DIGITAL GOVERNANCE COUNCIL

Building Digital Trust in Healthcare through Standards and Certification

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CONSEIL DE GOUVERNANCE NUMÉRIQUE

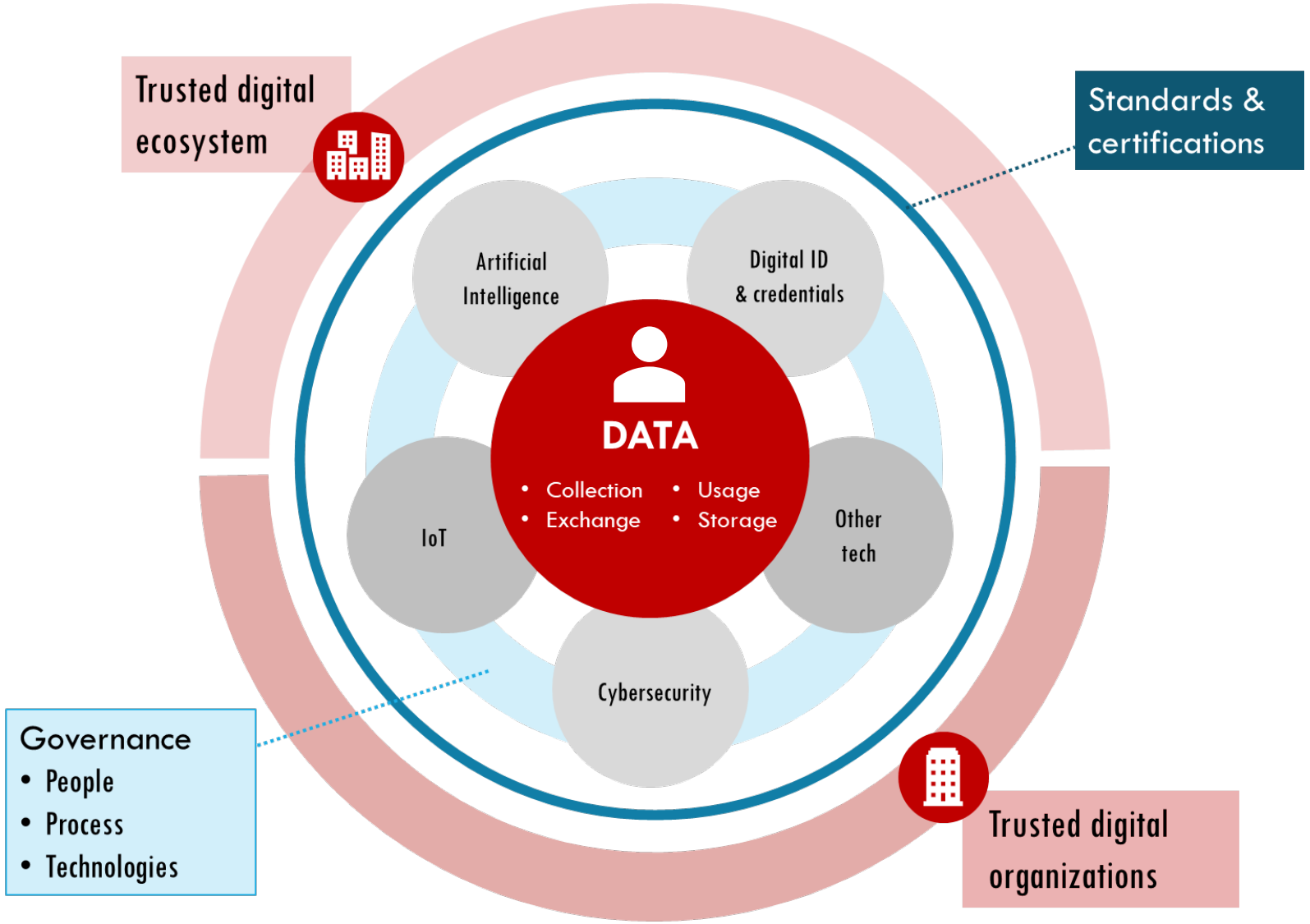
DIGITAL GOVERNANCE COUNCIL

WHAT IS DIGITAL GOVERNANCE

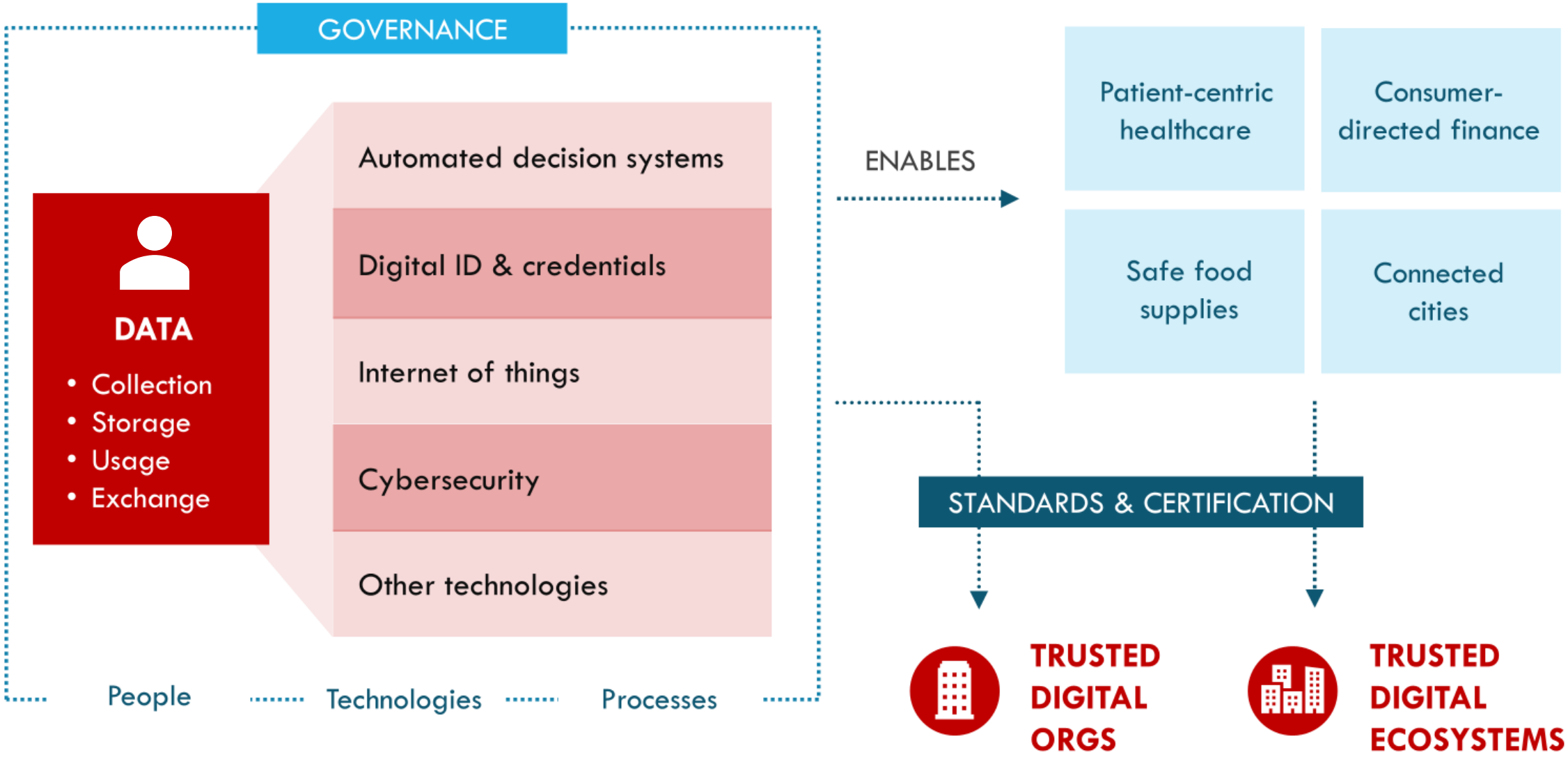
- With increasing reliance on digital systems and data in nearly every aspect of modern life, the need for strong digital governance has never been greater.

- As a discipline, digital governance establishes the processes, policies, standards, and accountability needed to manage effective and efficient use of technology across organizations and society.

