Centre for International
Governance Innovation

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About the Author

Michel Girard is a senior fellow at CIGI, where he contributes expertise in the area of standards for big data and artificial intelligence (AI). His research strives to drive dialogue on what standards are, why they matter in these emerging sectors of the economy, and how to incorporate them into regulatory and procurement frameworks. He highlights issues that should be examined in the design of new technical standards governing big data and AI in order to spur innovation while also respecting privacy, security and ethical considerations.

In addition, Michel provides standardization advice to help innovative companies in their efforts to access international markets. He contributes to the Digital Governance Council and to the standardization activities of the Digital Governance Standards Institute.

Michel has 22 years of experience as an executive in the public and not-for-profit sectors. Prior to joining CIGI, Michel was vice president, strategy at the Standards Council of Canada (SCC), where he worked from 2009 to 2018. At SCC, he led the design and implementation of the Standards and Innovation program, the Climate Ready infrastructure program, the Northern Infrastructure Standards Initiative and the Monitoring Standards in Canadian Regulations project. He managed the negotiation of standardization clauses in trade agreements including the Comprehensive Economic and Trade Agreement and the Canadian Free Trade Agreement. Previously, he was director of the Ottawa office at the Canadian Standards Association, director of international affairs at Environment Canada, corporate secretary at Agriculture Canada and acting director of education and compliance at the Canadian Environmental Assessment Agency. He holds a Ph.D. and a master's degree in history from the University of Ottawa.

Acronyms and Abbreviations

AHRI	American Heating and Refrigeration Institute
AI	artificial intelligence
ASABE	American Society of Agricultural and Biological Engineers
ASTM	American Society for Testing and Materials International
BNQ	Bureau de normalisation du Québec
CEN	Comité Européen de normalisation
CENELEC	Comité Européen de normalisation électrotechnique
CETA	Canada-European Union Comprehensive Economic and Trade Agreement
CGSB	Canadian General Standards Board
CRI	Centre for Regulatory Innovation
CSA	Canadian Standards Association
DGSI	Digital Governance Standards Institute
EA	European Accreditation
ETSI	European Technology Standards Institute
FPT	federal/provincial/territorial
HRSO	Human Research Standards Organization
HSO	Health Standards Organization
IAF	International Accreditation Forum
IAPMO	International Association of Plumbing and Mechanical Officials
ICT	information and communications technology
IEC	International Electro-Technical Commission

IEEE SA	Institute of Electrical and Electronics Engineers Standards Association
ILAC	International Laboratory Accreditation Cooperation
IoT	Internet of Things
ISED	Industry, Science and Economic Development
ISO	International Organization for Standardization
IT	information technology
ITU	International Telecommunication Union
JTC	Joint Technical Committee
LLM	large language model
NSC	National Standards of Canada
NSF	National Sanitary Foundation
P/T	provincial/territorial
PTAC	Provincial Territorial Advisory Committee
SCC	Standards Council of Canada
SDOs	standards development organizations
SIA	Statutory Instruments Act
TBT	Technical Barriers to Trade
UL	Underwriters Laboratories
ULC	Underwriters Laboratories of Canada
WG	working group
WTO	World Trade Organization

Executive Summary

Canada's current approach to rulemaking is not keeping pace with the deployment of new digital technologies. This paper proposes to modernize the Statutory Instruments Act (SIA) to bridge that gap, suggesting that mandatory standards, technical specifications and conformity assessment programs should be recognized as statutory instruments alongside regulations. This borrows from the European Union's "New Approach" established in 1985, whereby regulators can request that EU standards bodies develop mandatory standards as a compliance mechanism to laws, even while legislation is being drafted. Streamlining rulemaking is essential to help manage the harms associated with digital technologies as soon as possible after they are commercialized.

Introduction

Canada's current approach to rulemaking cannot keep pace with the deployment of digital technologies. In the past few years, we have seen many instances where disruptive digital technologies have been commercialized without regulatory oversight, including self-driving vehicles, fifth-generation networks, 3D printing and health/wellness Internet of Things (IoT) devices. This year, a new (and worrisome) use case is unfolding with the commercialization of a slate of large language model (LLM) transformer technologies, such as ChatGPT.

Canada is currently ill-equipped to handle the harms LLMs may inflict on society and the economy. It does not yet have a law to frame the use of high-impact artificial intelligence (AI). In the past two years, the federal government has tabled two versions of the Digital Charter Implementation Act in an attempt to respond to entirely new risks to privacy, health, safety and security brought about by new digital technologies. The second version of the Digital Charter Bill tabled last summer includes a proposed Artificial Intelligence and Data Act.[1]

Nine months later (almost an eternity in today's fast-paced high-tech world), the federal department of Industry, Science and Economic Development (ISED) tabled what is called a "companion document" to its AI legislation. The companion document aims to begin a conversation in Canada about "high impact" AI and how to manage it. Under an optimistic, best-case scenario, the legislation could receive Royal Assent in 2023 and the first regulations could be implemented sometime in 2025. Work to develop and adopt supportive standards and certification would only come after that (ISED 2023).

Canada's legislative machinery was not designed to keep tabs on digital technologies. It needs to be modernized to catch up with them. This paper argues that the SIA should recognize standards, technical specifications and conformity assessment programs as statutory instruments, alongside regulations. The standardization system has the necessary governance and checks and balances to develop normative documents that can replace regulations when necessary. Accredited standards development organizations (SDOs) operate under a codified set of rules and oversight from a federal body, the Standards Council of Canada (SCC). Standards developers must abide by a rigorous process to develop normative documents. This process is arguably as open and transparent as what federal authorities undertake when crafting regulations. Once standards are published, they can be updated as often as needed to reflect new developments in technologies and processes. By creating a formal pathway for federal authorities to require the development of mandatory standards, parliamentary accountability is not diluted. It is in fact expanded and strengthened. This additional pathway could help regulators intervene and set rules along with all interested stakeholders before irreparable harm is done.

Keeping up with the commercialization of new AI tools illustrates why change is needed. In a matter of a few months, most big tech platforms

1 Bill C-27, *An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts*, 1st Sess, 44th Parl, 2022, online: <www.parl.ca/Content/Bills/441/Government/C-27/C-27_1/C-27_1.PDF>.

have launched high-impact LLMs, such as OpenAI's ChatGPT 3.5 and GPT-4, Microsoft's Bing, Google's Bard, GitHub Copilot and Snapchat's My AI, among others (Dataiku 2023.) These new AI tools can produce original content in response to queries, drawing from data they have ingested and interactions with users. They can develop blogs, sketch package designs, write computer code, create websites or even theorize on the reason for a production error. A worrisome feature is the ability of LLMs to provide all manner of professional advice in fields such as legal, health and financial services without informing users about the data sources used to feed the analytics.

Although some of the services offered by LLMs are not ready for broad use in the marketplace, they have been made available nevertheless (Fowler 2023). This stems from what has been termed "the AI arms race" between platforms. The goal is to benefit from first mover advantage in what promises to be a huge and profitable marketplace (AFP 2023). As a result, guardrails have been removed, pre-commercialization testing has been curtailed and ethical considerations raised by employees during the testing phase have been pushed aside (Fried 2023).

Leading executives operating in the AI sector are keenly aware of the risks associated with LLMs. In a March 2023 interview with ABC News, OpenAI CEO Sam Altman acknowledged LLMs are set to reshape society and the economy but noted that there are significant risks associated with these new technologies. "I'm particularly worried that these models could be used for large-scale disinformation," Altman said. "Now that they're getting better at writing computer code, [they] could be used for offensive cyberattacks." He was emphatic that OpenAI needs both regulators and society to be as involved as possible with the rollout of ChatGPT — insisting that feedback will help deter the potential negative consequences the technology could have on humanity. "Society, I think, has a limited amount of time to figure out how to react to that, how to regulate that, how to handle it" (quoted in Ordonez, Dunn and Noll 2023). The following week, Google and Alphabet CEO Sundar Pichai told employees that Bard, its proprietary LLM, was launched as "an experiment" and warned, "As more people start to use Bard and test its capabilities, they'll surprise us. Things will go wrong" (Elias 2023).

Indeed, many things can go very wrong very quickly on many fronts, and there is limited time to respond. One concern stems from the existential risks inherent in the models. This point of view sees the future of AI as very concerning, especially as AI models are getting bigger and more powerful and can act in unintended ways (Edwards 2023). A second is related to the malicious use of these models from sophisticated spamming, deepfakes, automated harassment, hate speech, disinformation, cheating and deception. A third concern is about the commercial use of these models, when companies take foundational models and reapply them for already regulated purposes. They will be applied for higher-risk commercial uses with less human oversight, such as financial, health, wellness and legal advice, and are expected to perform almost any business processes and tasks involving queries, writing, communication, information exchange or analytics. Moving along that scale of complexity and human oversight, many argue that it is dangerous and irresponsible to apply these systems to uses far exceeding their current capacity and trusting them to make critical judgments (Christ 2023).

Now that the genie is out of the bottle, what can Canada do? Repeating what Altman stated, "society only has a limited amount of time to figure out how to react to that, how to regulate that, how to handle it" (quoted in Ordonez, Dunn and Noll 2023). Is Canada currently equipped to regulate the anticipated sectoral impacts of LLMs in a matter of months? Are we looking at a few years or should we collectively sit tight and set our sights to the end of this decade? Will Canadians agree that we can afford to wait that long before rules and standards are in place to manage LLMs and their sector-specific applications?

Even if there was unanimous political agreement across the spectrum to act, Canada's legislative and regulatory apparatus is just not designed to frame the use of any new digital technology in a timely fashion. We do not have the legal authorities to identify, investigate and manage harms before these technologies are commercialized. Under the current system, all we can hope for is to eventually influence new technologies, years after they have been on the market.

Canada's regulatory-making machinery dates back to the pre-industrial age. As mentioned above, under the current system, it takes years for new legislation to be drafted, debated

and voted on in Parliament. Additionally, the process of consulting on, designing and implementing supporting regulations that outline the "how" of complying with legislation also takes years. And regulations are the only approved statutory instrument in regulators' toolbox to ensure compliance to legislation.

