



**Standards Council of Canada**  
**Conseil canadien des normes**

**Canada**

# **Use of Standards in the Regulatory Regime: Canadian Experience**

**David Shortall**

**Standards Council of Canada**

Standards **experts**. Accreditation **solutions**.



## Purpose of the presentation

- Explain Canadian policies on referencing standards in regulations and the role of the Standards Council of Canada in this process
- Outline methods for referencing or incorporation of standards
- Provide case studies



## Standards and Regulations: A Comparison

Standards	Regulations
<i>Standards Development Process</i>	<i>Regulatory Development Process</i>
Standards development organizations (SDOs) facilitate the development of standards in response to requests from proponents	Governments take the lead in developing regulations
SDOs seek consensus on the content of standards	Governments consult interested parties, but do not necessarily seek consensus Regulations may reference standards or require the use of e.g. accredited conformity assessment bodies such as testing laboratories or certification bodies
<i>Conformity Assessment</i>	<i>Compliance Assurance</i>
Certification bodies, testing laboratories and management systems certification bodies carry out conformity assessment activities	Governments enforce their regulations themselves or remain accountable for enforcement when they rely on others to carry it out



## How do standards get incorporated in regulations?

- 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
- Reproduced directly in regulations
- Incorporated by reference into regulations
- Used as guidelines to elaborate rules found in statutes or regulations



## Standards development (1)

- **Inclusiveness**: Interest groups participation
  - Regulators
  - Producers and Consumers
  - Academics
- **Balanced Representation**: Equal representation of interest groups in:
  - Standards development and approval
  - Review and maintenance
- **Consensus**



## Standards development (2)

- **Scope of standard**
  - Only requirements essential for regulatory reference
  - Only technical issues
- **Structure**
  - Consistent and identifiable sections
  - Non-technical issues outside of normative content
- **Language**
  - Avoiding recommendations
- **References**
  - Clear indication of the preceding version



# Regulatory adoption process

## Referencing options

- Complete reference
- Qualified reference
- Partial reference
- Reference as good practice
- Reference as alternate
- Inclusive reference to standard



## Procedures for updating standards in regulations

- Periodical review of standards to determine relevance to current technology
- Notification from the SDOs to interested regulatory authority prior to the maintenance action
- Monitoring of status of referenced standards by regulatory authority
- RegWatch





## What is RegWatch?

- Search tool for identifying Canadian, foreign and international standards referenced in Canadian federal law
- Provides links to the full text of Canadian regulations that cite standards, and links to additional information about the referenced standards
- Allows to :
  - Search by keyword or standard number, developer, regulation
  - Find bibliographic information on Canadian, US and international standards referenced in Canadian legislation



## Example: ISO Standards in Canadian Regulations

- **Title of Standard:** Quality Management Systems - Fundamentals and Vocabulary
- **Standards Developer:** ISO
- **ICS Code:** 03.120.10: Quality management and quality assurance
- **Minister Responsible:** Minister of Health
- **Regulation:** Medical Devices Regulations
- **Enabling Statute:** Food and Drugs Act
- **Location Within Legislation:** section 1

“The definitions in this section apply in these Regulations...

"objective evidence" means information that can be proved true, based on facts obtained through observation, measurement, testing or other means, as set out in the definition "objective evidence" *in section 2.19 of International Organization for Standardization standard ISO 8402:1994, Quality management and quality assurance - Vocabulary, as amended from time to time.*

"validation" means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled, as set out in the definition "validation" *in section 2.18 of International Organization for Standardization standard ISO 8402:1994, Quality management and quality assurance - Vocabulary, as amended from time to time.*”

- **Link to Legislation:** <http://laws.justice.gc.ca/en/F-27/SOR-98-282/index.html>
- **Link to Standards Information:** <http://www.global.ihc.com/>



