Standards and public policy: A toolkit for national standards bodies

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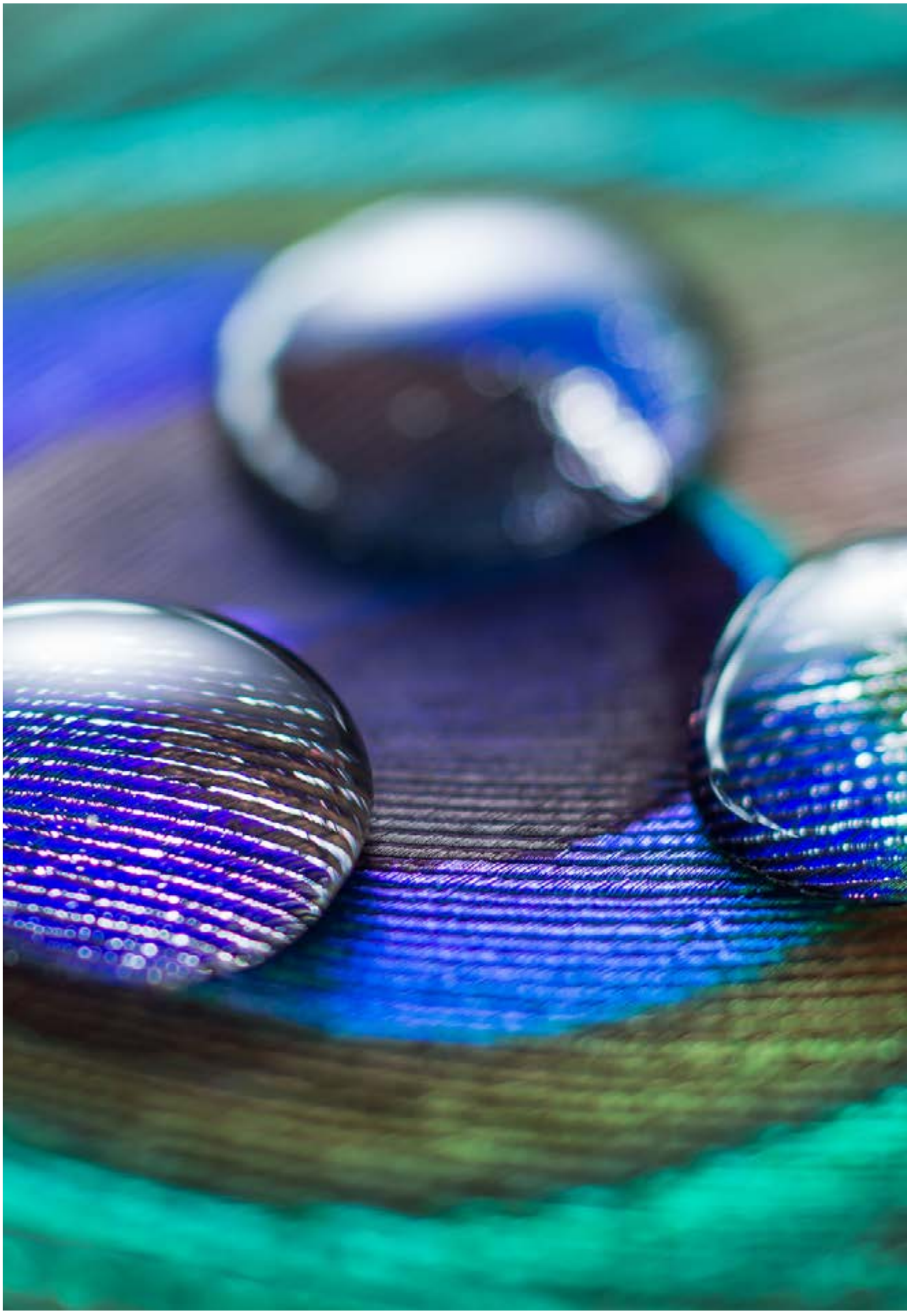

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Foreword

In a world characterized by unprecedented challenges spanning from globalization and economic growth to climate change, the significance of standards has never been more apparent. From the UN Secretary General calling for common standards to achieve net zero commitments; to governments, businesses and organizations working tirelessly to find solutions to facilitate the cross-border movement of data, goods and services. International standards have a central role to play in building trust in the transition to an inclusive, sustainable, resilient and digitally empowered future. Achieving these goals will require policymakers, and businesses, to collaborate and use all the levers available to them, including standards, to move forward at pace, with accountability and transparency.

Although every country is unique and needs to develop its own approach, it is clear that the most effective way to accelerate change and build trust is through a combination of regulatory requirements and voluntary international standards. We at ISO recognize that the true power of international standards lies not only in their technical specifications but also in their capacity to inspire innovation, facilitate trade and drive change and societal transformation. International standards developed by ISO, the International Electrotechnical Commission (IEC) and the International Telecommunications Union (ITU), jointly known as the World Standards Cooperation, are developed in line with the WTO TBT provisions and principles. These standards have a unique role to play in leveraging the longstanding standardization and assurance system to support policymakers and regulators to achieve their policy objectives, complementing regulation and legislation.

Based on the importance of the nexus between standards, regulation and policy, and upon request of our members, I take great pride in presenting the ISO standards and public policy: a toolkit for National Standards Bodies. The toolkit has been developed in collaboration with our members with the aim of equipping them to engage proactively with policymakers and regulators, by providing a practical framework on how International Standards, and conformity assessment, can support policymakers and regulators in preparing, adopting and applying policy, and in particular, technical regulations.

We recognize the pivotal role that standards play in shaping forward-looking public policies and good regulatory practices. Through collaboration, consensus, and the commitment to excellence, standards enable countries to navigate the complexities of our modern world while upholding the values of safety, quality, and integrity. Ultimately, the use of standards in public policy represents a commitment to a shared vision of progress, cooperation, and resilience. As we collectively endeavor to overcome challenges and seize opportunities, ISO remains dedicated to fostering a culture of standardization that transcends borders and empowers societies to flourish.

This is a “living” publication and ISO will provide capacity building support to its members as part of ISO’s Action Plan for developing countries, 2021-2025. We recognize that our members and policymakers urgently need more insight to learn how to exploit the standards we already have to support net zero transition and achieve economic, environmental and social policy objectives, to reduce the complexity of multiple standards and to address standardization gaps. To this end, together with our partners and members, we will develop thematic policy briefs for our members and work with them and their policymakers and regulators to demonstrate the power of standards and regulation working in harmony to achieve policy objectives in numerous sectors.

We welcome anyone interested in working with us to accelerate transformation through better use of standards to complement regulation and policy. I wish that this publication will lead to more endeavors and concerted efforts aimed at making international standards a driving force for the prosperous, inclusive, sustainable and digital future we want to build.

Sergio Mujica
ISO Secretary-General

Acknowledgements

This publication has been developed by the ISO Central Secretariat, under the overall guidance, oversight and coordination of Erich Kieck, Noelia Garcia Nebra, Cindy Parokkil and Francesco Dadaglio at the Capacity Building Unit, and with the support of international experts on standardization and the British Standards Institution (BSI).

The publication has greatly benefited from the substantive inputs from Michael Peet, Nigel Croft and Richard Lawson, and from the peer review of our members, in particular the Chair's Advisory Group of the ISO Committee on Developing Country Matters (DEVCO).

We would like to thank the Marketing and Communication team at the ISO/CS who provided support to the finalization of this publication.

The work was funded by the contribution from the Swedish International Development Cooperation Agency (Sida) within the framework of the ISO Action Plan for Developing Countries and we wish to greatly acknowledge the continuous and generous support of Sida to ISO's activities in developing countries.

Glossary of abbreviations

Abbreviation	Definition
CA	Conformity assessment
CAC	Codex Alimentarius Commission
CAB	Conformity assessment body
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GRP	Good regulatory practices
GSP	Good standardization practices
ICT	Information and communications technology
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ISO/ CASCO	International Organization for Standardization Committee on Conformity Assessment
ITU	International Telecommunications Union
MoU	Memorandum of understanding
NQI	National quality infrastructure

Abbreviation	Definition
NQP	National quality policy
NSBs	National standards bodies
NSS	National standardization strategy
OECD	Organisation for Economic Co-operation and Development
OJEU	Official Journal of the European Union
QI	Quality infrastructure
PPE	Personal protective equipment
RIA	Regulatory impact assessment
RTA	Regional trade agreement
SCC	Standards Council of Canada
SDGs	UN Sustainable Development Goals
TBT	Technical barriers to trade
TC	Technical committee
TR	Technical regulation
UN	United Nations
WSC	World Standards Cooperation
WTO	World Trade Organization

Purpose and intended audience of this document

What is the purpose of the document?

This document provides a framework on how International Standards[1] can support policymakers and regulators[2] in preparing, adopting and applying policy, and in particular, technical regulations (TRs). It is designed to equip national standards bodies (NSBs; ISO members) to engage proactively with policymakers and regulators. A better understanding of where standards, policy and TRs interact with the politico-legal and socio-economic objectives and fit within the national quality infrastructure (NQI), can help policymakers, regulators and NSBs to work together in a more effective manner. This document complements an earlier publication by the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) entitled *Using and referencing ISO and IEC standards to support public policy*[3] and the ISO Committee on Conformity Assessment (CASCO) online webpage entitled: *Conformity Assessment tools to support public policy*[4].

Who should use this document?

This document is primarily targeted at the governing body members, executives and personnel of NSBs who engage with government officials responsible for the development, oversight and/or implementation of public policies and associated regulations: Particularly — but not exclusively — in developing countries. The document is further intended for officials in ministries, legislatures, oversight bodies tasked with implementing policy, or other stakeholders supporting the development, review and/or implementation of TRs and associated standards.

What do standards contribute to public policy and regulations?

Standards provide practical tools and agile processes to improve public policy and ensure it is fit-for-purpose. Standards used or referenced in public policies and supporting regulations ensure that:

- trade is facilitated and unnecessary barriers to trade are avoided;
- the health and safety of citizens are protected;
- the environment is safeguarded;
- compliance is assured with the principles and measures embodied in the World Trade Organization (WTO) Agreements relating to Technical Barriers to Trade (TBT), Sanitary and Phyto Sanitary (SPS) measures and Trade Facilitation (TF); and
- international regulatory cooperation is enhanced.

1 Standards refer to International Standards unless specifically stated otherwise.
2 References to 'policymakers' also include regulators unless it is clear from the context that this is not the case.
3 https://www.iso.org/publication/PUB100358.html.
4 https://casco.iso.org/home.html.

International Standards equally provide solutions to policymakers and regulators to tackle global issues, including sustainable and inclusive economic growth, climate change, clean energy, mobility, and cybersecurity. It is to be noted that International Standards published by ISO contain best practices from experts around the world.

What are the benefits of using standards in developing and implementing public policy for the public and private sector?

Standards used in public policies and regulations provide benefits to the public and private sector and citizens through:

- better designed policies and regulations based on agreed requirements and norms;
- reduced costs and administrative burdens of associated regulatory requirements;
- increased trust and involvement of the private sector and consumers in regulatory processes; and
- enhanced confidence of trading partners and investors.

Turning the toolkit into action

The purpose of this toolkit is to ensure that all three main role players, with responsibilities in policy-making, regulation and standard setting, approach future challenges from a common foundation and understanding. Therefore it is essential to inform each of the related activities of the others.

Section 1: Technical guide

Chapters 2 and 3 focus on the foundations of public policy and policy challenges including the UN SDGs, and are therefore aimed at informing those responsible for regulation and standard setting.

Chapters 4, 5 and 6 which deal with regulation, good regulatory practices, and regulatory impact assessment (RIA) aim at providing a common understanding for policymakers, regulators and standards setters.

Chapter 7 provides information on standards in support of public policy and regulation, establishing the linkages and potential synergies between all three activities.