WHAT IS DIGITAL TRUST



TRUSTED DIGITAL GOVERNANCE



WHAT ARE DIGITAL GOVERNANCE STANDARDS

- Digital governance standards establish accepted practices. They can provide confidence that technology solutions are responsibly used and developed. They also stay in step with evolving technology and provide a framework for regulation and governance that adapt to emerging challenges and opportunities.

- They help guide marketplace behaviors, accountability and risks mitigation associated with digital technologies.

- It is important not to conflate standards development with legislation or regulation. They serve different purposes and have different implications for both providers of technology and their users.

- Standards are not static; they are regularly updated through expert discussions and agreement.

STANDARDS ARE IN EVERYTHING

EACH STANDARD HAS AN INTENDED PURPOSE

THERE ARE MANY TYPES OF STANDARDS

BUT ...

NOT ALL STANDARDS ARE EQUAL

STANDARDS ARE DEVELOPED BY MANY DIFFERENT ACTORS

WHAT IS A STANDARDS BODY

- Standards development organizations facilitate the development of voluntary consensus-based standards.
- Companies, public sector, academia and individuals can participate.
- A committee is formed and experts and individuals across society are invited to reflect their views and interests into the standard.
- Anyone can request a new standard and the standards development organization validates proposals through consultations.

HOW A STANDARD IS DEVELOPED CAN INFLUENCE ITS ACCEPTANCE AND USE IN THE MARKET

STANDARDS DEVELOPMENT PROCESS

Multi-Stakeholder Participation

- Governments, Regulators, Industry, Civil Society, Academics, etc.
- Geographical representation

Consensus-Based Decision-Making

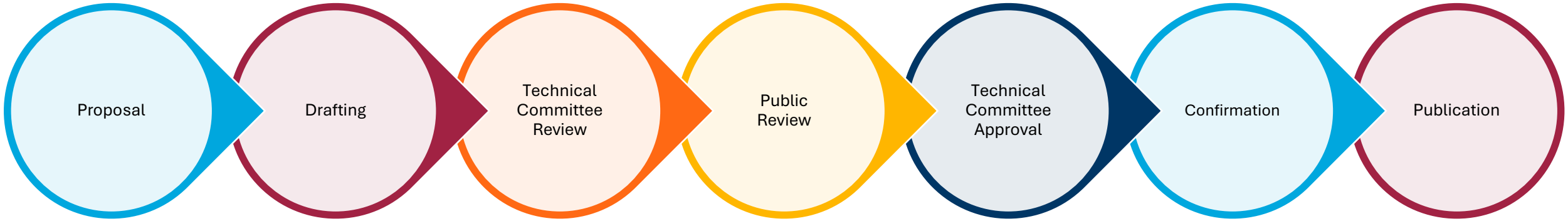
- Deliberate, rules-based process.
- Balance of interests

Transparent and Open

- Drafts available throughout project lifecycle for input
- No technical committee size restrictions; every stakeholder has a vote.

Current

- Standards are reaffirmed, revised or withdrawn at least once every 5 years.



KEY STAKEHOLDERS IN DEVELOPING STANDARDS

User: An interest category of those on a technical committee who predominantly represent end users of the subject product(s), material(s), or service(s) and who are not involved in any way in production and/or distribution of the subject product(s), material(s) or service(s). Consumers are one type of end user, and may be defined as, individual members of the general public, or consumer organizations, purchasing or using property, products or services for private purposes.

General interest: An interest category of those on a technical committee with a demonstrated interest and relevant expertise not associated with the production, distribution, direct use, or regulation of the product(s), material(s) or service(s).

Producer: An interest category of those on a technical committee who are predominantly involved in production (i.e., manufacture), promotion, retailing, or distribution of the subject product(s), material(s) or service(s).

Regulator: An interest category of those on a technical committee representing any federal, provincial, municipal, other government body, or body/authority designated by a government responsible for regulating the acceptability, sale or use of the subject product(s), material(s) or service(s), and those bodies that enforce these rules and regulations.