It is true that some experts are exploring new, flexible approaches to accelerate regulators' engagement with emerging technologies. Organizations such as the Centre for Regulatory Innovation (CRI) have been created for that very purpose.[2] Approaches such as regulatory experimentation, regulatory sandboxes (CRI 2022) or anticipatory regulations are being investigated (Armstrong, Gorst and Rae 2019). All acknowledge, however, that these approaches are still at the conceptual stage and have not been tested broadly in Canada. More importantly, these experimental approaches are not meant to be used as bona fide statutory instruments to replace regulations. Rather, the focus is on trying to find ways to somehow accelerate the regulation-making process to make it more responsive.

One needs to remember that the purpose of legislation is not being achieved when regulations remain stagnant as market conditions evolve in an accelerated manner. Legislative policy is about achieving government objectives through the use of laws, regulations and other instruments to deliver better economic and social outcomes and thus enhance the lives of citizens and business. When regulations do not keep up with technology, the opposite outcome can occur, making compliance to regulations irrelevant or possibly toxic because they are not managing preventable harms.

Yet there is a parallel, well-established and credible system that is available now. Federal authorities can use that system to set detailed requirements on the performance of products, services and systems. They can then rely on credible conformity assessment programs to certify that these requirements are being met through accredited, independent third parties, making them both scalable and auditable.

That system is called standardization. Standards, technical specifications and third-party certification by accredited bodies have been used by regulators to meet a wide range of health, safety and security objectives for almost a century. In Canada, the reliance on standards as a compliance mechanism to legislation was initiated when the first edition of the Canadian Electrical Code was published by the Canadian Standards Association (CSA) in 1927. Today, federal/provincial/territorial (FPT) regulators and chief inspectors routinely meet and engage with SDOs to set standardization priorities, develop and review new standards, adopt international standards, assess changes to existing standards and provide guidance on certification programs. They engage with industry, experts, consumers and users through technical committees and working groups to set performance benchmarks that can be described, measured, tested and approved in an objective way.

In our post-pandemic world, with new online engagement technologies and processes used by leading-edge SDOs, a new standard can be developed within a year, and a technical specification within a few months, all without having to seek a travel approval.

In 2020, there were 6,073 references to standards in hundreds of FPT regulations, and that number will continue to grow over time (SCC 2021, 21). Billions of products, devices, components and systems have been tested and certified through various compliance programs accredited by SCC. From a health, safety and security perspective, the system is proving to be effective time and time again. Although product recalls are unavoidable, very low rates of product defects resulting in accidents, injuries or deaths are reported.

Many believe that similar positive compliance outcomes can be achieved for digital technologies. Standards, technical specifications and certification solutions are squarely part of the equation when we look at new digital governance regulations being set around the world, from privacy, AI and digital identity to cybersecurity abroad (Pouget 2022). Several digital governance standards supporting federal and provincial legislation are either under way or are being contemplated in Canada (ISED 2023).[3]

Leading jurisdictions around the world have come to rely on mandatory standards as a compliance mechanism to legislation, bypassing the need

2 See www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/who-we-are.html.

3 See https://dgc-cgn.org/standards/find-a-standard/.

to develop and maintain detailed compliance regulations. In the European Union, the "New Approach" directive, established in 1985, recognizes mandatory standards as a complement to legislation. It sets a formal process for regulators to make standardization requests to Comité Européen de normalisation (CEN) and/or Comité Européen de normalisation électrotechnique (CENELEC), the European standardization bodies accountable for the coordination of the European standardization system. These requests are aimed at the development of mandatory standards to support EU legislation, and they can be made while a new legislation is being drafted, saving precious time. Once a requested standard is developed and published, there is a presumption of conformity among stakeholders, including industry, consumers and regulators at the national level (European Commission 2002).

The European legislator makes broad use of standards to support European Community legislation in both established and in emerging sectors. Taking into account the current reflections about governance, which encourage co-regulatory and self-regulatory practices, one expects the use of mandatory standards to increase in Europe, as delineated in its most recent standardization strategy (European Commission 2022a).

In Canada, however, standards remain a tool buried in legislators' toolboxes. The SIA merely describes standards as one type of document that can be incorporated in regulations.[4] It does not mention the standardization system, the process it uses to create consensus documents and its outputs. Since the act does not recognize mandatory standards and technical specifications as statutory instruments, it does not offer an official track for regulators to mandate their development and use. Mandatory standards do not appear as a compliance mechanism in the Cabinet Directive on Regulation either.

Although there are certainly many more Canadians actively participating in standards development work than there are regulators in this country, they are mostly operating under the radar. The author fully acknowledges that standardization is not a top-of-mind issue for most decision makers and regulators. This is why this paper presents detailed background information about what standards are, the consistent rigour that goes into their development and why they are important tools to achieve legislative objectives.

The first section focuses on the fundamentals of standardization, including standards development, certification, assurance and accreditation internationally and in Canada. It explains the role of SCC, accredited SDOs, certification bodies and accreditation bodies.

The second section provides information on the use of mandatory standards by federal, provincial and territorial authorities. It explains the various ways that standards are referenced as a compliance mechanism either directly in regulation or in other instruments, such as official lists of recognized documents.

The third section presents an overview of standardization activities focusing on digital governance to give a sense of the breadth and scope of work under way. It makes the point that there are probably published standards that could be used now by legislators to begin to manage some of the harms stemming from the misuses of LLMs.

The last section proposes high-level principles that should be considered when modernizing the statutory instruments, the Cabinet Directive on the Scrutiny of Regulations and companion legislation.

Fundamentals of Standardization

What Are Standards?

Although not visible to the average consumer, standards and conformity assessment activities keep the economy running. Standards describe the importance of a process, product, service or system. They provide a level playing field for industry and help build trust between participants in supply chains. They cover everything from the size of the simplest screw thread to the most complex information technology (IT) network. They serve as a "handshake" between various components of systems and allow for interoperability by ensuring that everyone is following the same standard.

4 *Statutory Instruments Act*, RSC 1985, c S-22, online: <https://laws-lois.justice.gc.ca/eng/acts/S-22/>.

Standards also play a pivotal role in protecting the health and safety of consumers in a wide number of sectors including food and consumer products, security, infrastructure and the workplace.

Standards are generally taken for granted by consumers and citizens. Their presence and use make our devices and products work better; for example, by ensuring that the connection between a smartphone and a Wi-Fi network happens. A lack of standards does get noticed by consumers; for example, when travellers must use adapters to charge electronics in a foreign country, or when clothing or shoe sizes vary from one brand to the next. The push for standardization can lead to government intervention when one market participant refuses to adopt a standard. One example that has been unfolding for the past decade involves European regulators and Apple regarding the use of a common charging standard for mobile devices in order to reduce waste from incompatible chargers and cables (Ray 2022). Their misuse can result in spectacular failures; for example, when a US$180 million spacecraft disintegrated because a contractor used the wrong measurement standard in the orbital insertion software (Harish 2022).

Standards cover a wide spectrum of subjects, from definitions, ontology classifications, metrics, measurement, manufacturing techniques and processes, to delivery systems and beyond. They set out requirements, specifications, guidelines or model characteristics that can be consistently applied to ensure that products, materials, processes, systems and services perform as intended — qualitatively, safely and efficiently. And many are drafted in a way that allows another party to test and certify that a product, process or system meets the requirements of a specific standard. Put simply, they make things work, save organizations money, help innovations spread, and facilitate efficient trade among provinces, countries, economic regions and the international community of nations.

The International Organization for Standardization (ISO) uses the following definition for technology standards: "A document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.... [Standards moreover] should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits" (ISO 2004).

Evolution of the International Standardization System

Thousands of organizations around the world are developing and maintaining more than one million standards and specifications. Many were created at the beginning of the twentieth century to support the emergence of new industrial sectors such as telegraphs, railways, steel, oil, motor vehicles, electricity, plumbing, boilers, pressure vessels, elevators, buildings and appliances. Some SDOs specifically focus on health and safety issues stemming from industrialization such as fire protection, or occupational health and safety. Often, national professional associations such as mechanical and electrical engineers as well as subdisciplines including gas, water, fire, pressure vessels and elevators created their own SDOs to develop and maintain the standards they needed to operate safely.

Health, safety and security issues have always been top of mind for those participating in standards development activities during the industrial age. Clearly, the standardization of pressure vessels, boilers, steel bridges, railways, elevators, pipelines or elevating devices brought costs down and allowed for interoperability. But, as importantly, standards were seen as an effective tool to manage risk, to reduce the number and severity of accidents, and to save lives. Engineers responsible for product design, manufacturers, operators, workers and consumers all had a stake in this.

After the Second World War, new international SDOs such as the ISO were created, and older ones such as the International Electro-Technical Commission (IEC) and the International Telecommunication Union (ITU) expanded their scope as trade liberalization discussions were gaining traction. Competing national standards covering the same products and processes were increasingly seen as non-tariff barriers to trade. Truly international standards were needed to support globalization and international supply chains. Some argue that the international standards development process is similar in some ways to international treaty making.

As new sectors emerged in the 1960s, additional SDOs and new standardization activities began to support increasingly complex sectors such as plastics and chemicals, business machines, telecommunications, computers and information processing, avionics and laboratory testing as well as services and management systems standards covering quality, risk or the environment.

The standards development, comment and approval process is highly structured, with a mandatory cross-section of stakeholder representation throughout, and codified in specific stages, with built-in timelines for clause-by-clause review, comments and written disposition, voting and balloting.

These structured steps allow stakeholder groups to review, debate, comment and vote — or sometimes to block and delay the publication of a contentious document. Before the 1980s, in-depth discussions on the various national approaches and best practices in place in different regions of the world had to take place before decisions could be made on the features of a new international standard. Means of communication were slower and less reliable at the time than they are now, forcing participants to meet in person for extended periods of time and to wait for documents to be physically mailed. However, these timelines were accepted because product line cycles were much longer than they are today.