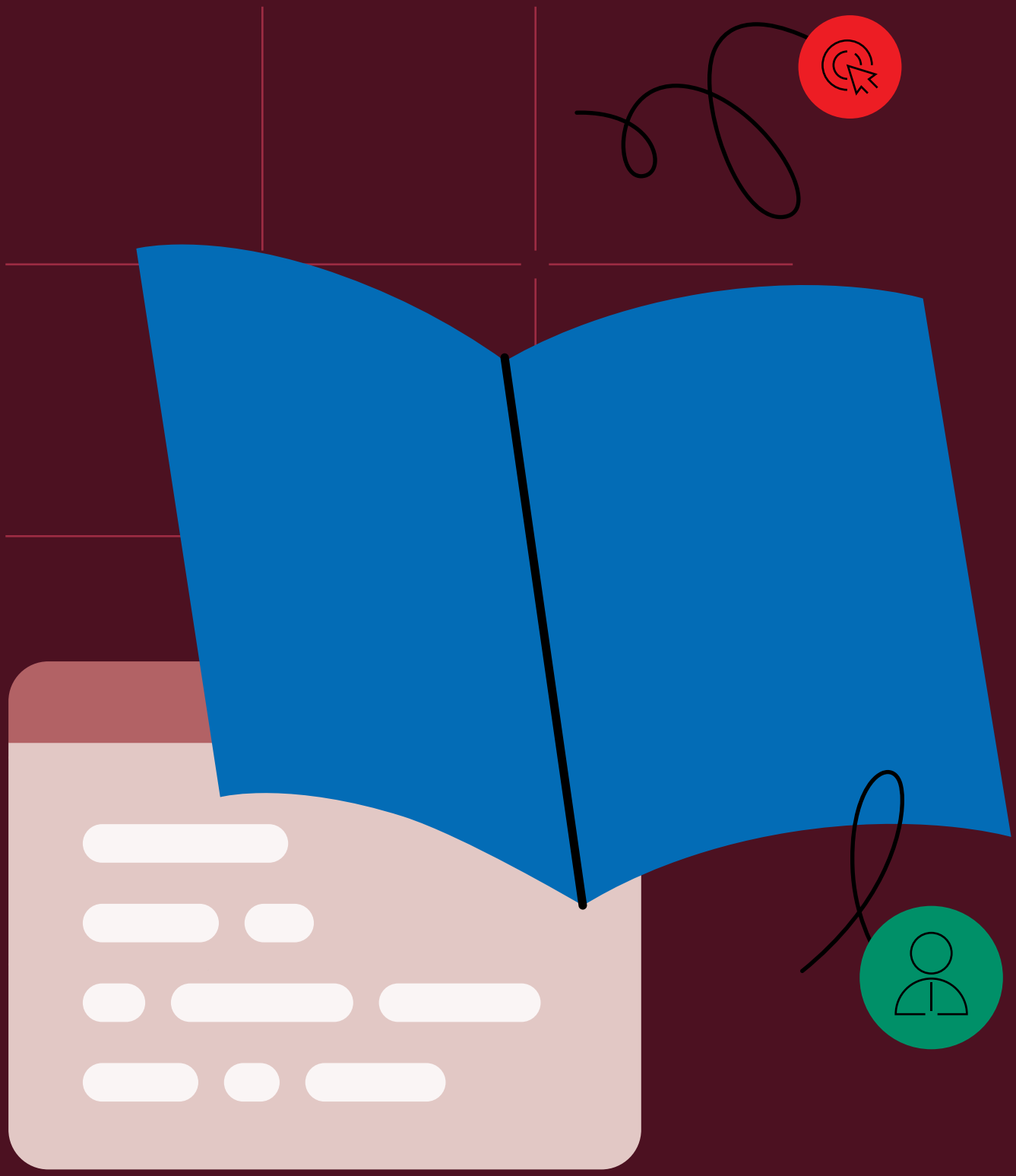
Chapters 8, 9 and 10, which refer to standards, TRs, and conformity assessment, provide information to policymakers and regulators on how the three elements interact, and how standards and conformity assessment (CA) can help to demonstrate compliance with regulations, thereby building trust and confidence.

Chapter 11 provides a basis for stronger future engagement between all three groups.

Section 2: A step-by-step guide for effective engagement between NSBs and public-policymakers

Chapter 12 is a step-by-step guide for NSBs to encourage even greater synergies as they work together with policymakers and regulators, fulfilling separate but equally important mandates, for the increased benefit of their respective national constituencies.

Section 1:
Technical guide



1. Introduction

As issues facing countries grow in complexity and reach, the need for appropriate policies and fit-for-purpose regulation can only increase. The importance of International Standards in helping address global challenges can also be expected to continue to grow, given that they sit at the nexus between policy and best practice technical know-how. At the national level, standards are an increasingly important part of a public policymaker's toolkit. A coherent approach to the use of standards in regulation assists governments as they strive to become more effective in serving their society, economy and environment.

There is no one best approach for developing standards and regulations in a coherent manner. This is a challenge for all countries – developed and developing alike. There is no "one size fits all" approach. Countries rarely share common histories and cultures. They also often have different developmental needs that shape and inform their strategic intentions and policy ambitions. Even where levels of development are similar, social contexts may vary and as a result there could be very different attitudes, for example, to governance and risk tolerance.

Institutions and structures have evolved – and continue to do so differently, and at different levels of intensity. Nevertheless, while it is not possible to develop a single blueprint, everything can be improved. NSBs have a crucial role to play in promoting the use of standards to the maximum benefit of society. It is important to remember, however, that standards and regulations are not the only instruments available to governments when addressing today's policy challenges. They can, and should, however, play an increasingly influential role, together with the wider quality infrastructure required to support their implementation.

2. Public policy

Public policy can be described as a statement of intent by government or other state actors. It is intended to give effect to a set of policy objectives to resolve problems or address various needs within society. In seeking to achieve a desired change, it can be focused on addressing problems, achieving transformation or a mixture of the two[5]. Stated another way "most public policies are aimed at guiding the delivery of public goods and services. However, some policies are designed to bring about change, while others seek to respond to change"[6].

Policymakers are often required to address a complex mix of real and/or perceived problems and associated challenges. They also need to ensure that their intended policy choices minimise any potential unintended consequences for those who may be impacted. Policy objectives can include economic ones, such as encouraging export led growth, and non-economic ones, such as the protection of human health and the environment.

Consideration of various alternatives is an important component in the public policy-making process. Such an activity aims to identify the possible courses of action, together with a comparison of their relative merits based on issues such as associated costs, benefits and risks[7]. Such a consideration often includes a formal appraisal process[8]. In evaluating the need for a policy, alternatives to the status quo position, i.e. 'do nothing', are referred to as the 'do something' options. These generally cover a range from light touch to intensive intervention. Policymakers consider conventional approaches alongside more innovative methods and identify the full range of policy instruments or projects that may meet the particular policy objective. This can include different sorts or scales of intervention. Regulatory solutions should be compared, for example, with private sector self-regulation, co-regulation, fully-regulated models, incentives including tax options, and voluntary action. Different standards or compliance procedures[9] for different groups may be appropriate, e.g. large and small businesses. Different levels of obligation should also be evaluated for achieving the desired policy outcomes (e.g. accreditation, monitoring, and inspection regimes, including voluntary standards, approved codes of practice or government regulation)[10].

Policy making should be evidence based. Policies and regulations should be based on the best available data and scientific expertise. This implies rational analysis at each stage of the policy-making process. In addition, it is important that regional and international perspectives are considered during any policy development initiative. Globalization has broadened the policy space beyond the boundaries of the nation-state. Gender mainstreaming is another important element that should be addressed by policymakers and appropriately integrated in public policies.

Consumers and producers rely on domestic, regional and international markets to facilitate their transactions. Markets left to themselves do not always produce outcomes that are aligned with national policy objectives. A public-policy intervention may then be necessary to address all or some of the identified shortcomings. Such an intervention might include the need to alter the incentives, or reduce the disincentives, faced by private sector actors wishing to enter or remain in the market.

5 See Cloete, F., De Coning, C., Wissink, H., and, Rabie, B. (2019), Improving Public Policy for Good Governance, page 7.
6 See Mohamed Sayeed, C. N. (2020), Public Policy Responses in a Time of Pandemic. https://www.researchgate.net/publication/348679587_Editorial_Public_Policy_Responses_in_a_Time_of_Pandemic.
7 See for example, A Practical Guide to Policy Making in Northern Ireland, chapter 5, available at https://www.executiveoffice-ni.gov.uk/publications/practical-guide-policy-making-northern-ireland.
8 See for example, the Step-by-step economic appraisal guidance for Northern Ireland at: https://www.finance-ni.gov.uk/topics/finance/step-by-step-economic-appraisal-guidance.
9 See the step-by-step economic appraisal guidance for Northern Ireland, step 4, para. 2.4.16 at: https://www.finance-ni.gov.uk/topics/finance/step-by-step-economic-appraisal-guidance.
10 Ibid.

3. Public policy in support of the UN SDGs

The United Nations Sustainable Development Goals[11] (SDGs), see Figure 1, provide a globally agreed example of how to address the complex problems facing all countries, in a holistic and sustainable way. The SDGs recognize that ending poverty must go hand-in-hand with strategies that improve health and education, reduce inequality, and spur economic growth – all while tackling climate change and working to preserve and restore our oceans and forests. They are typically stated in terms of policy goals, such as ending hunger and poverty.

Figure 1: United Nations Sustainable Development Goals

11 See the commitments made in Transforming our world: The 2030 Agenda for Sustainable Development at https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf.

Box 1: The United Nations Sustainable Development Goals (SDGs)

The 2030 Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, provides a shared blueprint for peace and prosperity for people and the planet. At its heart are the 17 SDGs, and their associated 169 specific targets, which represent an urgent call for action by all countries – developed and developing – in a global partnership.

Standards, in support of public policy initiatives and appropriate TRs, can contribute to the SDGs by defining requirements, best practice guidelines and other criteria for a whole range of topics.

ISO has published over 24 000 International Standards and related documents that represent globally recognized guidelines and frameworks based on international collaboration. These cover generic areas of activity, e.g. management systems or social responsibility and CA standards that apply to many, if not all, of the SDGs. ISO also publishes very specific standards such as those for environmental labelling, test methods for the analysis of drinking water, and determination of energy efficiency.

For each SDG, ISO has identified the most relevant standards that can assist policymakers. Some well-known examples of ISO management system standards[12] being used to provide requirements and/or guidance in support of SDG-related policy initiatives include:

- **SDG 2** (Zero hunger) – ISO has over 1 600 standards for the food-production sector designed to create confidence in food products, improve agricultural methods and promote sustainable and ethical purchasing, as well as support to the blue economy. These also cover a number of other areas including nutritional and safety testing, quality, packaging, and traceability. Examples include:
  - The ISO 22000 family of standards on food safety management, which help organizations identify and control food safety hazards. They provide a layer of reassurance within the global food supply-chain, helping products cross borders and bringing people food that they can trust.
  - Over 50 technical standards developed by ISO/TC 134, *Fertilizers, soil conditioners and beneficial substances*.
  - ISO's two main technical committees (TCs) dealing with food standards are:
    - ISO/TC 34, *Food products*
    - ISO/TC 234, *Fisheries and aquaculture*

Both develop standards and internationally-agreed documents in conjunction with other specialized international bodies including the UN Food and Agricultural Organization (FAO), Codex Alimentarius, World Organisation for Animal Health, and World Health Organization.

- **SDG 4** (Quality education) – ISO 21001 is aimed at education and specifies management system requirements for educational organizations to support the acquisition and development of competence through teaching, learning or research, and enhancing the satisfaction of learners, other beneficiaries and staff. ISO TC 232, *Education and learning services*, is responsible for this standard and has associated working groups (WGs) that address related topics, including language learning services (ISO/TC 232, WG 2), educational assessment outside the formal sector (ISO/TC 232, WG 4), and distance-learning services (ISO/TC 232, WG 6).

12 For brevity, the specific discipline of each standard is mentioned and not its full title. Further details can be obtained via the ISO Website at https://www.iso.org/management-system-standards.html#PopularMSS.

