards, applying to all products, including industrial and agricultural products
ULC	Underwriters' Laboratories of Canada
WTO	World Trade Organization: the international trade regime that succeeded the General Agreement on Tariffs and Trade