There is also a human dimension to the traditional technical standards development process. Members generally preferred to meet in person in order to build trust, understand other parties' perspectives, discuss issues thoroughly and even review contentious text line by line as a group, which added time to the development process.

Given that time is of the essence, Canadian SDOs are now able to develop national standards within a one-year time frame. SDOs operating in the information and communications technology (ICT) and digital governance spaces have adopted different approaches to further accelerate the standards development process. These organizations use online collaborative tools and software that allow participants to work on documents and meet exclusively remotely. New standards can be developed in months and updated annually to reflect new technologies and processes.[5] Technical specifications — setting essential health, safety and security requirements on new products, systems or processes — can be developed with the input of regulators and approved on faster time frames than standards.

The development of the international standardization system was not centrally planned by any stretch. Most international and industry-specific SDOs began small and remain not-for-profit organizations, even those managing tens of thousands of participants, standards catalogues exceeding 10,000 documents, global sales strategies and hundreds of employees. Many have become complex organizations that need to generate a steady stream of revenue as they do not benefit from government appropriations. Generally, SDOs do not charge large fees for individual members to participate in the standards development process. Many SDOs offer subscription fees for members to access standards in specific categories. Some large international SDOs such as ISO and IEC require member participation through national member bodies representing individual countries and charge national member bodies annual fees to participate. Adoption of international standards is done through voting and balloting of individual member bodies (one country equals one vote).

This explains why *voluntary* standards are not free. Once developed, they become copyrighted documents. Standards get published and sold to users. Buyers include all players in supply chains from raw materials producers, parts, components and systems providers to assembled good manufacturers, product testing laboratories and conformity assessment bodies. Some SDOs such as the CSA or Underwriters Laboratories (UL) have subsidiaries that generate revenues by performing conformity assessment services, including prototype product testing and certification. A portion of the profits generated from certification services can be re-invested in standards development activities.

The situation is different for *mandatory* standards. In the last decade, Canadian SDOs, like their international counterparts, have moved to make mandatory standards and safety codes (that is, those that are referenced in regulations) accessible to users. Some allow view-only access through their websites, while others, such

5 See https://dgc-cgn.org/standards/get-involved/.

as the DGSI, make all of their standards and specifications freely available to download.

Once a standard is developed, it does not stay static. It navigates through a periodic maintenance cycle. Technical committees will review the standards under their purview to make minor amendments and incorporate new features. For mature product lines, SDOs require a mandatory review of a standard every five years. If a standard needs significant changes, a new edition of the document will be issued. If no changes are required following a five-year review, the standard is labelled as stable; there is no need to purchase a new copy of the document. At the other end of the spectrum, standards associated with rapidly evolving technologies, products or processes can be updated at any time, sometimes multiple times in a given year. SDOs and resellers generally keep lists of clients who purchased or downloaded a given standard and advise them of new editions when available.

Principles for Standards Development and Maintenance

Standards are developed according to formalized rules that stipulate the processes to be followed involving engineers and other technical experts, regulators, and consumer interest and general interest groups. While standards are not neutral, they should balance competing interests in order to offer a technical solution that is broadly accepted and shares the benefits of technological compatibility as widely as possible. International standards development bodies must follow the World Trade Organization's (WTO's) six principles for standards development and maintenance. These principles are abstracted below as they shed light on the philosophy behind technical standards development activities both in Canada and internationally. Although adherence to these principles is time consuming, this somewhat plodding process remains relevant and widely accepted to this day.

Transparency

All essential information regarding current work programs, as well as on proposals for standards, guides and recommendations under consideration and on the final results, should be made easily accessible to at least all interested parties in the territories of at least all WTO members. Procedures should be established so that adequate time and opportunities are provided for written comments.

Openness

Membership of an international standardizing body should be open on a non-discriminatory basis to relevant bodies of at least all WTO members. This would include openness, without discrimination, with respect to the participation at the policy development level and at every stage of standards development. Developing country members, in particular, with an interest in a specific standardization activity should be provided with meaningful opportunities to participate at all stages of standard development.

Impartiality and Consensus

All relevant bodies of WTO members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier or suppliers, country or countries, or region or regions. Consensus procedures should be established that seek to take into account the views of all parties concerned, and to reconcile any conflicting arguments.

Effectiveness and Relevance

In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance-based rather than based on design or descriptive characteristics.

Coherence

In order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of

other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential.

Development Dimension

Constraints on developing countries, in particular, to effectively participate in standards development, should be taken into consideration in the standards development process. Tangible ways of facilitating developing countries' participation in international standards development should be sought. The impartiality and openness of any international standardization process requires that developing countries are not excluded de facto from the process. With respect to improving participation by developing countries, it may be appropriate to use technical assistance, in line with article 11 of the WTO Technical Barriers to Trade (TBT) Agreement. Provisions for capacity building and technical assistance within international standardizing bodies are important in this context (Wijkström and McDaniels 2013, 10–11).

When dealing with new technologies, Canadian regulators may be called upon to review international standards for possible adoption as mandatory standards in Canadian regulation. Having confidence that international SDOs adhere to these six principles will generate trust and facilitate the domestic review and adoption process. These principles also apply to accredited SDOs in Canada.

Conformity Assessment

Once a standard is developed, it is important to ensure it is used as intended. Conformity assessment is a method to determine whether products, services, processes, systems or persons meet specified requirements. Conformity assessment can involve certification, inspection and/or the testing of a product or system. It ensures that products and services are meeting required quality, safety and environmental standards, thus helping to safeguard the health and safety of consumers.[6]

First-party conformity assessment refers to an activity that is performed by the person or organization that provides the object. In the European Union, for example, it is possible for a company to self-declare that their products are in conformity with EU rules by performing tests in-house and applying the relevant CE mark (the universally recognized mark affixed to products and components).

Second-party conformity assessment refers to a conformity assessment activity that is performed by a person or organization that has a user interest in the object. For example, a firm could ask one of its employees who is a member of a chartered profession to perform an assurance engagement and issue an opinion on compliance to a given standard. Although second-party conformity assessment is not used widely for certifying tangible products in Canada, this approach can be used by firms that aim to voluntarily declare conformance to a management system standard.

Third-party certification involves contracts between manufacturers and certification bodies whereby prototypes and samples collected during production are tested against specific standards. Compliant products will bear the appropriate certification marks. Non-compliant products would be discarded. Here, the conformity assessment activity is performed by a person or body that is independent of the person or organization that provides the object and has no user interest in the object (Woodley 2016).

Accreditation and International Mutual Recognition

One of the fundamental objectives pursued by private sector participants in international standardization activities is "one standard, one test, one certification, applicable everywhere." This objective has been driving efforts over the past 70 years, first to "build bridges" between national/regional/continental systems, and then to make concerted efforts to migrate from national to international standards. These efforts were not planned or executed top-down. Rather, they followed market trends toward globalization and longer, more complex supply chains.

In order for products or laboratory test results to be recognized not only in the country where they originate but internationally, a system made up of a series of international mutual recognition agreements administered by multilateral bodies has been established around the world. Organizations

6 The logos of SDOs and conformity assessment bodies accredited by the SCC can be viewed at https://researchmoneyinc.com/wp-content/uploads/2018/01/SCC_PRE_Scale-Up-Through-Standards-Setting_2018-04-06.pdf.

such as the International Accreditation Forum, the International Laboratory Accreditation Cooperation (ILAC), the Asia Pacific Accreditation Cooperation and the Inter-American Accreditation Cooperation audit their members regularly. They provide an assurance to government, business and the consumer that organizations providing certification to a standard have the required competence and impartiality to do so as evidenced by fulfilment of international standards and requirements.

Most national accreditation bodies belong to these international organizations. Periodically, they invite peers from other countries to visit their facilities and audit their staff competencies, operations, quality management systems and complaint resolution processes. A determination can then be made as to whether service levels match international accreditation standards. A successful audit confers a status of accreditation to national accreditation bodies. As a result, it will be easier for products certified under a national accreditation body to be accepted in another country without having to go through duplicative certification processes elsewhere. Accreditation helps to underpin the credibility and performance of goods and services (International Accreditation Forum [IAF] 2019, 1).

In the context of compliance to mandatory standards covering digital governance, having mutual recognition agreements in place between Canada and other jurisdictions would be highly beneficial for Canadian firms. It would allow Canadian firms applying internationally recognized standards to comply with other legislation without having to undertake duplicative certifications or audits when exporting products or services abroad, whether it is privacy, cybersecurity or AI. The Canada-European Union Comprehensive Economic and Trade Agreement (CETA) allows for mutual recognition agreements to be negotiated and cemented between SCC and the European co-operation for Accreditation, its European counterpart.

Canadian Standards and Technical Specifications

Fundamentally, Canada's standardization system produces two types of documents: standards and technical specifications. Conformity to standards and technical specifications is managed through conformity assessment bodies accredited by SCC.

Standards

At the core of Canada's standardization system are National Standards of Canada (NSC). They describe the important features of a product, service or system. NSCs are developed through consensus by committees of affected stakeholders that may include representatives from industry, governments, academia and the public interest. Figure 1 showcases the process used for the development of standards under SCC-accredited SDOs.