- **SDG 7** (Ensuring access to affordable, reliable, sustainable and modern energy) – ISO 50001 for energy management systems was developed for organizations committed to addressing their impact, conserving resources and improving the bottom line through efficient energy management. It is designed to support organizations in all sectors and provides a practical way to improve energy use, through the development of an energy management system (EnMS). It provides requirements that policymakers can use to support their initiatives to promote energy efficiency. ISO/TC 301, *Energy management and energy savings*, which is responsible for this standard, focuses its work on developing standards to assist users to:
  - effectively measure, monitor, verify and validate energy savings due to decarbonization efforts related to energy;
  - effectively monitor and measure energy performance;
  - use quality data and sound energy accounting practices;
  - systematically identify and quantify energy performance improvements;
  - apply standardized methods for calculating, measuring and verifying energy savings; and
  - support transparent and effective evaluation and reporting of energy performance improvements and energy savings.
- **SDG 8** (Promoting inclusive and sustainable economic growth, employment and decent work for all) – the ISO 45000 series for occupational health and safety, specifies requirements that are aimed at providing a healthy and safe workplace. ISO 45001 for health and safety management systems builds on the success of earlier International Standards in this area such as the International Labour Organization's (ILO) ILO-OSH Guidelines, various national standards and the ILO's international labour standards and conventions. ISO/TC 283, *Occupational health and safety management*, is the responsible TC for this series of standards. Its work includes two new standards namely ISO 45006:2023, *Occupational health and safety management — Guidelines for organizations on preventing and managing infectious diseases*, which was published in December 2023, and the draft standard ISO/FDIS 45004, *Occupational health and safety management — Guidelines on performance evaluation*, currently under development at the time of publication of this toolkit.
- **SDG 9** (Industry, innovation and infrastructure) – The ISO 9000 series of quality management standards provides criteria for organizations that seek to improve the quality of their products and services and consistently meet their customers' expectations and applicable statutory/regulatory requirements. This is vital to generate confidence; not only in the context of industrialisation, but also for consumers. ISO 55001 for asset management, and ISO 41001 for facilities management, provide requirements that can support the maintenance of the infrastructure that is required for economic growth. Other areas to consider are: information and cybersecurity, protection of privacy, and interoperability of digital infrastructures to support industry, innovation and trade. For example, ISO/IEC JTC 1/SC 27, *Information security, cybersecurity and privacy protection*, has published over 230 standards, of which ISO/IEC 27001 on information security management system is widely used around the world.

- **SDG 13** (Climate action) – The ISO 14000 family of standards for environmental management, which falls within the ISO/TC 207, *Environmental management*, provide guidance and requirements for companies and organizations of any type that require practical tools to manage their environmental responsibilities. This includes demonstrating their commitment to comply with environmental legislation, the prevention of pollution and continually improving their environmental performance.
- **SDG 16** (Peace, justice and strong institutions) – The ISO 37000 series from ISO/TC ISO/TC 309, *Governance of organizations*, provides key principles, relevant practices and a framework to guide the governance of organizations. The requirements are equally applicable to governmental and non-governmental organizations (NGOs).
    - ISO 37000, which describes guidance on governance for organizations provides organizations and their governing bodies the tools they need to govern well, enabling them to perform effectively while behaving ethically and responsibly. It is the first International Standard for governance which applies to all types of organizations.
    - ISO 37001 for anti-bribery management, is the International Standard that allows organizations of all types to prevent, detect and address bribery by adopting an anti-bribery policy, appointing a person to oversee anti-bribery compliance, training, risk assessments and due diligence on projects and business associates, implementing financial and commercial controls, and instituting reporting and investigation procedures. It provides requirements that can be used by policymakers to address one of the world's most destructive and challenging issues.

Other ways in which standards and TRs can assist policymakers in achieving their objectives is exemplified in ISO's *London Declaration*[13]. This declaration underlines ISO's commitment to carbon neutrality and goals for achieving net-zero carbon dioxide emissions. The declaration is intended to enable policymakers, businesses, and organizations across the globe to accelerate their various contributions to climate action by using trusted standards that are aligned to robust net-zero targets that meet policy commitments and targets including those in the Paris Agreement, the United Nations SDGs and the United Nations call for action[14]. The symbiotic nature of standards and policy were further emphasised by António Guterres, United Nations Secretary-General. In his opening address at the Conference of the Parties in Glasgow in 2021 (COP 26) he called for the establishment of a group of experts to "propose clear standards to measure and analyse net-zero commitments from non-state actors".

ISO has also published a brochure[15] *ISO & SDGs – Contributing to the UN Sustainable Development Goals with ISO standards* that contains more information in this regard. The ISO Website provides resources[16] for NSBs to use in their interactions with policymakers and others who are looking for a concrete way in which their government or organization can make a meaningful contribution to the fulfilment of the SDGs.

13 See https://www.iso.org/ClimateAction/LondonDeclaration.html.
14 See Call for Action: Raising Ambition for Climate Adaptation and Resilience, https://www.adaptation-undp.org/sites/default/files/uploaded-images/call_for_action_on_adaptation_and_resilience_v_18_august_2021.pdf.
15 See https://www.iso.org/publication/PUB100429.html.
16 See https://www.iso.org/sdgs.html.

Box 2: Standards and gender

Gender disparities are a persistent form of inequality in every country, and despite remarkable progress in some areas, no country in the world — rich or poor— has fully achieved gender equality. All too often, women and girls are discriminated against in health, in education, at home and in the labour market — with negative repercussions for their freedoms.

The most relevant of all ISO's suite of standards is ISO 26000:2010, *Guidance on social responsibility*, which specifically addresses gender equality, and was developed taking the gender balance of experts into consideration. This standard can provide invaluable guidance for policymakers and regulators alike, in order to embed gender equality considerations into their policies and TRs.

There are a number of ways in which NSBs can collaborate with and support policymakers to address this important topic. ISO is a signatory of the UNECE Declaration on Gender Responsive Standards (see https://unece.org/trade/wp6/thermatic-areas/gender-resp-stds-decl) and seeks to embed gender equality across its entire range of standards. As a result of signing the Declaration, the ISO/IEC TMB Joint Strategic Advisory Group (JSAG) on Gender Responsive Standards (GRS) was established in 2020, with the mandate to increase the ISO and IEC technical communities' appreciation of, and competence, in developing GRS.

ISO IWA 34 entitled *Women's entrepreneurship — Key definitions and general criteria*, available on the ISO Website (https://www.iso.org/standard/79585.html), establishes a set of common definitions related to women's entrepreneurship, such as those for women-owned business and women-led business. The document defines women-led cooperatives and informal enterprises which can be used, for example, in women's economic empowerment programmes and for the collection of internationally comparable data on women's entrepreneurship, including the impact on local and national economies.

For more information, visit: https://www.iso.org/strategy2030/key-areas-of-work/diversity-and-inclusion.html

4. Regulation

According to Shafritz and Russel, "regulation has its origins in legislation"[17]. The same authors[18] note that "Agencies begin with some form of legislative mandate and translate their interpretation of that mandate into policy decisions, specifications of regulations and statements of penalties and enforcement provisions". As mentioned in the previous section, public sector policymakers are required to pursue a wide range of objectives. These may be related to safeguarding public health, protecting the environment or even addressing national security issues. The WTO recognizes this sovereign responsibility. The preamble of the WTO Agreement on TBT states that

> "no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement."[19]

Members of the WTO must take note of the basic principles and requirements embedded in the relevant WTO agreements when designing policy and regulatory measures. One means of government intervention in the marketplace is through regulation. Regulation is the exercise of control by government. It has many names, e.g. a rule, statute, law, act, ordinance, or decree. Regulation can be in the form of primary laws adopted by a parliament or secondary legislation adopted by ministries or even tertiary mandatory requirements adopted by institutions. It can be defined as *any action* by government that *imposes an obligation of compliance* on the part of all that are subject to its authority[20]. It is expressed in a document and contains requirements that are enforceable by law. For example, a producer in one country has to meet certain domestic regulations for producing and placing a product on the market (e.g. safety, sustainability). The same producer may have to adapt certain product characteristics to comply with the regulations in a foreign market.

The use of standards in regulation can support policymakers by providing solutions when designing measures, especially related to products, that fall within the scope of the WTO TBT Agreement. On one hand policymakers must understand that freer trade is recognized as a powerful engine of growth for economic and social development but at the same time it may also inadvertently bring serious threats to the health and safety of citizens as well as environmental concerns[21]. Policymakers and regulators therefore have to strike a balance between freer trade and the welfare of their citizens and the safeguarding of the environment. Over-regulation can hinder business and trade facilitation and thus impact the growth potential for a country whereas irresponsible deregulation could result in dire, long-lasting consequences.

Regulators have a variety of institutional forms. They may be a unit within a ministry. They could also be a separate entity with its own statutory foundation, governing body, staff, and executive management. The outcome of a particular regulation is highly dependent on the process used during its development.

17 See Introducing Public Administration, 2005, Shafritz & Russell, Pearson Education, Page 15.
18 Ditto.
19 WTO TBT Agreement, preamble (https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm). The full text of the TBT Agreement is available here www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.
20 This is derived from many, slightly different definitions of regulation, most of which are variations on the same theme (see for example, Collins dictionary (https://www.collinsdictionary.com/dictionary/english/regulation), Merriam-Webster (https://www.merriam-webster.com/dictionary/regulation) or the Cambridge Dictionary (https://dictionary.cambridge.org/dictionary/english/regulation). The OECD (https://stats.oecd.org/glossary/detail.asp?ID=3295) defines regulation as follows: "Regulation is broadly defined as imposition of rules by government, backed by the use of penalties that are intended specifically to modify the economic behaviour of individuals and firms in the private sector. Various regulatory instruments or targets exist..." (emphasis added).
21 See for example, https://www.wto.org/english/blogs_e/ddg_anabel_gonzalez_e/blog_ag_22mar22_e.htm.

Given the inherent difficulties associated with the equitable enforcement of regulations, there is a growing trend towards outcome or risk-based approaches to regulation, including greater self-regulation. Such approaches include collaborative responsibilities for market surveillance through a system which aims to share responsibility for proving compliance between the regulator and those being regulated. They are intended to incentivize compliance by "rewarding" good behaviour (such as earned recognition), reduce the cost burden of regulation on all actors, promote shared ownership and increased trust between the regulators and industry. Such approaches also aim to promote rather than stifle innovation.

In order to achieve the intended benefits inherent in a shared responsibility approach to policy deployment and associated regulations, voluntary standards, as published by ISO, have a major contribution to make. They assist those having to comply with regulations that are based on standards, because of the collaborative and transparent processes used in their development and maintenance. Compliance with such standards should not be seen as an add-on-cost, but as a worthwhile investment in providing a satisfactory and sustainable product, service or process.

Standardization encourages the involvement of business, governments, consumers, academia, civil society and other stakeholders, i.e. anyone who may be affected by it, in developing the technical specifications that may subsequently be used to give effect to the objectives of a regulation or legislation[22]. If people with a legitimate interest in, and detailed knowledge of, the particular product and processes participate in developing the technical requirements, they are likely to identify the least-cost options for achieving public goals, resulting in increased competitiveness and the least wasteful use of resources.

Box 3: One objective, many approaches

Defining a policy objective is usually easier than choosing the best instrument for achieving it. For a given objective, such as the limitation of atmospheric carbon dioxide emissions, numerous different instruments are available. There is therefore a need for criteria that allow the correct choices to be made, typically in the form of an assessment of their relative costs and benefits.

For example, consider some regulatory options for limiting atmospheric carbon dioxide emissions. An extreme, but unlikely, approach would see production of renewable energy through a state monopoly and the banning of energy production from fossil fuels altogether. This approach would perhaps achieve the objective but would also have major associated costs. A less interventionist approach would be to use a carbon tax, which would require emitters to internalize the social price of carbon dioxide emissions. Another approach would be to introduce legislation requiring new power-generation plants to satisfy certain criteria in terms of their ability to limit emissions.

