

# Use of Conformity Assessment in Regulation in Canada

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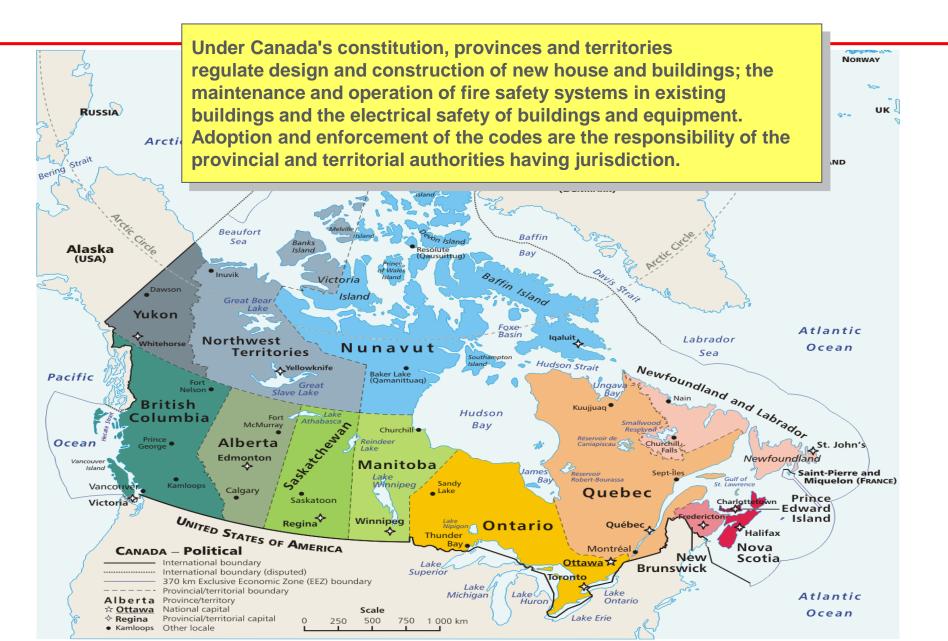


- Canadian Regulatory System
- Canadian Conformity Assessment System
- Canadian Standards System
- Case Studies
- Best Practices
- Innovations
- Gaps and Issues
- Key Takeaways





#### **Canadian Regulatory System**



## **Canadian Conformity Assessment System**

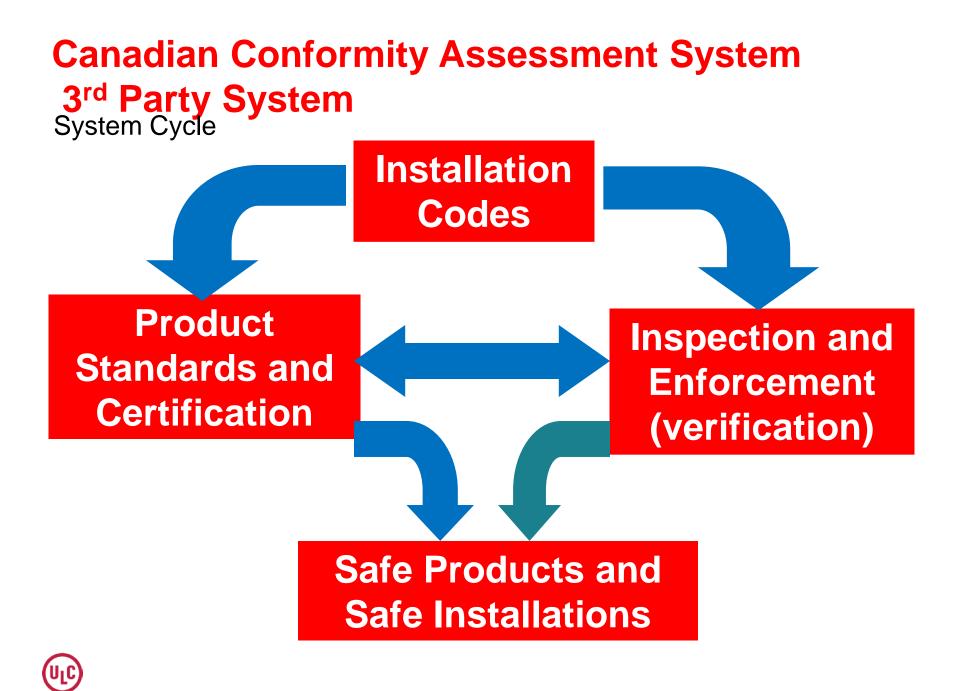
Certification bodies must participate and engage with the Standards Council of Canada (SCC) recognized Regulatory Councils in the product areas they are recognized in