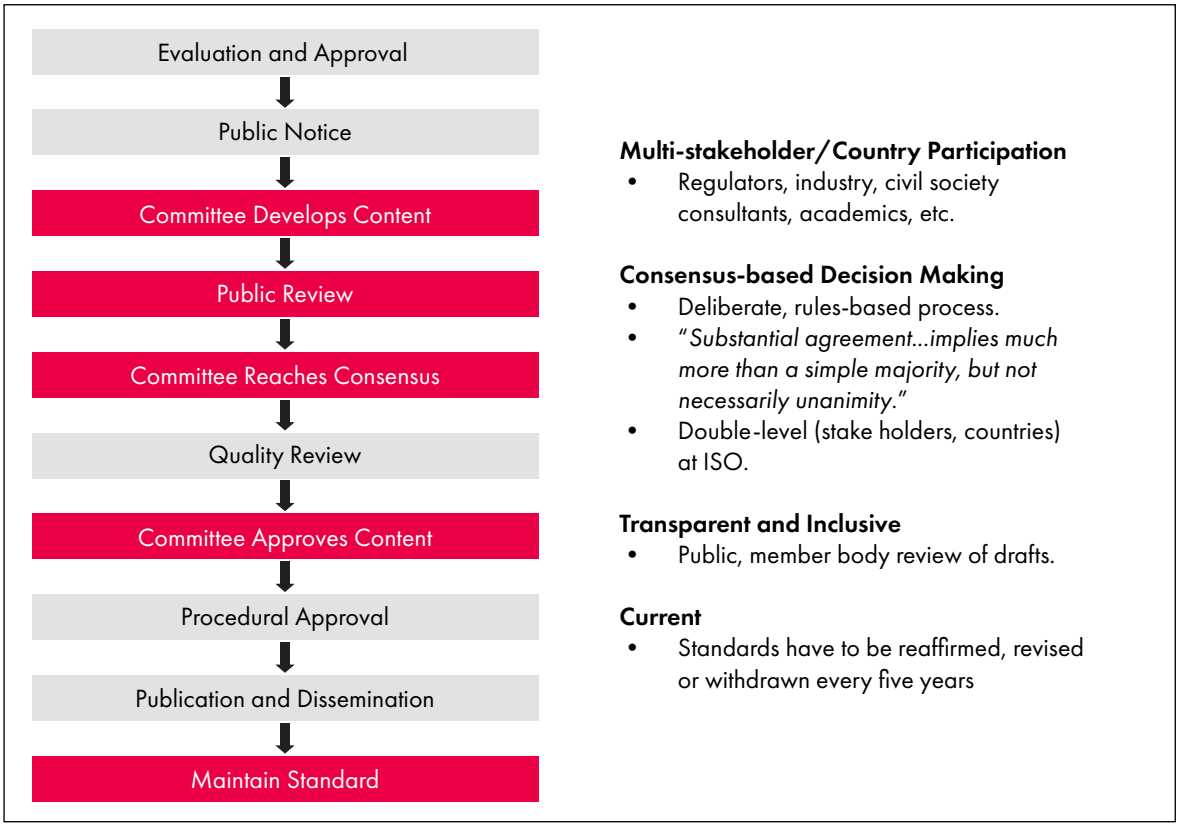
SCC accreditation requirements are fully aligned with accepted international standards best practices. They are mostly derived from annex 3 of the WTO TBT provisions. Additional requirements are taken from ISO and IEC (2019).

SCC's requirements are meant to ensure compliance with the following principles:

- consensus;
- equal access and effective participation by concerned interests;
- respect for diverse interests and identification of those who should be afforded access to provide the needed balance of interests;
- openness and transparency;
- open access by interested parties to the procedures guiding the standards development process;
- clarity with respect to the processes;
- safeguarding Canadian interest as the basis for the development of standards by SDOs;
- avoiding duplication of standards or overlap with the work of other SDOs or with the work of relevant international or regional SDOs; and
- adherence to established mechanism for duplication resolution (SCC 2019a).

Domestic standards development activities revolve around technical committees managed by an accredited SDO. SCC requires a balanced matrix of interests including industry, regulators, academics/technical experts and consumer representatives. Committee size generally varies from 16 to up to 32 members. The Digital Governance Standards Institute (DGSI), however,

Figure 1: How Canadian Standards Are Developed



Source: Girard (2019, 6).

adopted an online collaborative software to support standards development activities. It has seen some committees grow to more than 100 members. However, it must ensure that any committee has appropriate representation from every required stakeholder group.

The first official step in the process is for one accredited SDO to register a new work item in SCC's Central Notification System for approval. The notification must clearly demonstrate that no other international standards already exist, that there is a net benefit for the development of a new standard and that one or many stakeholder groups support the development of a new document.

If an international standard exists, it can be adopted as an NSC through a formal adoption process led by an accredited SDO. Generally, no deviations are made to international standards, although it is possible for the technical committee to do so.

The second step for the accredited SDO is to create a technical committee, establish the terms of reference for the new work item and to nominate a chair from volunteer members. The SDO assigns a secretary to the committee who is responsible for both upholding the process and drafting documents and minutes from the meetings. The SDO needs to ensure that participation in standards development is accessible to affected stakeholders and there is appropriate Canadian participation on technical committees.

The third step is the drafting of the document. Often, stakeholders will submit a "seed document" to launch deliberations by the committee. The committee meets and works its way through the various sections of the standard.

Once ready, the draft document will be made available for a public review period through the SDO website for a set period of time. The chair and secretary will then tabulate comments pursuant to various clauses of the standard. The committee must review and dispose of each comment submitted by stakeholders through the public review. Each decision by the

committee (to either accept or reject a comment) needs to be documented. It results in a new version of the document being produced.

A final version of the document is then submitted to technical committee members for approval through formal voting and balloting, administered by the secretary and the chair. There are detailed rules regarding approval, which are tabulated through letter ballots. The approval process must be based on evidence of consensus reached by the technical committee. It should not be used to block or obstruct the promulgation of standards. First and foremost, there must be enough representatives from each interest group who submit a vote. Interest groups include producers, government, general interest and users. Each voter can either approve a document as is, vote affirmative with comments, vote negative with comments or abstain.

The SCC voting rules are as follows:

- more than 50 percent (simple majority) of the members who are eligible to vote cast affirmative votes;
- a minimum of two-thirds of the votes cast are affirmative; and
- not more than one-quarter of the total number of votes cast are negative.

The SDO shall address negative votes according to its policies and procedures. Negative votes without justification, abstentions without justification, as well as unreturned and blank ballots, shall be considered not cast.

Each SDO then might interpret or develop additional policy requirements for approval that are audited by SCC. For example, some SDOs require at least one affirmative vote by a stakeholder directly impacted by the technology, process or system being standardized.

Once approved, the final version of the standard can then be translated. The standard is then submitted by the SDO to SCC for approval as an NSC.

The technical committee is not disbanded following publication. It can be reconvened at any time if significant changes require a revision of the document. It is also invited to reconvene for the five-year review of the document.

Central Notification System

When developing a new standard or updating an existing one, SDOs are required to submit a Notice of Intent on SCC's Central Notification System. Given limited resources and expertise available in the country, SCC does not permit the development and maintenance of duplicate NSCs nor the development of domestic standards when international standards can be used. As such, any time an SDO prepares to update an existing standard or develops a new one, it has an obligation to submit a Notice of Intent on SCC's database. Interested stakeholders have 15 days to declare whether they oppose the notification.

This mechanism allows industry representatives or regulators to declare whether another SDO should be entrusted with the development of a standard. This approach was developed to avoid the creation of virtual "monopolies" by specific SDOs and to allow industry and regulators to engage with all relevant SDOs and to choose relevant standards that meet their needs (SCC 2017).

Roles of Regulators

Canada does not impose restrictions on the use of specific standards in a given area or field. Although the use of international standards is encouraged, industry and regulators are free to choose the ones they will incorporate in their supply chain contracts or regulations. As indicated above, standards are routinely used by regulators as a compliance mechanism even though it is not formally recognized as a statutory instrument. 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.

Regulators therefore have an important role to play in the standards development process itself. When a Canadian standard is being developed, if there is an expectation that it will later be referenced in a regulation and become a mandatory standard, a group of regulators is expected to actively participate in the deliberations of the technical committee and in the drafting of the document. That is to ensure that the standard meets regulatory objectives. There is also an expectation that regulators who are part of the balanced matrix of interests for the committee should be comfortable enough with the final version of the text of the document to vote in favour of its publication.

Under the current framework, voting in favour of the publication of a document by a regulator does not imply that it will be automatically adopted in their jurisdiction. Regulators need to bring the published standard back to their respective jurisdictions to determine whether to either: adopt the standard in regulation as is; apply deviations to the requirements that can be added in the text of the regulation or to an addendum to the standard; or refrain from adopting the document.

Technical Specifications

In addition to voluntary standards, regulators also adopt technical specifications. The documents can be developed in the absence of a recognized Canadian standard without using the full consensus process normally associated with an NSC. A technical specification may be developed in a field where the technology, or a related aspect such as the regulatory environment, is undergoing rapid change and where speed of delivery, rather than full consensus, is of paramount importance. At a minimum, it is subject to limited peer review with the option of going to full public comment if it is deemed to be warranted (SCC 2019b).

Certification and Accreditation

Third-party certification of products and systems has been a cornerstone of Canada's health and safety framework for decades. It is based on accreditation programs managed by SCC. Third-party certification involves contracts between manufacturers and accredited certification bodies whereby prototypes and samples collected during production are tested against specific standards. Regulators are not involved in the product certification process and do not re-test certified products to verify compliance, unless systematic defects are reported by consumers.

Once tested by certification bodies, compliant products will bear appropriate certification marks. Products that do not bear appropriate marks are removed from store shelves through regular visits to retail stores by field inspectors reporting to chief inspectors. Most consumer products, infrastructure components and health and safety equipment are standardized and require third-party certification to demonstrate mandatory compliance to health and safety regulations. Up until the ratification of Canada's free trade agreement with the United States in the 1980s, only two certification bodies were responsible for the certification of consumer products in Canada: CSA and Underwriters Laboratories of Canada (ULC). Since then, the number of certification bodies accredited by SCC has been growing significantly.

Certification marks also bear specific identification numbers referring to the relevant standard used for testing the product. Certification bodies maintain comprehensive lists of certification marks and related standards on their websites, and these are constantly adjusted to match provincial requirements.

Canadian regulators and chief inspectors are overwhelmingly supportive of third-party certification by accredited bodies to manage the safety of consumer and infrastructure-related products.