A complementary alternative would be to work collaboratively with the power-generation industry and other stakeholders to identify a set of standards that could help reduce carbon dioxide emissions in an efficient way. These could be referenced in regulations. In practice, the role of standards is to develop the requirements for the safety, energy efficiency, and general state-of-the-art performance of the equipment which will enable utilities to fulfil their statutory and regulatory obligations.

22 It should be noted that many developing country NSBs develop and implement technical regulations in the form of mandatory standards. This is often perceived to be in conflict with respect to its role of developing "voluntary" standards. To address this perception, an NSB should ideally remain responsible for the development of the standard on which the technical regulation should be based, and the subsequent regulatory functions should be managed by an agency that is independent of the NSB.

In the case of safeguarding public health, International Standards and TRs[23] play a key role in helping societies and consumers. In a recent example, during the COVID-19 pandemic, the appropriate use of International Standards by regulators around the world allowed them to move quickly and ensure that requirements were available for the procurement and widespread use of Personal Protective Equipment (PPE)[24]. Private companies were able to rely on a set of International Standards, enabling them to rapidly retool or upgrade production lines to deal with the sudden and urgent demand for PPE. The policy response to COVID-19 involved a broad group of actors working in tandem, including regulators with the responsibility for health products, public health authorities and disease control centres, health professionals, the private sector, and NSBs.

Box 4: The relation between TRs and standards in the context of the WTO TBT Agreement

The WTO TBT Agreement is an international treaty that defines the relation between voluntary standards and TRs. The relation and the increased use of voluntary standards is to a large extent based on the requirements in Article 2.4 in the WTO TBT Agreement. (Similar or the same requirements can also be found in many bilateral and regional trade agreements.)

Article 2.4 in the WTO TBT Agreement states "Where technical regulations are required and relevant International Standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such International Standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

The overall objective of Article 2.4 is to establish transparency between members through the use of International Standards as a common reference when establishing mandatory requirements on products. Using the same reference is a way to harmonize the effects of the national legislation to facilitate trade. The article includes different provisions that are of interest:

- The first concerns **who** decides when a technical regulation is *required*. This is the responsibility of the legislative branch of each country, i.e. those that adopt mandatory TRs.
- The second concerns *relevant International Standards*. **How** is this decided and **by whom**? This decision is made by the relevant legislator, supported by their NSB, based on the issues at hand including the extent that the use of standards or parts thereof can support the legislator in reaching their legitimate objective.
- The third is that a TR shall be *based on* a relevant International Standard. The understanding of this term is unclear as no ruling by the WTO Dispute Settlement System is available. Direct or indirect references to a relevant standard, or parts thereof, would infer that a TR is based on a standard. The question arises as to whether legislators in other countries would consider the relevance of the chosen standard in the same way. In spite of the consensus that standardizers have established for the particular International Standard, such a decision is completely in the hands of the various legislators.
- The fourth, and final, issue is an exemption included in Article 2.4 from basing TRs on International Standards. If a legislator decides that the available standards are ineffective or inappropriate, or that there are no relevant standards available to support them in reaching their legitimate objective, other means can be used.

23 For more information on the difference between regulations and technical regulations see Section 5.
24 See, for example, the Web article Standards for making PPE and other Medical Devices during COVID-19 at https://libguides.uvic.ca/StandardsforPPE.

5. Technical regulations and standards

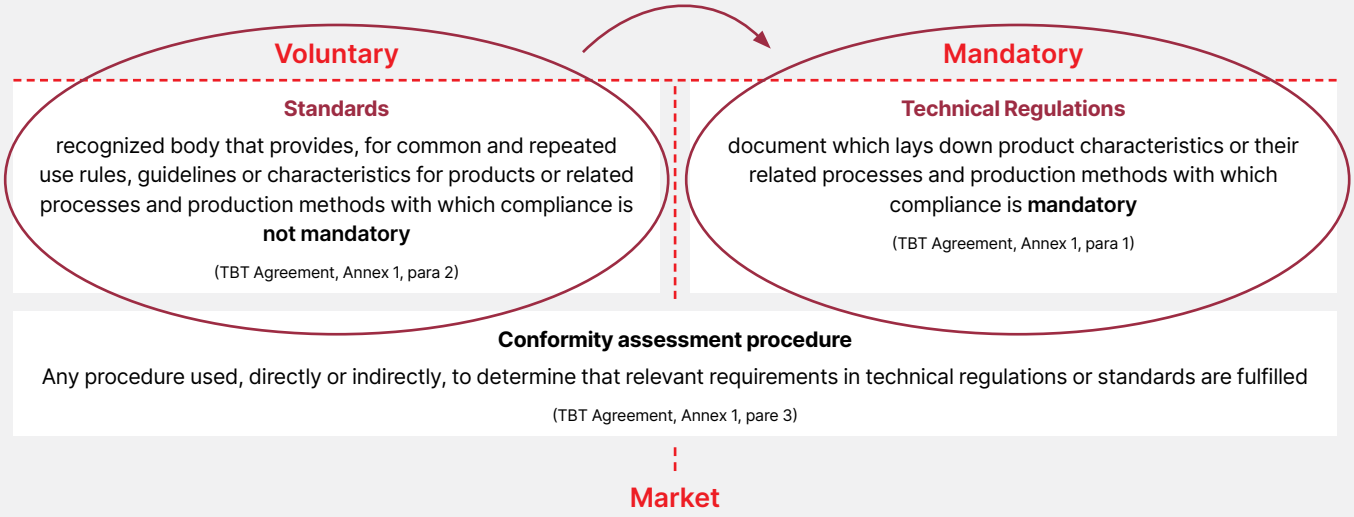
TRs are an important group of regulations relevant to standardization practice. The WTO defines a TR as a "document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory".

Like other regulations, TRs are prepared through a legislative process that is normally defined in a country's constitution or laws. A TR normally includes administrative provisions such as the accountability for the regulation and definition of the competent authority, guidance for the competent authority for interpretation of the regulation, the conformity assessment procedures to be used (i.e. inspection, testing, certification and validation) to demonstrate compliance with the regulation, enforcement mechanisms to be used, and sanctions to be applied in cases of non-compliance. Although sometimes confusing, the two terms, TR and standard, and the differences between them are further elaborated in Figure 2.

A NSB often drives some aspects of public policy, especially in countries where an integrated standardization approach has traditionally been adopted. In such cases they often develop standards that become mandatory, thus becoming by definition TRs. These standards are made mandatory either directly, under the legislation that established the NSB, or by a relevant ministry. Given the unintended restrictions to trade that such an approach often causes, many governments and NSBs recognize that there is a need for change. Where methods and procedures for preparing, adopting, applying and notifying TRs, in the context of the WTO TBT Agreement, either do not exist or are very weak, the use of International Standards together with tools such as RIA or good regulatory practices, can greatly assist them as part of undertaking such a change process.

The WTO TBT Agreement does, however, recognize that the use or full use of an International Standard may not be practicable. Fundamental climatic or geographical factors, economic or technological problems, are considered as legitimate reasons for not using International Standards. Every effort should also be made to reduce deviations to a minimum and such deviations should also be identified.

Figure 2: TRs and standards



6. Good regulatory practices

The Organisation for Economic Co-operation and Development (OECD)[25] describes good regulatory practices (GRP) as policies, tools, and institutions for ensuring that regulations are justified, of good quality and achieve policy objectives. GRP is also sometimes referred to as 'regulatory policy', 'regulatory reform' or 'regulatory quality'. The World Bank states that GRP is the:

> "systematic application of tools, institutions, and procedures that governments can mobilize to ensure that regulatory outcomes are effective, transparent, inclusive, and sustained. Adopting GRP can improve the regulatory environment and produce better conditions for sustainable growth and investment."[26]

GRP promotes the use of internationally recognized processes, systems and tools aimed at ensuring that regulatory outcomes are effective, efficient, transparent, inclusive and sustainable. One of the key recommendations of GRP is to use International Standards. Their use provides a harmonized, technical underpinning for regulations and helps to avoid or minimise technical barriers to trade. GRP promotes a risk-based approach. Two specific International Standards underpinning this are ISO 31000 (risk management – guidelines) and IEC 31010 (risk assessment techniques). Both of these standards can also be used in supporting RIA activities together with the many, more detailed, standards that are also often referred to in regulations. More information on RIA is provided in the next section.

The mandate of an NSB is to develop standards that are voluntary in nature. In some countries, these standards effectively become mandatory based on the institutional and legal framework under which the NSB operates. In developing countries NSBs are often part of government. In such scenarios, the NSB is often also required, and mandated, to perform regulatory activities. It is important to understand the fundamental differences between the development of TRs by applying[27] GRP versus the approach used for developing voluntary standards, namely those described in the ISO guide *Good Standardization Practices*[28] (GSP). Regulations aim to help achieve public-policy objectives, such as human health and safety or the protection of the environment. The development of a regulation normally considers inputs from various stakeholders but does not require their consensus for approval and promulgation. Best practice voluntary standards are developed using a consensus-based process involving all relevant interested parties. For more detail of GSP as applied by ISO please see section 9.3, paragraph 5.

GRP also provides for the periodic review and withdrawal of regulations which are no longer relevant or are unnecessarily costly and burdensome. No one is likely to question the rationale of protecting health, safety – or the environment. What matters is how countries use regulation and standards to pursue such policy goals. The steps[29] that need to be undertaken within a typical GRP initiative include harmonization towards International Standards and streamlining of conformity assessment procedures[30]. The adoption of and adherence to GRP helps governments to develop better regulations while also ensuring greater alignment with WTO principles and provisions.

25 The OECD has produced a series of instruments and documents on GRP. Examples can be found at: https://www.oecd.org/gov/regulatory-policy/recommendations-guidelines.htm.
26 World Bank 2019, see www.worldbank.org/en/country/malaysia/publication/regulatory-governance-for-development-and-growth-malaysias-experience-with-good-regulatory-practices.
27 For more information on the difference between regulations and technical regulations see Section 8.
28 See https://www.iso.org/publication/PUB100440.html.
29 See for example, OECD Recommendation of the Council on Regulatory Policy and Governance, 2012, pages 4 and 5, available at https://www.oecd.org/gov/regulatory-policy/49990817.pdf.
30 See OECD Guiding Principles for Regulatory Quality and Performance, Step 6, page 7, available at https://www.oecd.org/fr/reformereg/34976533.pdf.

The NSB should understand, and appropriately promote, the role of GRP as documented by the OECD, the World Bank and the WTO and the associated economic benefits. It may also be necessary for the NSB to take the initiative in encouraging the development or revision of a National Quality Policy (NQP)[31]. Such a policy usually encourages the referencing of standards in TRs, and the deployment of the respective good practices for both standards and TRs. Such an initiative supports and strengthens the environment within which NSBs work by ensuring that it is better aligned to the principles and best practices embedded in the WTO TBT Agreement.

The institutionalization and use of GRP within a country provides an important platform for developing a cohesive and mutually supportive regulatory framework. The subsequent application of such a framework helps ensure that regulatory interventions are developed and implemented in the same way across all spheres of government. It is important that the appropriate use of International Standards and the role of the NSB is also appropriately addressed in such a framework.

An example of a country adopting a more holistic approach to the oversight of TRs across government can be found in Korea. The Korean Agency for Technology and Standards (KATS), the ISO member in Korea under Ministry of Trade, Industry and Energy have been tasked by government to see where relevant laws include TRs. They are also required to inspect new TRs and assist in improving existing TRs of all agencies[32]. This responsibility includes the identification of areas where these TRs are different from International Standards.

In Canada, a Cabinet directive on regulation[33], emphasises the need for a whole-of-government approach in the development of regulations. It also specifically requires departments and agencies to take into consideration "the potential opportunities for incorporation by reference to internationally accepted standards"[34].

31 See UNIDO / International Network on Quality Infrastructure (INetQI), (2018). Quality Policy – Guiding Principles for more information, available at https://hub.unido.org/sites/default/files/publications/QP_GUIDING_PRINCIPLES_0.pdf.
32 See https://www.wto.org/english/tratop_e/tbt_e/th_sess_gpr_280317_e.htm.
33 See https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/cabinet-directive-regulation.html.
34 Ditto, paragraph 5.2.6.