STRUCTURE AND COMPONENTS OF STANDARDS

Standards bodies generally follow a structured format that include the following key components:

- **Title**: The title clearly identifies the subject matter of the standard.
- **Scope**: Defines the application boundaries and limitations of the standard, specifying what is covered and what is not.
- **Normative References**: Lists other standards, documents, or regulations that are referenced within the standard and are necessary for its application.
- **Terms and Definitions**: Provides definitions of specific terms used within the standard to ensure consistency and understanding among users.
- **Technical Content**: Describes the specific criteria, requirements specifications, guidelines, and practices relevant to the subject matter.
- **Annexes**: Additional sections or appendices may be included to provide supplementary information, examples, or technical details.
- **Bibliography**: Lists references cited within the standard, including relevant research papers, books, or other sources that contributed to its development.

EXPRESSION OF PROVISIONS

- Four specific terms with specific meanings define the types of actions expected in a standard; “can”, “may”, “should”, and “shall”:
  - **Can:** This term is used when an action is possible.
  - **May:** This term is used to indicate that an action is permitted or optional. It provides flexibility by allowing or suggesting a course of action but not mandating it.
  - **Should:** This term is used to indicate a recommendation. It suggests a course of action that is preferred but not necessarily mandatory. Non-compliance with “should” statements is not usually considered a violation of the standard.
  - **Shall:** This term is used to indicate a requirement. It is a strong term that signifies a mandatory action or obligation. Non-compliance with “shall” statements is typically considered a violation of the standard.
- These terms provide clarity and precision in the language of the standard, ensuring that the requirements are understood and implemented correctly. (ISO, n.d.)

NATIONAL VS. INTERNATIONAL STANDARDS

- The main difference between a national standard and an international standard lies in their scope and applicability:
  - **National Standards**:
    - Scope: Developed and maintained within a specific country by its national standards organization (e.g., BSI in the United Kingdom), DIN in Germany).
      - NOTE: Some countries, including Canada and the United States operate a decentralized model. The National Standards Body (SCC in Canada and ANSI in the United States) accredit organizations to develop national standards.
    - Applicability: Primarily intended for use within that country's jurisdiction or market.
  - **International Standards**:
    - Scope: Developed through international consensus by organizations like ISO (International Organization for Standardization) or IEC (International Electrotechnical Commission).
    - Applicability: Designed for global use and adoption, aiming to standardize practices, products, or services worldwide.

HOW YOU USE STANDARDS CAN INFLUENCE MARKETPLACE BEHAVIOURS

VOLUNTARY AND MANDATORY STANDARDS

- Standards can be either voluntary or mandatory.
- They can be market, regulatory, or consumer-driven.
- Standards are voluntary when organizations are not legally required to follow them. Organizations may choose to follow them to meet customer or industry demands.
- Standards are mandatory when they are enforced by laws or regulations, often for health or safety reasons.
- Failure to meet relevant voluntary standards could be cited in legal proceedings or in the unwillingness of consumers, governments and retailers to either distribute, buy, or sell a product or service. In some cases, they may be mandatory because of:
  - A connection to the technical environment (e.g. if the product must be interoperable with other products)
  - The standard being so widely accepted in the market that a deviation would not be accepted (e.g. the QWERTY standard for keyboards)
  - A buyer specifying certain standards (e.g. in procurement)
  - A customer requiring a certificate based on meeting certain standards
  - The law encouraging or requiring the use of a standard by having incorporated it by reference in a regulation.

INCORPORATION BY REFERENCE

- Although practices vary from one jurisdiction to the next, developed countries tend to reference many standards and conformity assessment obligations in regulations and contractual documents. The practice is referred to as incorporation by reference.
- Once a voluntary standard has been incorporated by reference in a regulation or in a related instrument such as a list of recognized standards, it is deemed to be mandatory in that jurisdiction.
- Suggested reading: Guidelines for Incorporating Standards by Reference in Regulations to Support Public Policy Objectives: https://scc-ccn.ca/resources/publications/guidelines-incorporating-standards-reference-regulations-support-public

FACTORS INFLUENCING ADOPTION OF DIGITAL GOVERNANCE STANDARDS

- **Technological Advancements:** New technologies may require updated standards.
- **Regulatory Requirements:** Compliance with laws and regulations.
- **Industry Trends:** Adoption driven by competitive pressures and market expectations.
- **Organizational Culture:** Willingness to embrace change and prioritize governance.