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 Standards System**

**PRODUCT/SERVICE** 

CERTIFICATION BODIES

ongoing, independent, third-party evaluations to determine

the requirements of applicable

display a certification mark

andards. Certified products usua

Certification organizations provide

whether a product or service meets

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 assessment that a management

system has all of the necessary

components and that it is being consistently applied

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.

#### INDUSTRY

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

#### CONSUMERS AND NON-GOVERNMENTAL ORGANIZATIONS

6Os ensure that the NSS takes into account societal concerns, including the environment, health, safety and privacy. Consumers and NGO representatives bring the human element to the development of standards and standards strategies.

## PARTICIPANTS, BENEFICIARIES AND PARINERS CALIBRATION AND TESTING LABORATORIES

alibration and testing laboratories test products and calibrate measuring equipment to verify that they meet the requirements of specific standard

## CONFORMITY ASSESSMENT ORCAN STANDARDS COUNCIL **OF CANADA**

The Standards Council of Canada oversees Standards Council of Canada the NSS. It accredits standardization Conseil canadien des normes organizations, verifying that they have the resources, structures and expertise to deliver trustworthy services. The Standards Council approves National Standards of Canada and also represents Canada in key regional and international standardization forums.

#### INTERNATIONAL AND REGIONAL STANDARDIZATION BODIES

International and regional standardization bodies work towards the global harmonization of standards to liberalize trade, address common societal issues and safeguard consumers. Their work towards the international acceptance of conformity assessment reports and marks can make it less costly and time-consuming to have products approved.

#### INSPECTION BODIES

Inspection bodies assess the safety and fitness for use of specific products and materials, confirming 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 that they are ppropriate to the work being performed

For more information about the National Standards System or to order copies of this poster, contact the Standards Council of Canada at (613) 238 3222, info@scc.ca, or visit, www.scc-ccn.ca.

#### STANDARDS DEVELOPMENT

Canada's standards development organizations work with some 15,000 volunteers to develop Canadian standards, and adopt or adapt

international standards for use in Canada.

#### ORGANIZATIONS

national **standards** system

#### 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.

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## **Case Study - Electrical Equipment**

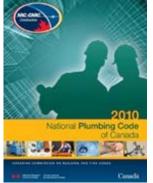


Electrical (Canadian Electrical Code)

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





## **Case Study - Building Materials**

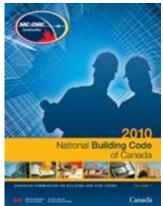
#### **Building (National Building Code of Canada)**

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

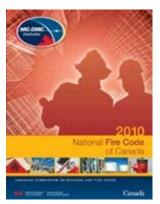
Example: Mineral Fibre Thermal Insulation

- Required to meet CAN/ULC-S702 and ULC-S129
- Testing and conformity assessment by 3<sup>rd</sup> party (UL)
- Certain product evaluated by 3<sup>rd</sup> 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 3<sup>rd</sup> 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.)

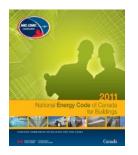
Energy Efficiency Regulation, Federally regulated

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<sup>rd</sup> Party Marks while the other mandates 3<sup>rd</sup> party but provides no guidance

- Standards references are not up to date in codes, regulation a 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.



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