7. Developing GRP

Regulators that operate under a dedicated legal mandate covering a particular area of activity may not be aware of the value of International Standards and the benefits of collaboration with their respective NSB. The NSB may need to dedicate time and resources to work with regulators to develop a deeper level of awareness on the value of using standards, including demonstrating how standards can assist them to achieve their regulatory objectives. This would also involve establishing dedicated collaboration and communication mechanisms with specific policymakers and regulators. Engaging initially with the more proactive regulators and ministries can often result in success stories that can then be used to convince those who are more sceptical. It is important that NSBs are aware of the responsibilities of policymakers and regulators and their key considerations when using or referencing standards to establish a fruitful partnership:

- Preparing and adopting policies and TRs, is the responsibility of policymakers and regulators. The NSB supports policymakers and regulators in identifying relevant International Standards when preparing and adopting policies and TRs.
- Deciding if the referenced standard will provide the only solution or be one of alternate solutions.
- Ensuring that the chosen standard is fit-for-purpose including the level and frequency of checks required to confirm its suitability for addressing policy or regulatory needs.
- Deciding how to reference the standard, directly or indirectly, the whole standard or only certain clauses or sub-clauses.
- Ensuring that ISO's and the NSB's copyright are respected as standards are not normally provided free of charge; and
- Updating the reference to the standard, to ensure that the policy or TR is kept up to date if the referenced standards are revised[35].

An example of close collaboration between NSBs and regulators is provided by the 'New Approach' to technical harmonization and standards policy, and the 'New Legislative Framework' that were adopted by the EU in 1985 and 2010 respectively. Under this EU approach, the directives prescribe only the essential requirements and administrative provisions needed to achieve the legitimate objectives being pursued. These are, among other things: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.

The task of drawing up the technical specifications required for the production, and placing on the market, of products conforming to these essential requirements, is entrusted to competent organizations in standardization (e.g. the European Committee for Standardization, CEN). The process also considers the current state of technology. The standards are not directly referenced in the directives but the relations between the standards and requirements in the directives is established through indirect referencing. This approach is fully aligned with the principles and requirements in the WTO TBT Agreement. Harmonized EU Standards are developed and used to support associated TRs. Public authorities are then required to recognize that all products manufactured, and services provided, in accordance with these harmonized standards, are presumed to conform to the essential requirements as defined by the relevant TRs.

35 Dated references give more control to the policymaker but can stifle innovation by the almost inevitable inertia due to the time between when a standard is revised and when the relevant regulations are updated. Undated references mean that the latest version of the standard is always considered to be the relevant one, with no changes required to the regulation. This usually only happens once legislators have the necessary involvement and confidence in the standards-development process.

Figure 3: Steps for considering the need for regulation

1. **Whole of government.** The development of regulation is best when done in a cooperative and coordinated manner throughout the whole government. Attribution of roles and responsibilities is important.
2. **Problem identification.** Regulation must address a problem – current or future (a market failure), and it needs to pursue a legitimate objective.
3. **Should the government act, and what's the right tool?** Once the problem has been identified, a further consideration will be whether government action is necessary in the first place. This also means considering the option of not intervening at all.
4. **Early notice.** Assuming regulation is appropriate and necessary, it is useful for stakeholders, including the NSB, and others at home and abroad, to be alerted about any anticipated activity.
5. **Design.** A subsequent step will be the design and development of the regulation itself. An important step in developing a regulation is to identify alternatives, including the use of International Standards, and then to compare these across a range of criteria. This will help ensure that the regulation is "fit for purpose". This can be done, for example, with a RIA.[36]
6. **Basis.** Regulations should be based on relevant International Standards whenever possible. It is important not to reinvent the wheel.
7. **Transparency and consultation**. Openness and accountability should be inherent in the making of the regulation. Automatic triggers aimed at engaging all relevant stakeholders should be built into the process.
8. **Decision.** At some point a decision needs to be taken; this means that one alternative is chosen over another. This decision can be taken, for instance, by a regulator or other body vested with authority. While it is not necessarily a consensus decision, it needs to be an informed one.
9. **Publication, reasonable interval, guidance and enforcement.** Once the measure has been finalized and adopted, it should be published together with the rationale and any assessments made (e.g. RIA). This can be done, for example, in an official gazette or public website. It is advisable to also notify the final text to the WTO.
10. **Monitoring and review.** Regulations shouldn't sit on the shelf gathering dust. It is important that the stock of regulation is monitored and regularly reviewed (for example through ex-post RIAs) for its continued fitness.

36 Regulatory impact assessment (RIA) (also called regulatory impact analysis) is a systematic process to assess likely benefits and costs arising from regulatory or non-regulatory alternatives for achieving a policy objective. It may be based on cost-benefit analysis and may consider quantitative and qualitative aspects.

8. Regulatory impact assessments

One element of GRP is the use of RIAs when necessary[37]. When an in-depth review is required, a RIA provides a systematic tool for assessing positive and negative effects of proposed and existing regulations. It promotes the use of a structured exploration of different options to address particular government policy issues or programs. The resultant analysis is then used to determine which of the different options would deliver the desired impact. The process assists policymakers and regulators in identifying any possible unintended consequences such as hidden costs or unexpected benefits. The scope of a RIA needs to be adapted to the nature of the law or regulation in question, and the anticipated consequences and effects the law or regulation is intended to achieve.

The use of a RIA provides a framework for gathering pertinent information that assists both policymakers and those in government who are responsible for approving subsequent recommendations. A RIA helps quantify, for a particular issue, the associated costs of compliance for businesses or citizens of potential alternatives. The same exercise also provides government officials with important insights into the potential costs of any associated enforcement activities they would be responsible for managing.

An important part of a best practice RIA is the careful consideration of alternatives. Analysing just one possible approach cannot provide an answer to the question of whether the public-policy objective could be achieved in a more beneficial manner. RIAs should be used to consider a range of possible interventions, including not intervening at all, as part of identifying the most effective and lowest cost alternative among the feasible options. A number of countries[38], including middle-income countries, now use different types of RIAs as part of their regulatory process.

37 For more information see https://www.oecd.org/gov/regulatory-policy/regulatory-impact-assessment-7a9638cb-en.htm.
38 Various country level examples can be found at https://www.oecd.org/regreform/regulatory-policy/ria.htm .

It is important to stress to policymakers that any RIA initiative should also actively consider the use of national, regional or International Standards when identifying and evaluating the alternatives including the potential need for a regulatory intervention. The associated CA needs, covered in more detail in Section 10, could also be addressed more cost effectively if such standards are referenced and used.

The NQI and associated regulatory framework (including various laws and regulations, sectors and different product areas developed over the years), have to some extent managed to serve their interests in the past. The NQI in many countries have developed in an organic way due to the absence of an appropriate and overarching government policy framework. Over time such an uncoordinated approach has become entrenched and can often lead to unintentional restrictions that hinder rather than support further development. A RIA can also be a very useful tool for evaluating the policies and associated regulations that direct and mandate the activities of the NQI of which the NSB is usually an important component. Such an exercise can help identify and address any unintentional restrictions to further NQI development in both the public and private sectors. The information gathered can also help ensure that future strengthening and expansion of the NQI enables it to better address health, safety and environmental challenges, and allows it to provide even more relevant support to companies seeking to obtain even greater benefits from their participation in the global marketplace.

Box 5: Regulatory impact assessment

An important component of GRP is the decision-making process used for developing regulations. Such a process should include inter alia the following steps:

1. Define the problem
2. Set down the policy objectives and policy goals
3. Ensure its relevance with government policy
4. Engage consultation with stakeholders
5. Describe the regulatory proposal
6. Identify the alternatives available
7. Conduct cost benefit analysis
8. Identify the preferred solutions
9. Set out the monitoring and evaluation mechanisms.

9. Standards in support of public policy and regulation

9.1 What are standards?

In order to discuss the role that standards can play in support of public policy and regulation; it is important that we begin with a shared understanding of what standards are. A standard should be considered as a formula or document that describes the best way of doing something. It could be about making a product, managing a process, delivering a service or supplying materials – standards cover a huge range of activities.

Standards are used to establish a best practice approach for achieving a desired outcome. The agreed methodology can then subsequently be used as part of ensuring consistent results, for example, in manufacturing a product, managing a process or delivering a service.

9.2 How do standards promote economic growth?

All economies need growth that is sustainable and inclusive. The SDGs speak of international trade being "an engine" for growth and poverty reduction. However, trade is not an end itself. The quality of economic growth, including the increase in benefits for all of society and minimising negative impacts on the environment, is also essential. Standards can play an important role because they often provide readily available best practices, and tools, for addressing aspects needed to underpin the quality of growth. They can also simultaneously contribute to the achievement of the SDGs[39]. The benefit of internationally-agreed standards is that they contain a built-in legitimacy. They are based on collaboration – between the NSBs of countries and their respective stakeholders – and are founded on consensus. As such, they provide essential guidance for government, industry, and consumers alike, and help societies move their development trajectory towards more sustainable and inclusive growth.

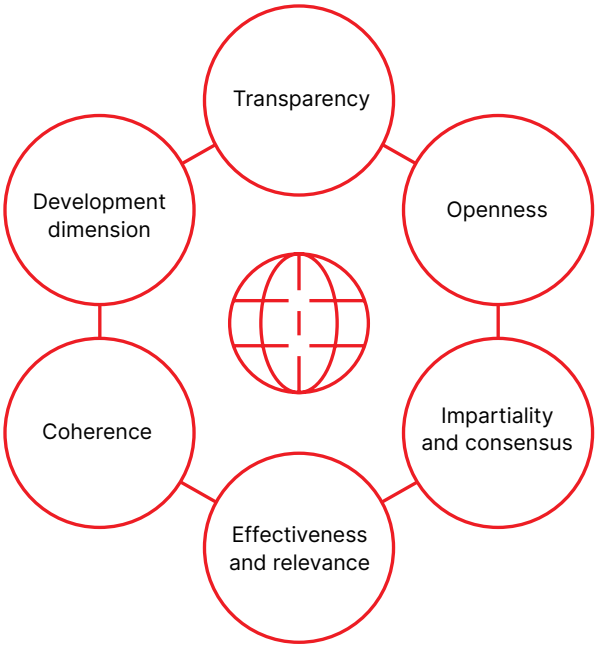
Standards help spread knowledge. Although sometimes difficult to measure, knowledge transfer is an essential component for economic growth. A Canadian study[40] shows that the growth in the stock of standards contributes positively to productivity and total real gross domestic product (GDP) growth. Similarly, a UK study[41] from 2022 concluded that 23% of the United Kingdom's GDP growth during the past 100 years can be attributed to the impact of standards and 38% of all productivity growth.

In 2010, ISO led a study to quantify the microeconomic benefits of standards, more specifically the economic contribution the use of standards makes to company profits. The study covered around 30 companies and over 20 countries across the globe using the ISO methodology. The study revealed that the contribution of standards to the gross profit of companies ranged from 0.15 % to 5 % of the annual sales revenue.

39 See UNIDO (2019). Rebooting Quality infrastructure for a Sustainable Future. https://sdghub.com/project/rebooting-quality-infrastructure-for-a-sustainable-future/.
40 See Standards Council of Canada (2015), Getting Aligned. How Adopting Standards Affects Canada's Productivity and Growth, Conference Board of Canada. p.16. For more detail, see here https://www.scc.ca/en/about-scc/publications/general/getting-aligned-how-adopting-standards-affects-canadas-productivity-and-growth.
41 Available at https://www.bsigroup.com/globalassets/documents/about-bsi/nsb/cebr/bsi-uk-final-report-1.2-apr22.pdf.

9.3 How are International Standards developed?

The WTO TBT Committee has agreed on a set of *Six Principles for the Development of International Standards, Guides and Recommendations*[42]. These principles are:



These principles were agreed with a view to guiding international standardization bodies for developing International Standards. They are intended to ensure that International Standards strengthen and support global trade. Significantly, the additional guidance provided by the committee is also inspiring similar work outside of the ambit of the WTO. For example, up to a quarter of 260 Regional Trade Agreements (RTAs) in force have made these six principles mandatory, by making them applicable to RTA Parties.