POLICY LEVERS

- Regulation
- Insurance
- Public recognition
- Tax breaks
- Subsidies
- Assurance
- Grants
- Procurement
- Research
- Certification

CONFORMITY ASSESSMENT

- Demonstrating conformity with standards can provide individuals, companies, nations, and governments with confidence in the suppliers, products, or services they use. It can also help businesses be competitive, facilitate trade, create market advantages, and improve social wellbeing.
- Conformity assessment activities can provide several types of assurance for which a product, process, system, person, or body meets established criteria (requirements) contained in any normative document.
- The World Trade Organization Technical Barrier to Trade Agreement (WTO TBT Agreement) encourages the use of standards and regulations as the normative documents for the basis for conformity assessment procedures: https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

CONFORMITY ASSESSMENT PROCEDURE

- A conformity assessment procedure (or at times referred to as a scheme or program) refers to a way of determining that relevant requirements are fulfilled, whether in regulations or standards.
- Conformity assessment procedures include prescribed ways of sampling, testing, inspecting, evaluating, and/or verifying to assure conformance, competence, registration, accreditation, or approval. Procedures may include any combination of these ways to assess conformity.
- Conformity can be assessed by a body that is independent of any party interested in the outcome of the assessment or assessed by any party that is interested in the outcome of the assessment.
- Akin to standards, conformity assessment procedures can range from voluntary and self-regulated to mandatory programs.

EXTENT OF CONFORMITY ASSESSMENT ACTIVITY

SOURCE: ISO CASCO Conformity Assessment tools to support public policy.
https://casco.iso.org/key-considerations.html

POWERING TRUST IN CANADA'S DIGITAL ECONOMY

The Digital Governance Council is a member-led organization committed to instilling confidence in the responsible design, architecture, and management of digital technologies for Canadians.

CONSEIL DE GOUVERNANCE NUMÉRIQUE

DIGITAL GOVERNANCE COUNCIL

Convening an executive forum for members to share best practices, identify digital governance gaps and prioritize collective action.

Proving out new technologies and delivering proofs of concept and common building blocks to manage risks and opportunities associated with the use of digital technologies, in partnership with other leading organizations.

Developing technology governance standards through the Council's independent Digital Governance Standards Institute.

Validating and verifying organizations against digital governance standards through the council's digital trust conformity Assessment Program.

INNOVATORS IN OUR ORGANIZATIONS, EMBRACING DIGITAL, CHAMPIONING CHANGE, AND DRIVING THE ADOPTION OF CANADIAN TECHNOLOGIES

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TOGETHER WE ARE TACKLING THE LEADING QUESTIONS SURROUNDING TECH INNOVATION

CANADA'S TECH-FOCUSED, ACCREDITED STANDARDS DEVELOPMENT ORGANIZATION

PLAYING A CRITICAL ROLE IN DEVELOPING MUCH-NEEDED NATIONAL STANDARDS FOR DATA GOVERNANCE, DIGITAL IDENTITY, CYBERSECURITY, ARTIFICIAL INTELLIGENCE AND MORE