Regarding management system standards, such as the ISO 9000 series focusing on quality or the 31000 series focusing on risk management, registration and certification is conducted through audits carried out by certified professionals, often through large auditing firms.

SCC manages 10 accreditation programs that oversee various types of conformity assessment activities including third-party certification. Most are based on ISO and IEC accreditation standards:

- management systems certification bodies;
- product, process and service certification bodies;
- inspection bodies;
- greenhouse gas validation/verification bodies;
- bodies performing the certification of persons;
- SDOs;
- testing and calibration laboratories;
- medical testing laboratories;
- proficiency testing providers; and
- good laboratory practices facilities (SCC 2019a).

As mentioned above, SCC also administers the implementation of the Conformity Assessment Protocol under CETA. The protocol is expected to facilitate trade for businesses in Canada and in Europe. Under the protocol, SCC and the European cooperation for Accreditation are building mutual recognition of accreditation programs

and assessments. When fully implemented, laboratories located in Canada will be enabled to perform tests on Canadian products using relevant EU standards in order to certify they meet European requirements before being shipped, and vice versa. This will eliminate the need for duplicative testing and certification.

Key Players in Canada's Standardization System

As mentioned above, Canada's standardization system is very decentralized. As a result, a large number of organizations have been created to develop standards and safety codes. This section focuses on key players, starting with SCC followed by accredited SDOs. Each of Canada's SDOs specializes in specific sectors and can be approached for the development of mandatory standards.

SCC

SCC is a federal Crown corporation reporting to the minister of ISED. It was established in 1970 to coordinate Canadian participation in international standardization activities, manage Canadian accredited SDOs and respond to national standardization priorities. A Provincial Territorial Advisory Committee (PTAC) was created to seek input from provincial and territorial governments. Both SCC's council and PTAC were entrusted to set comprehensive Canadian standardization strategies for key sectors of the economy nationally, regionally and internationally.

Its Standards and International Relations Branch is responsible for the accreditation of SDOs, the approval of NSCs, the management of participants and mirror committees at ISO and IEC and the interface with other standards bodies through bilateral arrangements or through participation in regional standardization bodies. SCC's participation in multilateral accreditation agreements allows for the mutual recognition of accreditation programs around the world. They are the base from which a jurisdiction can recognize test results from laboratories located outside of its jurisdiction, thereby avoiding the obligation to perform multiple rounds of duplicative testing for a specific product.

SCC also maintains bilateral agreements with other standardization bodies to facilitate a dialogue and resolution of bilateral standardization issues.

In 2010, SCC began its involvement in trade and innovation policy through the creation of a Policy Branch, which later became the Strategy and Stakeholder Engagement Branch. It focuses on three key deliverables: the development of Canadian positions and supportive clauses for standards and conformity assessment chapters in bilateral and multilateral trade agreements; the alignment of standards and safety codes incorporated by reference in FPT regulations to reduce internal barriers to trade; and the development of strategies to help Canadian innovative companies become standards makers internationally.

SCC's Accreditation Services Branch manages the accreditation programs listed in the previous section and provides services to more than 600 customers.

In 2021, SCC had a staff of 149 and a total budget of $29.5 million. SCC's total revenues were $10.3 million. Its federal governmental appropriation totalled approximately $19.2 million (SCC 2021).

Accredited SDOs

SCC began its operations in 1970 with four Canada-based accredited SDOs. Starting in 2012, it began to accredit US-based SDOs in order to reflect the growing use of US standards by industry and in safety codes and FPT regulations. The initial four SDOs accredited by SCC following its creation in 1970 are presented first. SDOs being accredited by SCC in a second phase starting in 2012 are then presented with a short synopsis of standards under development.

- **CSA:** CSA was created in 1919 in Ottawa to adopt, adapt and develop standards supporting Canada's industrialization. It developed new standards, testing and product certification programs across sectors starting with railways, electrical, plumbing and gas, then branching out to other industrial and infrastructure sectors. CSA assists regulators and chief inspectors in developing safety codes covering electrical, gas, elevators and bridges. CSA Group is a globally active organization with testing and certification operations in North America, North and Southeast Asia, China, Europe and India. Regarding its standards development division, membership now stands at 10,600 members, a significant growth over the 7,500 members registered in 2009. In 2021, it published

572 documents, including 134 new standards (CSA Group 2022, 8).

- **ULC:** ULC is an independent product safety testing, certification and inspection organization. It was created in the 1920s to support the need for fire protection standards. Since then, it has expanded its range of services to building and construction materials, building envelope performance and environmental performance standards in addition to fire suppression, fuel burning and distribution equipment. It provides ongoing support to the Council of Canadian Fire Marshals and Fire Commissioners.
- **Canadian General Standards Board (CGSB):** CGSB is a standards development body created in 1934 by the Government of Canada. It reports to the federal department of Public Works and Government Services Canada and developed standards to support the Government of Canada and the military in their procurement activities.
- **Bureau de normalisation du Québec (BNQ):** BNQ was created in 1961 by the Quebec government. In addition to traditional areas such as concrete structures and construction materials, it focuses on emerging sectors such as 3D printing; hydrogen; sustainable, responsible management of public events; and sustainable horticulture practices.
- **American Society for Testing and Materials (ASTM) International:** ASTM International was created in 1898. It maintains more than 13,000 standards covering a wide array of sectors. It received SCC accreditation in 2013. ASTM International has more than 30,000 members across 140 countries. There are more than 1,400 Canadians are participating in ASTM International committee work.
- **UL:** UL was created in 1894. Its standards catalogue is more than 1,700 documents. UL has more than 14,000 employees and operates in 140 countries. It received SCC accreditation in 2013.
- **American Heating and Refrigeration Institute (AHRI):** AHRI is a North American trade association representing more than 300 Canadian and US manufacturers of air conditioning, heating and commercial refrigeration equipment.
- **National Sanitary Foundation (NSF):** NSF was founded in 1944 to protect and improve global human health. NSF facilitates the development of public health standards and certifications that help protect food, water, consumer products and the environment.
- **Health Standards Organization (HSO):** HSO is a Canadian SDO focusing on standards for the health-care sector. It was accredited as an SDO in 2017. The parent organization, Accreditation Canada, is also accredited by SCC as a conformity assessment body. HSO has developed more than 100 standards related to the health-care and social services sectors.
- **DGSI:** Members of the CIO Strategy Council created the Digital Governance Council and DGSI in 2023. Its work program includes more than 35 new work items in areas such as AI systems, cybersecurity, digital identity and credentials, biometrics, data governance in the health-care sector, electoral voting technologies as well as privacy and access control.
- **International Association of Plumbing and Mechanical Officials (IAPMO):** IAPMO is a large US-based standards and certification body. It manages uniform codes for plumbing, mechanical and solar as well as swimming pools.
- **Human Research Standards Organization (HRSO):** HRSO is a not-for-profit Canadian organization that focuses on human research. It received its SCC accreditation in 2020 and focuses on topics such as the development of human research protection programs, ethical issues and conducting research during publicly declared emergencies.
- **Accessibility Standards Canada:** Accessibility Standards Canada creates accessibility standards for federally regulated entities and federal organizations. It is working on 11 standards covering topics such as the built environment, signage, employment and emergency measures.
- **American Society of Agricultural and Biological Engineers (ASABE):** Accredited in 2023, ASABE maintains more than 100 standards in the fields of agricultural equipment and machinery.

Standards in FPT Regulations

Although practices vary from one jurisdiction to the next, developed countries tend to reference a large number of standards and conformity assessment obligations in regulations. The practice is defined as incorporation by reference. This section provides an overview of standards incorporated by reference in FPT regulations. The information is generated by SCC through its monitoring standards in regulations initiative. It also shows alternative approaches to use standards as a compliance mechanism through lists of recognized standards.

Standards in Federal Regulations

At the federal level, there were 1,535 standards referenced in 2020 (SCC 2021). Communications made by SCC before the pandemic showed 1,377 references to standards in 135 Canadian federal regulations maintained by 19 departments and agencies. A significant proportion of references to standards are static as opposed to "as amended from time to time," which requires regulators to routinely amend regulations to keep up with the latest edition of a given standard. More information on the consequences of using the static method of incorporation can be found below. Examples of regulations include those covering occupational health and safety, construction and infrastructure energy efficiency requirements; environmental protection; consumer products; electrical, oil and gas; elevators; pressure vessels; medical devices; and organic foods. Figure 2 shows a distribution of references to domestic, other national or regional SDOs or international standards in federal regulations and related instruments in 2018.

The trend has been for regulators to increasingly rely on US-based or international standards in regulations, reflecting global supply chain considerations and the need to reduce technical barriers to trade. When deciding on the merits of adopting an international standard, regulators can take two approaches: reviewing and adopting an international standard without deviations; or asking a Canadian SDO through a technical committee or working group to review the international standard for adoption as an NSC, again with or without deviations.

As mentioned above, standards were found in 135 federal regulations in 2019. Table 1 shows the main topics of regulations referencing standards. It reflects a fairly wide variety of topics where standards and conformity assessment programs are used as a compliance mechanism.

Standards in Provincial Regulations

At the provincial/territorial (P/T) level, there were 4,538 standards referenced in 2020 (SCC 2021). SCC's annual report for 2018–2019 shows 4,461 references to standards in P/T regulations as shown in Figure 3 (SCC 2019c).

As provinces and territories were overwhelmingly using the static method of incorporation (more on this below) and are not in a position to routinely update regulations, approximately half of the references are outdated. It is time consuming and challenging for regulators to routinely engage with responsible ministers and get approvals to make small changes to regulations in order to update references to standards. This explains, in part, why many regulations contain out-of-date references to standards.

The proportion of US-based standards in regulations is slowly increasing and replacing outdated domestic standards. Most of the mandated standards in regulations and in safety codes are related to the construction and operations of infrastructure.