ISO standards are developed by applying the WTO TBT principles using a robust consensus-driven process of international standardization in which involvement is open to NSB representatives from all 169 member countries (August 2023). NSBs are at the core of the international standardization process and play an important role in representing national interests at the international level. ISO standards[43] contain the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent such as industry and commerce, government, consumers, labour, academic and research bodies, organizations primarily devoted to promoting or assessing the use of standards and NGOs. Each NSB has the opportunity to contribute to the development of ISO standards and is strongly encouraged to do so such that their challenges are reflected and to encourage the formal adoption of the International Standard as the national standard to facilitate trade. This being said, NSBs retain the right to develop and publish their own independent national standards.

NSBs also have an important role to play in regional standardization activities. Regional standards are produced through a process of regional standardization where involvement is open to relevant bodies from countries from only one geographical, political or economic area of the world. As a result of NSBs' participation in international and regional standardization activities, they can be conduits for the transfer of global best practice into the economy and are uniquely positioned to support their governments to use standards and international standardization processes as an additional tool to achieve policy objectives.

ISO has also developed a guide, *Good Standardization Practices*[44], to assist members in implementing GSP. GSP incorporates three additional principles to those specified in the WTO TBT Agreement, namely stakeholder engagement, due process, and national adoption. The last principle is particularly important. National adoption is one of the keys in the use of International Standards to reduce TBTs. A summary of ISO's strengths in meeting the principles of standards development is contained in Box 6.

Note: Numerous bodies have been established to develop and publish International Stand-ards. The value of ISO standards, like those of the IEC and International Telecommunications Union (ITU), are that they reflect the principles listed above and meet the principles of the WTO TBT Agreement.

42 See https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm.
43 https://www.iso.org/standards.html
44 Available at https://www.iso.org/publication/PUB100440.html.

Box 6: ISO's strengths in meeting the principles of standards development

International Standards should be:

- **Developed in response to a need in the market:** ISO does not decide when to develop a new standard but responds to a request from industry or other stakeholders such as regulators or consumer groups. Typically, a sector or group communicates the need for a standard to its national member (NSB) who then contacts ISO with a request to initiate the process.
- **Based on global expert opinion:** ISO standards are drafted by groups of experts from all over the world, nominated by their NSB or by a relevant liaison organization, who contribute to the work of specific TCs. These experts discuss and agree all aspects of the standard, including its scope, key definitions, and content, before submitting the draft for comment and ballot in a multi-stakeholder consensus-building process at the TC level.
- **Developed through a multi-stakeholder process:** TCs are made up of experts in the specific discipline that is under consideration, nominated by their respective NSBs or by relevant liaison organizations. They typically include participants from industry, government, consumer associations, academia, and NGOs, depending on the specific focus of the standard that is being developed.
- **Based on consensus:** ISO's standards-development process incorporates a double-layer of consensus – among experts from market players at the drafting stages, and among countries (via their NSBs) at the formal commenting and voting stages prior to publication.

9.4 How can standards be used in support of public policy?

Public policymakers at the national level have many options to choose from when looking for a solution to a particular domestic issue. They could develop their own guidance in-house, which can then be referenced in a subsequent policy. Such an option can be expensive in terms of the time, money and expertise required. It may also inadvertently create trade barriers. The use of unique country-specific solutions could effectively restrict access by suppliers from other countries to its domestic market. Policymakers could also choose to make use of existing voluntary standards, especially when these are based on an International Standard developed in line with the six WTO TBT principles. The ISO and IEC guidelines on the incorporation by reference of standards within legislative text are useful tools in this regard[45].

The principles for developing ISO and IEC standards related to or supporting public-policy initiatives[46] address important dynamics confronting the ISO community – the relationship between ISO standards and public policy as well as the unique needs and concerns of one major class of ISO standards users, namely, governments. It is important that ISO and the IEC make their portfolio of standards more visible to public authorities and, equally important, ensure that their standards address the relevant needs and concerns of public authorities. This will support their global relevance and applicability worldwide, as it has been shown that ISO and IEC standards are capable of providing valuable support to the implementation of public policy. ISO and the IEC are effective providers of voluntary standards that support the programmes of government authorities, who need standards that meet the WTO TBT criteria and that support TRs and/or procurement actions.

45 See Using and referencing ISO and IEC standards to support public policy, available at https://www.iso.org/publication/PUB100358.html and ISO/CASCO Conformity Assessment tools to support public policy at https://casco.iso.org/home.html.
46 See https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100359.pdf.

When ISO or IEC standards are anticipated to support a public-policy initiative, the relationship between the standard and the public-policy initiative should be clearly understood among all concerned parties. The interaction of standardization and public policy or regulation should be anticipated and the intervention of the public authorities in the standards-development process should occur as early as possible. It should be noted that in many cases, experts representing regulatory authorities are actively participating in the development of ISO and IEC standards both as members of the relevant international committees and/or at the pertinent national mirror committees to ISO and IEC technical bodies. The following four principles have been established to guide ISO and IEC committees developing standards related to or supporting public-policy initiatives. These principles align with those of the WTO, guide the relations between standardizers and the legislative arms of countries and ensure that ISO and IEC standards can properly support and be used by public authorities. The four principles are:

1. ISO and IEC are committed to creating market-driven International Standards, based on objective information and knowledge on which there is global consensus, and not on subjective judgments, in order to provide credible technical tools that can support the implementation of regulation and public-policy initiatives;
2. ISO and IEC are committed to developing International Standards that are market relevant, meeting the needs and concerns of all relevant stakeholders including public authorities where appropriate, without seeking to establish, drive or motivate public policy, regulations, or social and political agendas;
3. ISO and IEC recognize that the development of regulation, public policy and/or the development and interpretation of international treaties are the role of governments or treaty organizations; and
4. ISO and IEC standards supporting regulation, regulatory cooperation and public policy are best developed within ISO and IEC structures and under operational approaches and participation models that have been proven successful and that are detailed in the ISO/IEC Directives.

The WTO emphasises the voluntary nature of a standard[47] noting that it is a "document…with which *compliance is not mandatory*" (emphasis added). The use of existing standards as an option could save policymakers considerable time and money in achieving a widely agreed solution to a particular issue. In this scenario, the potential risk of generating one or more technical barriers to trade is also greatly reduced.

When people think about standards and public policy, they often think first and foremost about standards being used or referenced in TRs (i.e. supporting a legislative action). This is indeed one of the main ways that standards are used by policymakers, but it is not the only one. There is ordinarily no legal obligation to follow a standard. Standards are voluntary in the sense that producers are free to conform with them, or not. The exception to this is when legalisation and similar instruments specify certain standards, such as for specialized products used within a sector governed by legislation.

Governments often differ in their attitude to regulation. Some will intervene heavily in markets, while others will be more willing to initially rely on market forces. Attitudes to risk also vary. Some governments act on scientific evidence, while others may take a more precautionary approach in the absence of full information. Whatever approach is adopted, standards have proven to be excellent vehicles to consolidate and promote good practices in all aspects of society. By pooling knowledge (and especially innovatory knowledge, once it has become widely accepted), the consensus-based standards-development process represents an effective means of collating, promoting, and disseminating know-how and methods to support public policies in general.

47 See https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm.

Many countries are using standards in support of their public-policy activities. Examples are:

- Malaysia encourages public and private entities to adopt various management system standards, including: ISO 9001 (quality management systems); ISO/IEC 27001 (information security management systems); ISO 22301 (business continuity management systems) for network channel interface (NCI) and Cloud service providers; ISO 45000 series of standards on occupational health and safety management systems, and; ISO 37001 (anti-bribery management systems) to support regulation aimed at addressing this issue.
- In Trinidad and Tobago, the Ministry of Trade and Industry has conducted awareness campaigns to highlight the country's consumer protection policies based on product standards and good manufacturing practices for the food industry. Incentives have also been developed for the tourism industry together with a voluntary tourism certification scheme.
- Canada's regulatory road map supports regulatory modernization and considers the role of International Standards in support of regulatory cooperation[48]. The use of certification to the ISO 9001 series of quality management standards is also used to support quality initiatives in public procurement.
- Morocco uses national and other standards applicable in Morocco under international agreements, in the majority of their specifications for public contracts. Product certification based on ISO/IEC 17065 is also used in support of public procurement activities. In the area of energy management, mandatory energy audits based on the ISO 50000 series of standards have been introduced.
- The Botswana Tourism Organization uses standards to support its tourism marketing and promotion strategies, specifically by the grading and classification of tourist accommodation facilities.
- Germany has introduced tax rebates and subsidies for companies that implement the ISO 50001 standard for energy management systems.
- Colombia is developing TR based on standards for safety, interoperability, charging infrastructure and components to promote the use of electric vehicles as part of their commitment to reduce greenhouse gas emissions by 20% by 2030. There are also government campaigns to support/reactivate the economy through the development of voluntary standards for sustainable tourism.
- The National Technical Regulations Act of 2017 in Zambia includes provision for the use of standards in TR in Zambia.

The use of existing voluntary standards by policymakers and/or regulators has several advantages. Only part of the existing voluntary standard may be sufficient for the purpose of the regulations to achieve the policy objectives. Even in such cases, the use of standards ensure a high degree of technical expertise. Whenever voluntary standards cover a wide range of aspects which may not be the intention of policymakers and regulations to regulate, the latter have, therefore, to choose and include only those essential requirements to achieve the objectives.

48 See https://tc.canada.ca/en/corporate-services/acts-regulations/international-standards-targeted-regulatory-review-regulatory-roadmap.

10. Conformity assessment

The WTO TBT Agreement also has provisions that address conformity assessment (CA). These procedures are used to determine whether products fulfil specified requirements including those in TRs or standards. CA is the term given to techniques and activities that ensure a product, process, person, organization etc, or any combination thereof, fulfils specified requirements. It matters as it gives confidence and assurance. It can be used on a voluntary or regulatory (mandatory) basis. Regulators use CA to help them implement public-policy objectives, including TRs, to confirm compliance and take corrective actions where necessary. When designed and used appropriately, mandatory CA requirements can enable efficient market operation and access, and protect health, safety and the environment. By relying on CA in accordance with International Standards, regulators and the market can be assured that statements of conformity are well-founded and legitimate. This also assists in avoiding regulation that may add unnecessary costs to the economy and reduce competitiveness of domestic production, and that may be substantially different to those in other economies which can lead to technical barriers to trade.

Figure 4: Scope of the WTO TBT Agreement

Technical regulations

- Lay down **product characteristics** or their related **processes** and **production methods**.
- Compliance is **mandatory**.
- May deal with terminology, symbols, packaging, marking and labelling requirements.

Standards

- Are **approved by a recognized body** which is responsible for establishing rules, guidelines or characteristics for products or related processes and production methods.
- Compliance is **not mandatory**.
- May also deal with terminology, symbols, packaging, marking and labelling requirements.