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DATA

CAN/DGSI 100-1: DIGITAL PROTECTION

CAN/DGSI100-2: 3rd PARTY ACCESS TO DATA

CAN/DGSI 100-4: REMOTE ACCESS INFRASTRUCTURE

CAN/DGSI 100-5: HEALTH DATA & INFORMATION

CAN/DGSI 100-6: DIGITAL CONTACT TRACING

CAN/DGSI 100-7: DATA STEWARDSHIP

CAN/DGSI 100-8: GEO-RESIDENCY & SOVEREIGNTY

CAN/DGSI 100-9: ZERO-COPY INTEGRATION

ARTIFICIAL INTELLIGENCE

CAN/CIOSC 101: ETHICAL DESIGN AND USE OF AI

DGSI/WA 126: AI FOR FINANCIAL INSTITUTIONS

CYBERSECURITY

CAN/CIOSC 104: CYBERSECURITY CONTROLS FOR SMEs

CAN/DGSI 112: NOS FOR CYBERSECURITY PROFESSIONALS

DIGITAL TRUST

CAN/DGSI 103-1: FUNDAMENTALS

DGSI/TS 115: DIGITAL CREDENTIALS AND DIGITAL SERVICES

INTERNET OF THINGS

CAN/DGSI 105: CYBERSECURITY OF INDUSTRIAL IoT

PRIVACY

CAN/DGSI 109-1: PRIVACY PROFESSIONAL QUALIFICATIONS

CAN/DGSI 109-2: CANADIAN INFORMATION PRIVACY PROTECTION FRAMEWORK

STANDARDS: DGC-CGN.ORG/STANDARDS/FIND-A-STANDARD

THESE STANDARDS ENABLE

CONNECTED CITIES

CAN/DGSI 106: DIGITAL TWINS SERIES

PATIENT-CENTRIC HEALTHCARE

CAN/DGSI 103-2: DIGITAL TRUST AND ID – HEALTHCARE

OPEN BANKING

CAN/CIOSC 110-1: OPEN FINANCE

SAFE FOOD SUPPLIES

CIOSC/TS 114: AGRICULTURAL BLOCKCHAIN

GET INVOLVED: DGC-CGN.ORG/STANDARDS

MAKING DIGITAL TECHNOLOGY SUSTAINABLE AND TRUSTED

DIGITAL TRUST CONFORMITY ASSESSMENT

Strengthen stakeholder trust and confidence in your organization's digital governance with our independent reviews and audits, specifically crafted for your organization seeking validation and verification on its digital practices

Review	Audit
• The Digital Governance Council reports on your organization's evaluation of its specific systems, tools or processes against defined requirements	• The Digital Governance Council reports on its thorough examination of your organization's specific systems, tools or processes conformity with defined requirements

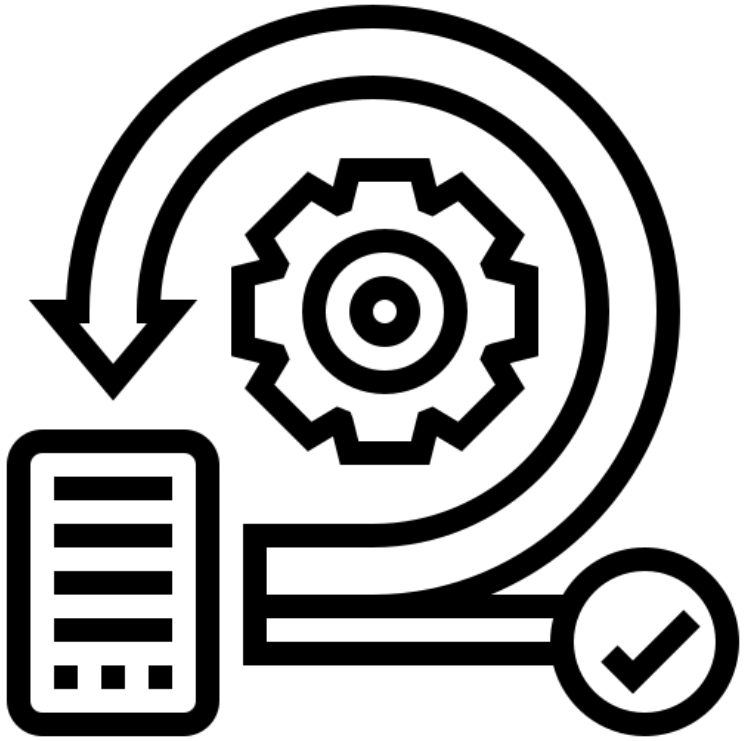
WHAT IS THE DIFFERENCE BETWEEN VALIDATION AND VERIFICATION

- Validation and verification are conformity assessment activities that result in a statement of conformity
- Verification confirms that past events met specified requirements (truthfulness), where validation confirms that requirements for intended future use are fulfilled (plausibility)
- The claims for validation and verification are separate and do not need to be combined

ASSESSMENT PROCESS

1. **Engagement:** Complete application, scoping, define requirements, planning and team formation.
2. **Evaluation:** Discovery, gather evidence to requirements and analysis
3. **Decision:** Criteria assessment and conclusion

Ongoing Feedback & Monitoring



GET INVOLVED

DGC-CGN.ORG

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