Use of Conformity Assessment in Regulation in Canada

Presented by G. Rae Dulmage, Director, Standards Department, Government Relations Office and External Affairs
Outline

• Canadian Regulatory System
• Canadian Conformity Assessment System
• Canadian Standards System
• Case Studies
• Best Practices
• Innovations
• Gaps and Issues
• Key Takeaways
Under Canada's constitution, provinces and territories regulate design and construction of new houses and buildings; the maintenance and operation of fire safety systems in existing buildings and the electrical safety of buildings and equipment. Adoption and enforcement of the codes are the responsibility of the provincial and territorial authorities having jurisdiction.
Canadian Conformity Assessment System

Certification bodies must participate and engage with the Standards Council of Canada (SCC) recognized Regulatory Councils in the product areas they are recognized in.

SCC accreditation is required by the regulators.

The SCC Canada accredits Standards Development Organizations and various types of conformity assessment organizations:

• Testing and Calibration Laboratories
• Management Systems (QMS and EMS) Certification Bodies
• Personnel Certification Bodies
• Product/Service/System Certification Bodies
• Inspection Bodies
Canadian Conformity Assessment System
3rd Party System
System Cycle

Installation Codes

Product Standards and Certification

Inspection and Enforcement (verification)

Safe Products and Safe Installations
Canadian Standards System

The National Standards System (NSS) is Canada’s network of people and organizations involved in the development, promotion, and implementation of standards. Through the collaborative effort of the system’s members, standards help advance the social and economic well-being of the country and safeguard the health and safety of Canadians.

Participants, Beneficiaries, and Partners

Conformity Assessment Organizations

INTERNATIONAL AND REGIONAL STANDARDIZATION BODIES
International and regional standardization bodies work towards the global harmonization of standards to facilitate trade, address common societal issues, and safeguard consumers. Their work promotes international acceptance of conformity assessment reports and marks, making it less costly and time-consuming to have products approved.

INSECT BODIES
Inspection bodies ensure the safety and fitness for use of specific products and materials, ensuring that the associated facilities, equipment, and systems are appropriate to the work being performed. Inspections are not limited to physical assets and can also include the assessment of services.

PERSONNEL CERTIFIERS
These organizations assess individuals’ competencies to ensure they are appropriate to the work being performed.

STANDARDS COUNCIL OF CANADA
The Standards Council of Canada oversees the NSS. It accredits standardization organizations, verifying that they have the resources, structure, and expertise to deliver trustworthy services. The Standards Council approves National Standards of Canada and advances Canada’s key regional and international standardization forums.

STANDARDS DEVELOPMENT ORGANIZATIONS
Canada’s standards development organizations work with members to develop Canadian standards and adopt relevant international standards for use in Canada.

MANAGEMENT SYSTEMS CERTIFICATION BODIES
Management system standards like the ISO 9000 and ISO 14000 series help organizations to produce consistent quality or to address environmental impact. Certification bodies provide objective, third-party assurance that a management system has all of the necessary components and that it is being consistently applied.

CONSUMERS AND NON-GOVERNMENTAL ORGANIZATIONS
Consumers and NGOs ensure that the NSS takes into account societal economy, including the environment, health, safety, and privacy. Consumers and NGO representatives bring the human element to the development of standards and standards strategies.

PRODUCT/SERVICE CERTIFICATION BODIES
Certification organizations provide ongoing, independent, third-party evaluations to determine whether a product or service meets the requirements of applicable standards. Certified products usually display a certification mark.

INDUSTRY
Industry relies on the standards and conformity assessment services of the NSS to develop and market products globally. Industry participation helps ensure standards and standards strategies are good for business.

GOVERNMENTS
Governments rely on the NSS to help them negotiate trade agreements as part of the regulatory system. Government participation ensures that the NSS supports trade and public policy.

For more information about the National Standards System or to order copies of this poster, contact the Standards Council of Canada at 1-877-252-3000, info@sc-csn.ca, or visit www.sc-csn.ca
Case Study - Electrical Equipment

Electrical (Canadian Electrical Code)

• Provinces and Territories are responsible for Public Safety
• Legislation and Code adoption mandate 3rd Party certification
• Only exception to certification is Special Inspection (Field Evaluation)
• Standards (CSA and ULC) are listed in Canadian Electrical Code.
• Example: Ground Fault Circuit Breakers
  o Required to meet CAN/CSA-C22.2 No. 144-M91 (R2011) as per Provincial and Territorial Legislation
  o Testing and conformity assessment by 3rd party (UL)
  o Compliance to standards = Certification Mark
  o With Certification comes acceptance in the Canadian Marketplace
Boiler and Pressure Vessels and Plumbing Case Studies

Plumbing / Gas (National Plumbing Code of Canada and CSA B149.1)
• Provinces and Territories are responsible for Public Safety
• Legislation and Code adoption mandate 3rd Party certification
• Special Inspection allowed for equipment not available as certified
• Example: Plastic Plumbing Fixtures
  o Required to meet CSA B45.0 and CSA B45.5 Standards
• Example: Gas Fired Low Pressure Boilers
  o Required to meet ANSI Z21.3/CSA 4.9 Standard
(Both the plumbing and gas certification process is identical to Electrical)
Case Study - Medical Device