Conformity assessment procedures

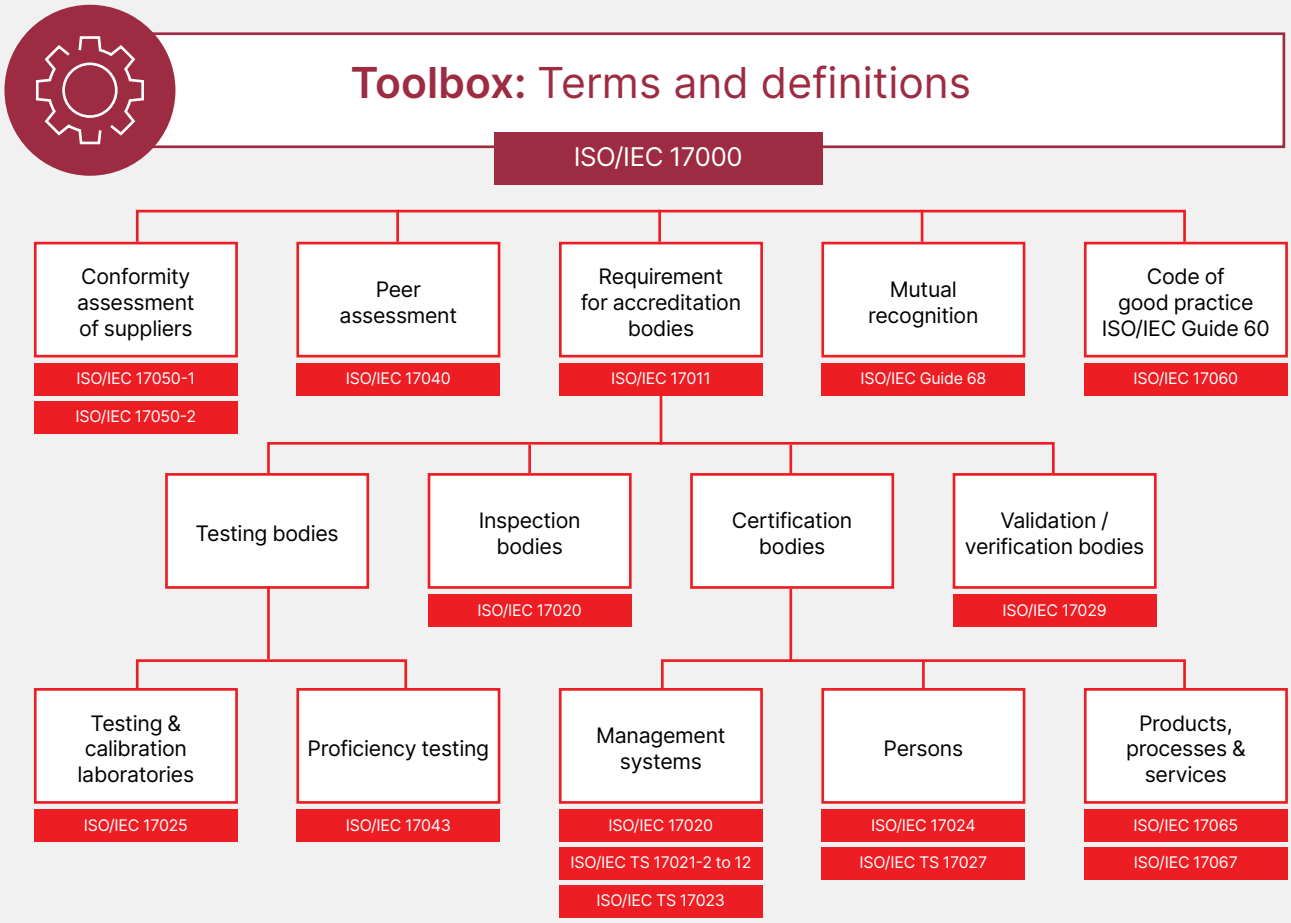
- Used to determine that **relevant requirements** in TR or standards **are fulfilled**.
- They include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; and registration, accreditation and approval.

Regulators normally require conformity to be demonstrated prior to regulated products being placed on the market. However, CA requirements should not restrict trade, inhibit innovation or negatively impact on competitiveness. In addition, CA procedures and administrative procedures should be commensurate with the risks associated with non-compliance. Less stringent conformity[49] requirements should be required if the risk is low. Regulators need to ensure that their compliance[50] requirements help achieve the policy objectives at the least burden for suppliers and users. Regulators could also rely on accredited CA bodies to provide testing and certification of regulated products. In the WTO TBT Agreement, Members are obliged to use international guides and recommendations as a basis for their CA procedures to be used within the framework of TRs, subject to the exceptions listed in the Agreement.

There is a set of International Standards published by the ISO Committee on Conformity Assessment (ISO/CASCO) related to CA[51]. These standards cover the activities of test laboratories, inspection bodies and certification bodies and ensure a common basis for the evaluation. They provide a common foundation by defining (among other things), validation of test methods, determination of acceptance criteria, choice of sampling methodologies, and personnel competence criteria. As with using International Standards as the basis for developing TRs, there is also a need for NSBs to engage with regulators to encourage their use of the ISO/CASCO standards to ensure

49 Conformity is normally used in the context of (voluntary) standards
50 Compliance is normally used in the context of mandatory requirements such as those mentioned in regulations
51 See https://www.iso.org/committee/54998/x/catalogue/p/1/u/0/w/0/d/0.

Figure 5: ISO/CASCO's toolbox of CA standards



conformity with TR. ISO/CASCO's suite of CA standards, the ISO/CASCO toolbox as shown in Figure 4, collectively provide confidence in the various forms of CA that are used to support public policymakers and regulators.

NSBs should emphasise to policymakers and regulators that the use of the standards in the ISO/CASCO Toolbox[52] provides confidence in CA activities, whether these are related to trade promotion and facilitation or to demonstrate compliance to social and/or environmental policy-related requirements. ISO and the United Nations Industrial Development Organization (UNIDO) have published a comprehensive, user-friendly publication *Building Trust – The Conformity Assessment Toolbox*[53] that covers all aspects of CA and its role in international trade, that can be useful for NSB interactions with regulators[54].

CA procedures for testing, sampling, inspection, and certification of products and services provide consumers and regulators with increased confidence in the integrity, safety and trustworthiness of products and services. The use of a competent CA body (CAB) identified through them being accredited by an internationally recognized accreditation body (AB), adds value to manufacturers' marketing claims, and, ultimately, to the products themselves.

CABs may be public or private entities that provide services such as testing, inspection, validation and verification, and certification of products, processes, people, or management systems. Some CABs operate internationally while others operate locally, sometimes in collaboration with international partners. ISO's CA standards are also highly relevant in the context of the SDGs and sustainability more generally. They offer the tools to demonstrate that the specifications of sustainability-related TRs and standards are met, and thereby provide trust and confidence to regulators and the market[55].

52 Full details can be found at https://casco.iso.org/toolbox.html.
53 See https://www.iso.org/publication/PUB100230.html.
54 ISO - Building trust - The Conformity Assessment Toolbox
55 Examples on the use of CA to support public policy can be found at: https://casco.iso.org/examples.html

11. Engaging with policymakers and regulators

The international trade regime established by the WTO agreements requires that certain rules and principles are followed. These include non-discrimination, trade liberalisation, transparency, predictability, and fair competition. The obligation of members of the WTO to follow the rules and principles embedded in their agreements requires that the NQI is also appropriately aligned with these rules and principles. A modern, well-functioning and fit-for-purpose NQI is often required for a country to benefit from international trade more fully. Many countries however lack the necessary infrastructure to meet the quality standards for entering global markets. Participation in world trade increasingly requires that suppliers comply with standards, TRs, and sanitary and phytosanitary measures[56]. The necessary alignment of the NQI is increasingly achieved through the preparation and adoption of a National Quality Policy (NQP) within which the roles and responsibilities of all stakeholders and interested parties, both public and private, are defined. The NQP also provides the framework for the necessary legislation to be developed and adopted. The roles and responsibilities of each component of the NQI are established, including those of the NSB and the support they often provide to legislators.

Many NSBs in developing countries are governmental institutions or organizations of public law (i.e. statutory bodies). Their roles and responsibilities are often defined in a 'Standards Act'. These institutions are most commonly multi-disciplinary covering areas such as preparing and adopting standards; providing CA services such as testing, inspections and certification; in some cases, providing consultancies and training; and in other examples, functioning as regulatory authorities when ensuring compliance with mandatory standards. Although the standards are in principle voluntary, some are made mandatory through provisions in the Standards Act or in some cases through referencing in TRs. The NSBs therefore play a central role in influencing the national markets in many developing countries and therefore there is a well-established relation between the NSBs, and ministries and regulatory authorities. It is common that the legislator and regulators see the NSBs as an important player in setting the requirements governing the marketability of products on the national markets.

In some countries, obtaining political buy-in for standards development can be challenging. Many within government still do not understand the relevance and importance of a well-functioning NQI, including voluntary standards, in supporting public policy and regulation. The role of International Standards in the context of trade facilitation is also often misunderstood. The role is often less understood in new and emerging policy areas such as cybersecurity, data, AI and sustainability. Policymakers and regulators believe that the development of standards should start with a national focus that is aligned with the national context and priorities. This is of course the correct approach. NSBs should emphasise that, rather than wasting resources by re-inventing the wheel, they could capitalize on the available International Standards and adopt or adapt these for use within the national context to fulfil the legitimate objectives pursued. An important initiative in this respect is the development and implementation of a national standardization strategy (NSS).

56 See, for example, page 3 in the document World Bank (2019), Ensuring Quality to Gain Access to Global Markets - A Reform Toolkit, available at https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf.

Box 7: Examples of collaboration mechanisms between NSBs and policymakers/regulators

Bosnia and Herzegovina: At the invitation of the regulatory body, representatives of the Institute for Standardization of Bosnia and Herzegovina (ISBIH) participate in working groups that prepare TRs, applying their knowledge on standardization.

Jamaica: Under the auspices of the Ministry of Industry, Investment and Commerce (MIIC), a Technical Regulations Unit was established and operationalized within the Bureau of Standards Jamaica (BSJ). The main mandate of the Unit is to advance the work of utilizing technical regulations as opposed to compulsory standards in support of the National Quality Policy (NQP) and the National Quality Infrastructure (NQI). This also includes the transition of compulsory standards to TRs.

Mongolia: Representatives of ministries and agencies are appointed as full or observer members of technical committees on standardization.

Trinidad and Tobago: Trinidad & Tobago Bureau of Standards (TTBS) has formal MOUs with established regulators such as the Environmental Management Authority and the Occupational Health and Safety Agency.

Uganda: Various regulators develop their regulations based on, or referencing, the national standards. In some cases, cooperation is further strengthened through the establishment and implementation of MoU's with respective regulatory bodies.

Zambia: The NQI is defined through the implementation of four laws: The National Technical Regulations Act, The Metrology Act, The Standards Act and the law on Zambia Compulsory Standards Agency. The collaboration between these institutions and ministries is governed by these laws.

South Africa. The Department of Trade, Industry and Competition (the dtic) oversees the legislative work, policy and governance oversight of South Africa's Quality Infrastructure institutions. South Africa's NQI is a system of setting requirements and demonstrating that these requirements are complied with in order to build confidence in the economy. The national system is composed of four public entities, namely: South African Bureau of Standards (SABS), the National Regulator for Compulsory Specifications (NRCS), the South African National Accreditation System (SANAS); and the National Metrology Institute of South Africa (NMISA).

When developing a NSS, the NSB determines the needs of the various stakeholders related to standards. Such a determination process should include engagement with public policymakers so that the NSS also reflects their ongoing needs. Appropriate engagement, as opposed to communication, throughout the NSS process with stakeholder representatives is crucial. Such engagement should build trust and help clarify the actual standardization needs of the different stakeholder groups. It should also be used to determine if International Standards are available, and applicable, in addressing a particular need. NSBs should emphasise that such an approach supports the harmonization of technical regulation between WTO Members. It is therefore one of the main reasons why the WTO TBT Agreement encourages members to participate in International Standards development. This helps ensure that they are able to express their needs, within their particular developmental context, and are provided with the opportunity to influence an International Standard to ensure that it is relevant for their situation.

ISO has published a methodology for developing NSSs which focuses on socio-economic analysis but more importantly it emphasises stakeholder outreach, engagement and consultation. The NSS therefore also provides an effective mechanism for NSBs to forge partnerships and deepen relationships with policymakers, regulators and other stakeholders. The NSBs need not only to support policymakers and regulators in their use of standards for regulated functions but also provide the necessary guidance and support regarding the CA procedures that would be required.