Standards in Safety Codes

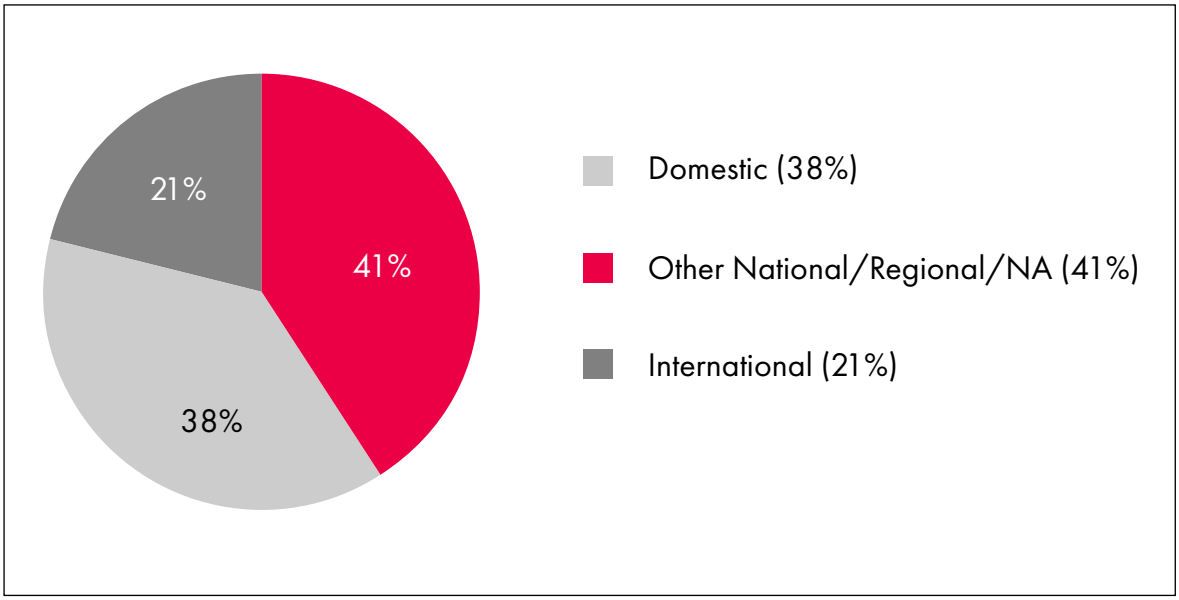
Additionally, provinces and territories also routinely incorporate a number of safety codes in regulations (building, fire, plumbing and energy efficiency in buildings), which should be added to the numbers listed above. A cursory review of safety codes shows annexes with close to 1,200 references to standards. Table 2 provides an estimate of standards found in the main safety codes used in Canada.

Incorporation Methods

Using standards as a complement to regulations provides many benefits to both regulators, industry and consumers:

- For regulators, there is no need to "reinvent the wheel" when addressing common issues. If we take electrical safety and interoperability, for

Figure 2: Distribution of References to Standards in Federal Regulations



Source: Girard (2018).

example, regulators benefit from participating, along with industry and consumers, in the development and maintenance of a common electrical code that can be adopted by all jurisdictions when a new edition is published. Adopting common standards also meets WTO obligations to reduce non-technical barriers to trade.

- For industry, the adoption of common standards by regulators reduces the need for multiple testing and certification to access P/T markets.
- For consumers, the adoption of common standards makes it easier to acquire products that can operate in multiple environments and that are certified to perform to a given benchmark with the added advantages of increased competition and lower prices. One of the most critical consumer aspects is trust: standards provide consumers with a basis for trust. Labels and certification marks provide consumers with something to trust and an organization that is accountable for safety, reliability or efficiency claims.

Under the current framework, there are five ways to reference standards and technical specifications to support regulatory and legislative objectives.

Directly into a Statute or Regulation

Although rare, a regulatory authority may choose to reproduce the wording of a standard and/or accreditation program directly into the legislative/regulatory text. Regulators also sometimes incorporate a specific paragraph or sentence from a given standard in regulations. It should be noted that references to specific clauses or subclauses, tables, figures or annexes of a standard should always be dated. This is because any amendment to, or revision of, a standard could lead to an alteration of its internal numbering (ISO and IEC 2014).

Static References

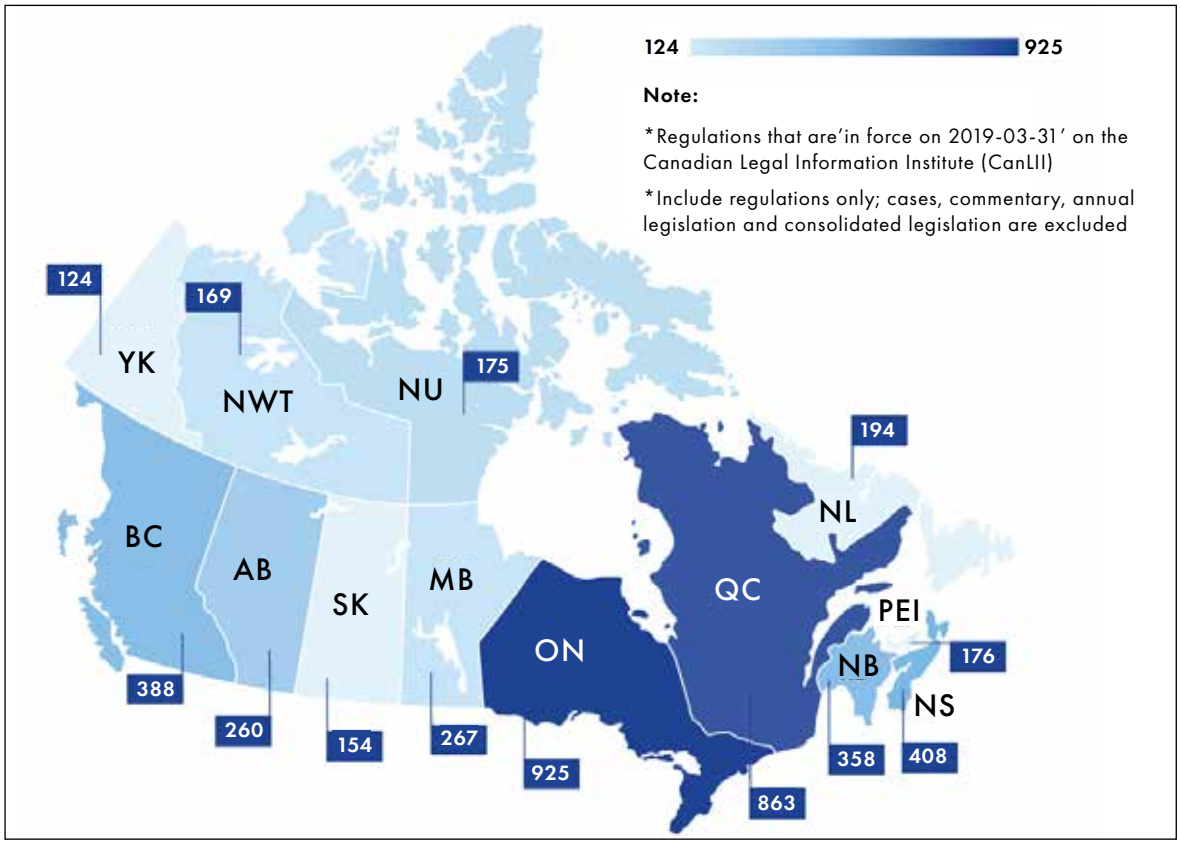
Regulators are often using the static method of incorporation, also called direct dated references. Direct dated referencing is when the number and title of the standard is referenced and used with its date of publication (see Box 1). This means that only a particular edition of a standard can be used. This can help provide legal certainty by indicating the exact technical solution that may be used to comply with the regulation. Such legal certainty can help give assurance to the regulator and clarity for those who have to comply with the law. This is the most restrictive reference.

Table 1: Main Topics of Regulations Referencing Standards in 2019

Department/Agency	Topic
Canadian Food Inspection Agency	Organic products regulations
Environment Canada	Benzene in gasoline
Environment Canada	Federal halocarbon
Environment Canada	Storage tank systems for petroleum products
Environment Canada	Sulphur in gasoline
Environment Canada	Volatile organic compounds
Environment Canada	Renewable fuels
Health Canada	Consumer chemicals and containers
Health Canada	Controlled products
Health Canada	Hazardous products
Health Canada	Toys
Health Canada	Radiation-emitting devices
Health Canada	Safety of human cells, tissues and organs for transplantation
Health Canada	Tobacco reporting
Ministry of Labour	Occupational health and safety (general, aviation, maritime, oil and gas, onboard trains)
Natural Resources Canada	Oil and gas installations
Natural Resources Canada	Energy efficiency
Natural Resources Canada	Offshore petroleum installations
Natural Resources Canada	Onshore pipelines
Transport Canada	Cargo, fumigation and tackle
Transport Canada	Flammable liquids bulk storage
Transport Canada	Life-saving equipment
Transport Canada	Liquefied petroleum gases bulk storage
Transport Canada	Motor vehicle safety
Transport Canada	Navigation safety
Transport Canada	Ship station (radio)
Transport Canada	Small vessels
Transport Canada	Transportation of dangerous goods

Source: Manual search by the author.

Figure 3: Distribution of Standards in P/T Regulations



Source: SCC (2019c, 37).

Box 1: Static Reference Example

The AI system shall conform with CAN/CIOSC 101:2019: Ethical Design and Use of Automated Decisions Systems.

Source: Author.

As Amended from Time to Time

Regulators also use the "as amended from time to time" incorporation method, also called direct, undated reference. A regulation would quote only the number and title of a specific standard and not the date (see Box 2). In the case of a revision of a referenced standard, the regulation itself does not need to be adapted as the reference automatically corresponds to the latest edition of the standard. In other words, the regulation allows the use of subsequent revised editions of the same standard. This allows for the regulation to reflect new technologies, processes or approaches without amending it.

Box 2: As Amended from Time to Time Example

The AI system shall conform to the latest edition of CAN/CIOSC 101: Ethical Design and Use of Automated Decisions Systems.