## Example: Canadian National Standards in Regulations

- **Title of Standard:** *Risk Management: Guideline for Decision-Makers*
- **Standards Developer:** Canadian Standards Association (CSA)
- **ICS Code:** 03.120.99: Other standards related to quality
- **Minister Responsible:** Minister of Transport
- **Regulation:** Canadian Aviation Regulations
- **Enabling Statute:** Aeronautics Act
- **Location Within Legislation:** section 1

“The Minister may, in writing, on application by the operator of a designated airport, authorize the operator to cease providing an aircraft fire-fighting service if the operator demonstrates by means of a risk analysis based on **Standard CAN/CSA-Q850-97 entitled Risk Management: Guideline for Decision-makers as amended from time to time** that the cessation of the aircraft fire-fighting service will not result in an unacceptable risk to aviation safety.”

- **Link to Legislation:**
  - <http://laws.justice.gc.ca/en/A-2/SOR-96-433/index.html>
- **Link to Standards Information:**
  - <http://www.standardsstore.ca/eSpecs/index.jsp?language=en>



## Example: Foreign Standards in Canadian Regulations

- **Title of Standard:** *Safety Standard for Conveyors and Related Equipment*
- **Standards Developer:** American Society of Mechanical Engineers
- **ICS Code:** 13: ENVIRONMENT, HEALTH PROTECTION, SAFETY  
53: MATERIALS HANDLING EQUIPMENT
- **Minister Responsible:** Minister of Labour
- **Regulation:** Marine Occupational Safety and Health Regulations
- **Enabling Statute:** Canada Labour Code
- **Location Within Legislation:** section 12.19

“Equipment used in the mechanical transmission of power shall be guarded in accordance with sections 7 to 10 of **ANSI Standard ANSI B15.1-1972, Safety Standard for Mechanical Power Transmission Apparatus**, dated July, 1972.”

- **Link to Legislation:** <http://laws.justice.gc.ca/en/L-2/SOR-87-183/index.html>
- **Link to Standards Information:** <http://www.global.ihs.com/>



## Case Study: Medical Devices Manufacturing

- Canadian regulations require that medical devices be manufactured under a certified quality management system that meets the criteria of the international standard ISO 13485. The corresponding Canadian national standard is CAN/CSA-ISO 13485
- To address this regulatory requirement Health Canada and SCC developed a third party certification program called Canadian Medical Devices Conformity Assessment System (CMDCAS)
- SCC accredits organizations that certify the management systems of medical device manufacturers. Under CMDCAS, only SCC accredited certification bodies are eligible to certify a medical device manufacturer's management system

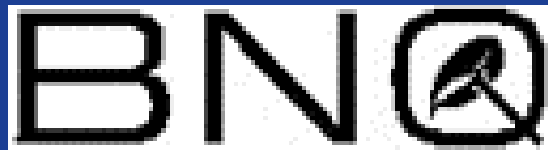


## Related Links

- **Standards Council of Canada:**
  - see: [www.scc.ca](http://www.scc.ca)
- **Guide for regulators on using standards**  
[Key Considerations in the Development and Use of Standards in Legislative Instruments](#)
  - see: <http://www.scc.ca> → 'Publications'
- **Use of International standards in technical regulations (ISO/IEC )**
  - see: <http://www.ifan.org>
- **Canadian Medical Devices Conformity Assessment System**
  - see: <http://www.hc-sc.gc.ca> → [Home](#) → [Drugs & Health Products](#) → [Medical Devices](#) → [Quality Systems \(ISO13485\)](#)
- **Accreditation programs:**
  - see: <http://www.scc.ca> → 'Products and Services' → Accreditation programs



## Canadian Standards Development Organizations



- The Canadian General Standards Board

See: <http://www.bnq.qc.ca>



- The Bureau de normalisation du Québec

See: <http://www.pwgsc.gc.ca/cgsb/home/index-e.html>



- The Canadian Standards Association

See: <http://www.csa.ca>



- Underwriters Laboratories Inc.

See: <http://www.ulc.ca>