Medical Devices (Various Standards)

- Regulated by Health Canada
  - 3 elements – Device License; ISO 13485:2003 CMDCAS and a Medical Device Establishment License
  - Classes I to IV
  - Health Canada, Medical Devices Regulation list appropriate standards.
- Electrical products require 3rd Party Certification
- Example: Medical Equipment
  - Required to meet C22.2 No. 601.1 and others.
  - Testing and conformity assessment by 3rd party (UL)
  - Compliance to standards = Certification Mark
Case Study - Building Materials

Building (National Building Code of Canada)
Adopted by all Provinces and Territories which allows for Certification and Evaluation to standards
Building Code for Construction
Standards listed in National Building Code therefore mandatory requirement
Example: Mineral Fibre Thermal Insulation

• Required to meet CAN/ULC-S702 and ULC-S129
• Testing and conformity assessment by 3rd party (UL)
• Certain product evaluated by 3rd Party (Not certification)
• Certification = Mark, Evaluation = Report for AHJ acceptance
Case Study - Fire Protection

Fire (National Fire Code of Canada)
Adopted by all Provinces and Territories which allows for Certification
Fire Code applies after construction for Occupancy
Standards listed in National Fire Code therefore Mandatory requirement
E.g.: Fire Alarm Control Panels
  • Required to meet CAN/ULC-S527
  • Testing and conformity assessment by 3rd party (UL)
  • Compliance to standards = Certification Mark
  • With Certification comes acceptance in the Canadian Marketplace
Case Study - Energy Efficiency

Energy Efficiency

Provincial and Territorial Legislation adopt National Energy Code of Canada for Buildings

Additional Federal legislation sits with Natural Resources Canada (NR Can.)

Energy Efficiency Regulation, Federally regulated NRCan. Regulation harmonizing with Department of Energy (DoE) United States

Canada United States Regulatory Cooperation Council

Example: Clothes Dryers

- Required to meet CAN/CSA-C361-92
- EE testing and Conformity Assessment by 3rd Party (UL)
- Energuide Label mandatory for Consumer acceptance
Case Study - Special Inspection

Special Inspection (SPE-1000 for Electrical, SPE-3000 for Electromedical (Draft), CSA B149.3 for Gas)

Provincial and Territorial legislation allows for Special Inspection
Used where no Canadian standard exist, for limited production products and one of a kind.

Special Inspection Bodies Accredited by Standards Council of Canada
Example: Large Wind Turbine

• Required to meet SPE-1000 Evaluation
• Tested and Evaluated in the field
• Label for one of a kind piece of equipment
• Not a substitute for product certification

(Same process for Electromedical to the SPE-3000 and for Gas appliance to the B149.3)
Best Practices – Conformity Assessment

Initial Evaluation
Product Testing
Periodic Factory Inspection
Mark of Conformity

• CB Mark on Product

• Manufacturer and Product Listed in a Published List of Materials and Equipment

• Internal Audits and Controls

CB is audited regularly by the Standards Council of Canada

CB must maintain active and sustained communication with the Regulatory Groups and be aware of and engaged in standards development
Innovation

Regulatory Impact Analysis Process Improvement
• Building, Fire, Plumbing and Energy Code Project

Referencing Standards within Canada’s National Model Code System
• Undergoing implementation

Greater and continuous National Coordination:
• National Public Safety Advisory Council, Provincial and Territorial Advisory Council, Standards Development Organization Advisory Council and Provincial and Territorial Policy Advisory Committee on Codes

Drive to be early implementers of innovation
Gaps and Issues

Gaps – Provincial and Federal Conformity Assessment requirements and Regulatory Systems do not always interconnect
  - Timing of Code and standards adoption not consistent

Issues – One Code system maintains 3\textsuperscript{rd} Party Marks while the other mandates 3\textsuperscript{rd} party but provides no guidance
  - Standards references are not up to date in codes, regulation at the federal and provincial/territorial level
  - Same jurisdiction but different regulations calling up different standards
Key Takeaways

Conformity Assessment System in Canada is well established
• Regulatory, Conformity Assessment and Standards are well connected

Public expectation is for consistent and open Conformity Assessment in all sectors

Regulation is divided and can cross over sectors
Accreditation is a requirement and an expectation
Standards are the point of assessing conformity

Regulators have provincial or territorial power
• Regulator implements and interprets
• Local authorities enforce

One code per sector with provinces and territories have full application
Health Canada and NRCan have federal power on Consumer Product, Medical Devices, Natural and Health Products and Drugs
THANK YOU.

G. Rae Dulmage
Director, Standards Department, Government Relations
Office and External Affairs
ULC Standards and Underwriters Laboratories of Canada
171 Nepean Street, Suite 400
Ottawa, Ontario K2P OB4
T: +1 613 755 2729 Ext. 61429
Direct: +1 613 368 4429
F: +1 613 231 5977
Email: rae.dulmage@ul.com