Source: Author.

Referencing a Standard with Additional Requirements

Regulators sometimes determine that adherence to a given standard is not enough in itself to meet legislative objectives and will spell out additional requirements in the regulation. A

Table 2: Estimated Number of Standards Referenced in Safety Codes

Title	Estimated Number of References
Canadian Electrical Code (2012)	539
Canadian Building Code (2010)	315
Canadian Fire Code (2010)	135
Canadian Plumbing Code (2010)	102
Canadian Energy Code for Buildings and Houses (2010)	94

Source: Manual search by the author.

"weak" voluntary technical standard can therefore be incorporated in a regulation with additional requirements spelled out. For example, there are many standards covering the energy efficiency performance of consumer goods and appliances. However, some jurisdictions will set the energy efficiency bar higher and spell out amendments to the standards in the regulatory text. When the new regulation is published, it may get noticed by technical committees in charge of the standard and may result in updates to subsequent editions to keep the document relevant.

Lists of Recognized Standards

Regulators may be faced with ongoing and significant changes in technologies and processes that are subject to constant changes and new features. One approach would be to update a regulation on an ongoing basis to make the relevant additions and subtractions of relevant standards as required. However, this process can be costly and time consuming for the regulatory authority.

A more flexible approach is to maintain an official list of recognized standards displayed on a government department website. For example, Health Canada maintains the Therapeutic Products Directorate List of Recognized Standards for Medical Devices. It is published by authority of the minister. The list, which contains more than 200 standards pertaining to medical devices, is regularly updated without the need to update the medical devices regulations. New standards are added, new editions of existing standards replace older versions and standards associated with discontinued products or processes are removed. The list is maintained "to provide guidance for manufacturers on the use of standards in demonstrating compliance with the *Safety and Effectiveness Requirements* (section 10 to 20) and *Labelling Requirements* (section 21 - 23) of the *Canadian Medical Devices Regulations* (Regulations)" (Health Canada 2023). Because standards are not recognized as statutory instruments, the lists of recognized standards are featured in guidance documents and described as administrative instruments. They do not have force of law but allow for the required flexibility in approach (ibid.).

This approach is also used by Transport Canada in support of its dangerous goods regulation and by the Ministry of Labour regarding approved occupational health and safety standards. That being said, relatively few departments and agencies are taking full advantage of listing designated standards on approved lists. One of the reasons why may simply be that the current Cabinet Directive on Regulation and the SIA are both silent on this approach to compliance and special authorities to manage lists are deemed necessary in enabling legislation.

Yet other Commonwealth jurisdictions have taken steps to broaden its use. For example, following Brexit in 2020, the UK government introduced a master "List of Designated Standards" available on a government website. Businesses can use the list to demonstrate that their products, services or processes comply with essential requirements of legislation.[7] The UK government created a designation process that allows the British Standards Institute (SCC's equivalent in the United Kingdom) to submit new standards for consideration by government officials. Australia also maintains evergreen lists of mandatory/recognized standards on

7 See www.gov.uk/guidance/designated-standards.

government websites covering issues such as high-risk consumer products[8] or medical devices.[9]

Digital Governance Standards, Certification and Legislation

The use of standards and certification programs to support compliance to legislative and regulatory objectives is not limited to traditional, established sectors. Authorities accountable for the development of digital governance laws and regulations are also setting their sights on standards and third-party certification as compliance mechanisms. Legislators in the European Union and the United States are engaged in standards development activities in a growing number of technical committees and working groups. The catalogue of published standards and standards under development probably contains documents that can be adopted by regulators to help manage the harms associated with LLMs.

Standards Development Activities in the Digital Governance Sector

Thousands of global technical standards were necessary to support the creation of the internet and the World Wide Web. One can easily imagine that a large number of standards will also be required to manage the myriad of digital governance issues created by the deployment of the internet and global platforms. A cursory review reveals a dozen major international standards bodies and consortia involved in developing standards and specifications to manage interrelated, value-laden issues such as privacy, ethics, trust and fairness.

In 1987, the ISO and the IEC established Joint Technical Committee 1 (JTC 1) by merging ISO Technical Committee 97 (information technology) and IEC Technical Committee 83 (information technology equipment). JTC 1 is seen by many as the leading body making progress in coordinating activities for data management, big data and AI. Its purpose is to develop, maintain and promote standards in the fields of IT and ICT. Since its creation, JTC 1 has published more than 3,200 standards and publicly available specifications covering a wide array of subjects including programming languages, interconnection of IT equipment, user interfaces, cloud computing, cybersecurity, data security, big data, data management and interchange, and more recently, the IoT and AI.[10]

It manages a substantive proportion of the two organizations' standards catalogue (ISO maintains more than 20,000 standards and IEC more than 10,000). JTC 1 operates through a matrix of subcommittees, working groups and advisory groups, which are connected to more than 100 liaison bodies. For example, Subcommittee 42 focuses on big data and AI through four working groups (WGs):

- WG 1: Foundational standards (concepts and terminology);
- WG 2: Big data (overview, definitions, reference architecture);
- WG 3: Trustworthiness (biases in AI systems, overview, robustness of neural networks); and
- WG 4: Use cases and applications.

The Institute of Electrical and Electronics Engineers Standards Association (IEEE SA) has been active in the ICT sector for decades through a large number of technical standards for electronic products, such as the ethernet and Wi-Fi as well as software engineering management. In 2017, IEEE had more than 1,100 active standards, with more than 600 standards under development. Regarding big data analytics, IEEE launched in 2017 a global consultation and outreach initiative called Ethically Aligned Design: A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems. IEEE is now spearheading the development of 15 ethical AI standards under its 7000 series ranging from algorithmic bias consideration, managing privacy when developing

8 See www.productsafety.gov.au/product-safety-laws/safety-standards-bans/mandatory-standards.

9 See www.tga.gov.au/standards-guidelines-publications-medical-devices-ivds.

10 See https://jtc1info.org/.

AI systems to automated facial analysis technology with the input of more than 2,000 participants.[11]

IEEE SA also launched the development of an Ethics Certification Program for Autonomous and Intelligent Systems, which represents the first attempt to design and deploy an international compliance mechanism toward ethical AI standards. If successful, the new program could provide certification for algorithmic bias, accountability and transparency.[12]

In 2018, IEEE led the creation of OCEANIS, the Open Community for Ethics in Autonomous and Intelligent Systems, along with 15 SDOs that joined as founding members and 19 members from the private sector. It is intended to act as a high-level global forum for discussion, debate and collaboration for organizations interested in the development and use of standards to further the development of autonomous and intelligent systems. Its creation could spur greater collaboration and cooperation among standard-setting bodies focusing on algorithms, sensors, big data, ubiquitous networking and technologies.[13]

The ITU, the UN agency accountable for global standards covering telecommunications and ICT, is the custodian of the International Telecommunication Regulations treaty. It maintains more than 4,000 normative documents, including standards. The ITU is an active player in the development of data sharing, IoT and smart cities standards. It provides comprehensive training on AI and digital skills.[14]

The European Technology Standards Institute (ETSI) produces standards and specifications for ICT-enabled systems and is focusing on issues such as blockchain, AI, augmented reality and autonomous networks standards. ETSI has published more than 45,000 standards and specifications, which are routinely incorporated by reference in European regulations. It has an ambitious work program related to big data analytics, cybersecurity and privacy to facilitate compliance with the GDPR (ETSI 2022).

The Internet Engineering Task Force is actively engaged in standardization efforts for application programming interfaces, IoT devices, security and privacy considerations.[15]

In Canada, as mentioned above, the newly created DGSI has recently received approval to submit its standards and specifications for review and recognition as international standards. As its approved standards carry both the ISO and IEC logos, DGSI should be considered an international standards development body.[16]

Mandatory Standards

It is still early days, but it is already clear that standards will play an important role in establishing a health, safety and security framework for digital technologies. For example, the recently released Companion Document to Canada's Digital Charter Implementation Act states that following royal assent of Bill C-27, the Government of Canada is intending to conduct consultations to focus on a number of issues, including the "types of standards and certifications that should be considered in ensuring that AI systems meet the expectations of Canadians" (ISED 2022).

Similarly, Ontario's draft AI commitments and actions recognize the importance of referring to standards when developing AI rules and requirements. Following public consultations, the province heard that the third most important action for AI to serve all Ontarians according to respondents was to "engage with sector leaders and civil society to develop a standard for 'trustworthy AI' and a process to certify that vendors are meeting the government's standard."[17]

Additionally, the Ontario government mentioned the reference and use of DGSI's NSC on automated AI decision systems in its recent release of beta principles for the use of ethical AI. This includes guidance to the Ontario Public Service to document how the use of data-driven technologies in processes, programs or services align with ethical principles, governance

11 See https://standards.ieee.org/initiatives/autonomous-intelligence-systems/.

12 See https://standards.ieee.org/industry-connections/ecpais.html.

13 See https://ethicsstandards.org/.

14 Seewww.itu.int/en/Pages/default.aspx.

15 See www7.ietf.org/topics/security/.

16 See https://dgc-cgn.org/standards/find-a-standard/.

17 See www.ontario.ca/page/ontarios-trustworthy-artificial-intelligence-ai-framework-consultations#section-3.

frameworks and industry standards.[18] In February 2023, the Government of Ontario broadened its commitment to digital governance standards and certification and announced a partnership with DGSI to "build a world-class data driven digital jurisdiction" (DGSI 2023).

Internationally, the EU AI Act, tabled in 2021, states that standards and certification will be used as the preferred compliance mechanism to frame high-risk AI applications in the delivery of products, devices, systems, networks and services. The European Union will require the adoption of enterprise-wide quality management and risk-management standards for organizations developing algorithms as well as for organizations using them. Organizational compliance to these management system standards will be audited by independent third parties. New certification schemes are expected to be developed to cover AI systems to be deployed in the services sector.

Additionally, the European Union has labelled AI applications embedded in standardized consumer products and machines as high-risk AI. New performance standards are likely to be developed to frame the use of AI chips in various product categories. New testing protocols will be developed to certify that products and devices using AI chips are safe and trustworthy (European Commission 2021). In December 2022, it submitted a comprehensive standardization request to European standards coordination bodies, CEN and CENELEC, in support of the implementation of the AI Act (European Commission 2022b). Again, it should be noted that the request has been submitted while the AI Act and regulations have not been completed yet. As such, it is labelled as a "possible future standardization request to the European standardization organizations."

The request is comprehensive. It covers 10 subject areas, ranging from high-risk management systems for AI systems; quality of data sets to build AI systems; record keeping, transparency and information provisions; human oversight; accuracy specifications; robustness; and cybersecurity for both developers and users. It sets a deadline of January 31, 2025, for the adoption of these standards by CEN and CENELEC, in time for the promulgation of the AI Act legislation and regulation. In their deliberations, CEN and CENELEC will determine for each subject area whether international standards have been published, whether they can be adopted without deviations or whether adaptations are required; when to participate in standards development work currently under way; and when to invest in entirely new standards and technical specifications (European Commission 2022).

The Government of the United Kingdom has also signalled its intention to implement a high-risk AI regime that will be deemed equivalent to the EU AI Act (UK 2021). As such, it will manage high-risk AI through the use of standards and certification programs in regulation. In December 2021, it committed to become a world leader in the development of a series of supportive standards and certification programs through the creation of an AI Standards Hub.[19] The ultimate objective of the hub is to create an effective AI assurance ecosystem through the management of appropriate levels of assurance based on risk across sectors and domains. As a public/academic/private collaborative, it may be a model of interest to Canadian regulators.

In the United States, the National Institute of Standards and Technology released its long-anticipated AI Risk Management Framework standard (AI RMF 1.0) in January 2023. The framework was developed following an executive order from the White House in 2020. It provides voluntary guidance for organizations to use when managing AI risks to individuals, organizations and society by incorporating trustworthiness considerations into the design, development, use and evaluation of AI products, services and systems. It is anticipated that this new standard will be applied by federal government agencies using high-risk AI and that organizations doing business with the government will have to implement it. This standard is also expected to be adopted by states and other national governments (National Institute of Standards and Technology 2023).

18 See www.ontario.ca/page/beta-principles-ethical-use-ai-and-data-enhanced-technologies-ontario.

19 See https://aistandardshub.org/; see UK (2022) for background information.

Modernizing Canada's SIA

In order to make Canada's regulatory system more responsive, modernizing the SIA should be seriously considered. This is the legislation that sets out Canada's legislative development machinery and provides clarity on the purpose and use of laws and regulations. As currently configured, it recognizes regulations as a statutory instrument to outline the "how" to comply with legislation. But it is silent on standards, technical specifications, safety codes or regulatory sandboxes as alternatives to regulations to articulate that "how."

As we have seen, leading jurisdictions have recognized standards and technical specifications as statutory instruments that have a role to play that is distinct from regulations. In the European Union, the so-called New Approach, in place since 1985, allows the Commission to make formal standardization requests to CEN-CENELEC, its standardization coordination body. These requests send an unmistakable signal that mandatory standards and conformity assessment programs will be developed while enabling legislation is still being refined and approved.

This in effect sets a parallel track for the co-creation by regulators and interested stakeholders of compliance mechanisms to legislation. Once the standards are published through the New Approach process, there is a "presumption of conformity" that will apply to all stakeholders within a set time period. It may not even be necessary for legislative authorities to reference the mandatory standards in a legal instrument; industry is expected to abide by them.

Through the New Approach, the European legislator had professed its faith in the accountability of the European standards system to work on behalf of the citizenry. The expectation is that the system should be organized by and for the parties concerned, on the basis of coherence, transparency, openness, consensus, independence of special interests, efficiency and decision making based on national representation. There is a flip side to that coin, however: both the European Commission and member states can, at any time, table formal objections against any harmonized European mandatory standard, in effect enabling the legislator to course correct (European Commission 2002, 13). The role of harmonized standards and the responsibilities of the European standardization organizations, first delineated under the New Approach, have been refined in subsequent regulations.[20]

With that in mind, and in the spirit of offering non-partisan advice on innovative governance ideas that have been tested internationally, one could envisage the following changes to the SIA, the Cabinet Directive on Regulations and companion legislation.

Recognize Mandatory Standards, Technical Specifications and Conformity Assessment Programs as Statutory Instruments

The act could formally recognize as statutory instruments three types of documents: NSCs; technical specifications developed by SCC-accredited SDOs; and SCC conformity assessment programs that have been designated by a federal authority as mandatory for the purposes of compliance with a federal legislation.

This recognition would allow federal authorities to engage with SCC-accredited SDOs to develop, adopt or adapt mandatory standards/technical specifications to support compliance to existing or new federal legislation. It would also allow federal authorities to designate which SCC conformity assessment program should be used to report and certify conformity to a given standard. In other words, when thinking about compliance mechanisms to legislation, federal regulators could therefore choose between a regulation, a mandatory standard, a technical specification, a conformity assessment program or a combination of these instruments.

As mentioned above, there would be many public policy benefits to recognize standards as statutory instruments. Authorities could direct the development of mandatory standards or technical specifications when issues arise regarding the performance of a technology already commercialized or to address harms

20 EC, *Regulation 1025/2012 on European standardization amended by Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015*, [2015] OJ, L 316, online: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R1025-20151007&from=EN>.

that are deemed important enough to require immediate action. Owners of the technologies would have a vested interest in participating in the standards development process knowing that compliance to new requirements will become mandatory and failure to comply could trigger penalties. In addition, standards and technical specifications can remain "evergreen" and be updated and modified as required when changes to the technology they frame warrant it.

Enable Authorities to Make Standardization Requests

The act could enable authorities to make formal standardization requests to SCC-accredited SDOs for the development, adoption or adaptation of a mandatory standard/technical specification/conformity assessment program. It would set the parameters regarding the description of essential requirements that need to be met to comply with an existing/draft legislation or with a regulation. It would also establish a process leading to the review of the request by impacted SDOs, the timelines for the development and approval of documents, and the options available to trigger their entry into force.

Provide New Pathways to Trigger Entry into Force

The act could delineate new pathways that federal authorities could use to trigger the entry into force of mandatory standards/technical specifications/conformity assessment programs. In addition to incorporation by reference in a regulation, authorities could also be enabled to trigger entry into force by displaying mandatory standards/technical specifications/conformity assessment programs to official lists of recognized standards approved by authorities. Precedents already exist for this. Another pathway could be to empower authorities to require compliance through an order in council. It is understood that documents could be added or removed from lists at the discretion of authorities. The proposed pathways would significantly improve timelines and reduce delays leading to better outcomes without weakening Parliament's powers over these instruments.

Authorize the Creation of Regulatory Sandboxes

There will be instances where standardization may not be the right vehicle to create adequate compliance mechanisms to legislation. When such cases arise, the SIA could allow federal authorities to formally create regulatory sandboxes for the co-development of a compliance mechanism to manage risks associated with a new technology, system or process. The concept of regulatory sandboxes has been defined by the CRI (2022) as "a facility, created and controlled by a regulator, designed to allow the conduct of testing and experiments with novel products or processes prior to their full entry in the marketplace." They provide a safe place where industry and regulators can undertake experiments and learn from them. To industry, they offer access to testing in something approximating a real-world environment, but usually in a limited regulatory subsector, for a limited period of time, and within a safely circumscribed space that a regulator can adequately supervise (ibid.).

Enabling federal authorities to formally create a regulatory sandbox through the SIA would be very helpful when regulators are pressed for time in identifying, responding to and managing harms. As a first step, a regulatory sandbox could help determine whether an innovative product or service can be covered within existing regulation, whether a new compliance mechanism must be designed or whether entirely new legislation is required. Here, one needs to allow for testing and experimentation of products, processes or systems not only *before* they are commercialized but also *after* their entry into the marketplace, which has become the norm with most digital technologies.

As it identifies risks and potential for harms, a regulatory sandbox could then issue high-level guidance. It could aim to create, test and implement a compliance program in line with existing legislation. It could also aim to meet essential requirements identified in draft legislation as it is being debated and studied in Parliament through a parallel track.

Conclusion

It is time for Canada to design its own "New Approach" to streamline digital rulemaking. The limitations of our rulemaking system are clear when looking at the use case of the commercialization of a first generation of LLMs.

By modernizing the SIA, any federal authority could direct the development of mandatory standards or technical specifications and set requirements in order to address specific harms as they are uncovered in the marketplace. These harms could be application specific (for example the use of deepfakes, the provision of advice, coding, the creation of reports, digital twins, and so on) or associated with specific sectors (finance, health, education, human resources, use in consumer products, and so on).

The tension between the exciting opportunities created by LLMs and the unintended risks they generate is guaranteed to be further exacerbated when new generations of sector-specific applications are commercialized. Bill Gates (2023) recently opined "we should keep in mind that we're only at the beginning of what AI can accomplish. Whatever limitations it has today will be gone before we know it." There will be a surge of companies working on new uses of AI as well as ways to improve the technology itself. And once data scientists find a path to generalize a learning algorithm and run it at the speed of a computer, legislators will have to cope with "strong AI" — systems that can achieve everything that a human brain can while removing limits on the size of its memory or the speed at which it operates. Looking forward, one can envisage the merging of the human mind with machines and begin to see the far-reaching implications on society.

The benefits of modernizing the SIA go beyond managing risks associated with digital technologies. They could apply to legislation across the whole of government. One could think of use cases in other sectors such as health care and wellness where technological advances outpace regulatory oversight, or horizontal issues such as climate change where both mitigation technologies and environmental conditions are changing at a breathtaking pace. In essence, modernizing the SIA is about making government more responsive to a host of new risks. Canada cannot capture the opportunities that disruption can create if it continues to lag, rather than lead, in risk identification and management.

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