For NSBs to be invited to engage with and support regulators as important role players, they must have the necessary legal basis, or a level of authority, assigned by government to fulfil such a role. Such recognition is crucial for getting regulators to engage with them, especially if they have to use standards in their TRs and need to work with or through the NSB. It has been observed that without this recognition from the government, at the operational level, regulators tend not to cooperate or refer to standards in their work. The role of NSBs therefore needs to be clearly defined, typically as part of a NQP, to facilitate the development of standards. Sound engagement also relies on NSBs being able to speak the language of policymakers and regulators to successfully convince them to use International Standards as an additional policy tool to achieve their policy objectives. As part of supporting their members in addressing policy issues, ISO plans to provide policy briefs. These will be focused on key and emerging policy issues with linkages to the important role that standardization can play in helping to address them. The ISO policy briefs are aimed at supporting member NSBs to proactively reach out to policymakers and regulators with appropriate advice, guidance and potential solutions.

A key principle of both good policy-making and GSP, namely transparency, requires that the content of legislation and regulations, which may include references to standards, should be easily accessible. Being easily accessible, however, does not imply that standards should be made freely available. Under the ISO business model, the sale of standards plays an important role in ensuring that the system is fairly financed. The user who benefits from using a standard is required to pay. This model of financing keeps participation costs down, allows for the broadest possible stakeholder participation and, ensures that ISO International Standards are developed in a neutral environment without undue influence from individual sponsors.

Section 2

A step-by-step guide for effective engagement between NSBs and public-policymakers

12. Overview

This part of the document aims to provide NSBs with a path towards better collaboration with policymakers and regulators in their country and/or region. When explaining to governments and the public the potential contribution of standards to public policy, NSBs need to emphasise that their contribution far exceeds that normally associated with international trade and correcting market deficiencies.

Within the context of NSBs interacting with policymakers, there are three hierarchical levels in the standards-development process that are relevant:

NSBs are at the core of the standards process. Although every NSB has the opportunity to contribute to the development of International Standards, they also retain the right to develop and publish their own independent national standards. The preferred option, as encouraged by the WTO, is for the NSB to participate actively in the consensus-building process at the international level. Such participation makes it easier for them to formally adopt the International Standard unchanged[57], as the national standard. In some examples, they may also adapt the International Standard with proper justification so as to still meet the six principles of the WTO, while not always using the reference number of the International Standard.

Regional and sub-regional standards bodies including:

- The European Committee for Standardization (CEN)
- The Pacific Area Standards Congress (PASC)
- The African Organisation for Standardization (ARSO)
- The Pan American Standards Commission (COPANT)
- The Caribbean Community (CARICOM) Regional Organisation for Standards and Quality (CROSQ)
- The ASEAN Consultative Committee for Standards and Quality (ACCSQ)
- The Southern African Development Community (SADC) cooperation in Standardisation (SADCSTAN)

Some of these regional organizations develop standards in their own right, with the involvement of their member NSBs, or they may formally adopt International Standards and publish them as regional standards.

57 It should be noted that many new NSBs will initially be 'standards takers' in that these bodies adopt standards. Sometimes standards are also adopted by countries that did not participate in the development process for legitimate reasons such as lack of suitable experts. The NSB standards-adoption process usually allows for modifications, including cases where country representatives did not participate in the development of a standard, but there is a need adopt the standard anyway. NSBs could, after due consideration of the national context, modify provisions in such cases if this is deemed necessary and appropriate.

International Standards bodies: The three best-known global standardization entities are the IEC, ISO, and the ITU who, under the umbrella of the World Standards Cooperation (WSC), work together to advance and strengthen the voluntary consensus-based International Standards system.

The guidance that follows is a process-based, step-by-step approach building on experiences obtained in different countries (each with their own specific context). In addition to answering the question of "what" to do, the text guides the reader through the practicalities of the "why", "who" and "how" of each step. For each step, some of the challenges that are likely to be encountered are mentioned, together with ways to overcome or mitigate them.

It is recognized that most NSBs already have some form of relationship with policymakers, ministries and other governmental authorities. Such relationships are normally based on the cooperation derived from the role that some NSBs have traditionally played at the core of the NQI. The key objective is to ensure that the NSB and the relevant policymakers and regulatory institutions understand and play their respective roles, within the context of GRP. This section of the document therefore is intended to be used by NSBs to enhance collaboration in a way that is participative, sustainable and mutually supportive. Although there is no universal template that can be used, the steps that need to be undertaken in order to develop and implement a sustainable collaboration between NSBs, policymakers and regulators are typically very similar.

As will be seen, the process is divided into five key stages, as follows:

1. **Stage 1** – Understand the national context — Understand who are the relevant players in terms of policy-making and the development of TRs; what are the key policy objectives and what are the relative priorities
2. **Stage 2** – Conduct a gap analysis – Understand where there is a need for greater collaboration between the NSB and policymakers and regulators
3. **Stage 3** – Build and/or strengthen bridges between the NSB and policymakers and regulators – Establish mutual trust and a common sense of purpose and collaboration
4. **Stage 4** – Establish action plans for future NSB collaboration with policymakers and regulators – Develop prioritized and budgeted long-term and short-term plans
5. **Stage 5** – Implement, monitor and evaluate the plan – Ensure effective and sustainable implementation

Each stage is then sub-divided into clearly identifiable steps, as shown in Table 1 that follows.

Table 1: Five-stage approach for effective NSB engagement with policymakers and regulators

Key stages	Detailed steps	Objective/Output	Level
1. Understand the national context		Clear view of **who** are the players; **what** are the key policy objectives; **what** are the relative priorities (**when**)	Strategic, management and process
	1. Identify key government policy areas, structure and departments.	A clear understanding about government policy priorities, and of the various actors within government with whom the NSB needs to communicate and potentially collaborate, to support the achievement of these policies.	Management
	2. Identify current roles and responsibilities of key stakeholders.	Understanding of the stakeholders who have an interest and role to play in policy-making and the regulatory landscape; their roles, responsibilities and potential interactions with the NSB.	Management
	3. Verify linkages with NQP (if any) and other QI institutions.	Confirmation of the formal basis for the NQI (including existing legislation and the NQP, should this exist). Understanding of the relationships and key interactions of the NSB within the NQI, the need to establish formal links with other institutions and/or to develop or update the NQP.	Strategic
	4. Identify current roles and responsibilities for TRs.	Identification of the various regulatory bodies in the country, together with their areas of responsibility and authority.	Process

Key stages	Detailed steps	Objective/Output	Level
2. Conduct a gap analysis		Understand where there is a need for greater collaboration between the NSB and policymakers and regulators.	Strategic and management
	1. Identify the current approach to standards by regulators.	Understanding of the different approaches to develop TRs (including any existing role of the NSB as a *de facto* regulator).	Management
	2. Review standards portfolio that is available to support public policy.	Linkages identified that are needed to support regulators; potential for supporting other policy options.	Management
	3. Review CA capabilities.	Actual and potential use of standards as a basis for CA.	Management
	4. Review market surveillance capabilities.	Actual and potential use of standards as a basis for market surveillance.	Management
	5. Establish priority policy areas for the NSB.	Definition of where the NSB should focus its resources.	Strategic
3. Build/strengthen bridges between the NSB and policymakers and regulators		Establish mutual trust and a common sense of purpose and collaboration.	Strategic, management and process
	1. Build awareness within NSB about benefits of collaborating with policymakers and regulators and assign responsibilities for coordination.	Linkages identified that are needed to support regulators; potential for supporting other policy options.	Strategic and Management
	2. Build awareness within government about the role of the NSB.	Actual and potential use of standards as a basis for CA.	Strategic
	3. Build and/or strengthen bridges between the NSB and policymakers	Actual and potential use of standards as a basis for market surveillance.	Management and process

Key stages	Detailed steps	Objective/Output	Level
4. Establish action plan for future NSB collaboration with policymakers and regulators		Prioritized and budgeted short-term and long-term plans.	Strategic, management and process
	1. Establish long-term collaboration mechanisms for the NSB with policymakers and regulators.	Defined responsibilities/authorities for collaboration with specific policymakers and regulatory bodies.	Strategic
	2. Develop plans to ensure an ongoing constructive relationship between the NSBs and policymakers/ TR developers.	Clearly defined responsibilities, authorities, budgets and priorities.	Strategic and management
	3. Advocate the plan among involved institutions.	Obtain buy-in from all relevant interested parties.	Strategic and management
5. Implement, monitor and evaluate the plan		Ensure effective and sustainable collaboration	Strategic, management and process
	1. Obtain endorsement from government body.	High-level support for collaboration between NSB and policymakers/regulators.	Strategic
	2. Conduct workshops at the relevant levels.	Sound working relationship established between NSB and policymakers/regulators.	Strategic, management and process
	3. Establish mechanisms for review and ongoing dialogue with policymakers and regulators.	Schedule established for review meetings and revision of collaboration mechanisms.	Management

Stage 1
Understand the national context

No two countries are the same in terms of how they address national policy objectives. This also includes how they subsequently achieve them, or their approach to regulations that aim to protect their citizens' health and safety and the environment.

This first stage aims to establish a clear view of who the players are at the national level; what the key policy objectives are, and what the relative priorities are both for policymakers and regulators and for the NSB. Some examples of the factors that directly impact the relationship and level of collaboration that can or should be developed between the NSB and government policymakers / regulators, are as follows:

International context – This can include, for example:

- key drivers and global trends that can have an impact on the country's aspirations and objectives
- relationships with, and perceptions and values of, international business partners and the international community in general (including cultural, social, political, legal, regulatory, financial, technological, economic, and natural factors as well as the competitive environment)
- form and extent of contractual relationships and adherence to international norms and conventions including, for example, membership of the WTO

National context – This can include, for example:

- government policies, economic objectives, and development strategies
- information systems, information flows and decision-making processes (both formal and informal) that provide insights into how the government operates
- the country's national culture and associated traditions
- standards, guidelines and models adopted by the country, including the extent to which the NSB has traditionally been mandated to develop TRs
- relationships with external stakeholders, such as international aid and/or funding agencies in the case of developing countries

NSB's organizational context – This can include, for example:

- governance, structure, roles and accountabilities
- relationships with, and perceptions and values of national stakeholders
- the NSB's capabilities, in terms of resources and knowledge (e.g. financial resources, time, people, intellectual property, processes, systems and technologies)

Some of these factors are broad in nature, and go beyond the scope of this document, but they need to be borne in mind when planning the NSB's strategic and operational relationships. On a more pragmatic level, this first stage in the development of sound collaboration between the NSB and policymakers/regulators requires a clear perspective about who are the interested parties in terms of policy-making; what are the key policy objectives, and what are the relative priorities.

Stage 1 can be divided into four individual steps as follows:

- 1.1 Identify key government policy areas, structure and departments
- 1.2 Identify current roles and responsibilities of key stakeholders
- 1.3 Verify linkages with NQP (if any) and other QI Institutions
- 1.4 Identify current roles and responsibilities for TRs.

Step 1.1 Identify key government policy areas, structure and departments

→ Intended outcome

A clear understanding about government policy priorities, and of the various actors within government with whom the NSB needs to communicate and potentially collaborate, to support the achievement of these policies.

→ Why?

To enable the NSB to be more effective in its relationships with government policymakers and regulators, and to make full use of its limited resources to have greater impact where they are most needed.

→ What?

Identify key government policy areas, the structures, departments and legislatures responsible for these and the key people (influencers) within them.

→ How?

Desk-based research (Internet and other); personal knowledge of NSB personnel (including board members, technical committee members and NSB staff).

→ Who?

Depending on the human and financial resources available, this first step could be assigned to a specific department or person within the NSB or could potentially be outsourced to a consultant knowledgeable in the national government structure, roles and responsibilities.

→ Challenges and mitigation measures

The information needed will usually be publicly available, but not necessarily all collected in one place, or in a single document. In countries where the ICT infrastructure is limited, it might be necessary to make use of both formal and informal pre-existing contacts within specific government departments, and then to "follow the chain" of information provided to identify other relevant policymakers. Traditionally, the NSB will have good links with the Ministry of Industry and Commerce (or equivalents), so this would be a good place to start.

Step 1.2 Identify current roles and responsibilities of key stakeholders

→ Intended outcome

Understanding of the stakeholders who have an interest, and role to play, in policy-making and the regulatory landscape; their roles, responsibilities and potential interactions with the NSB.

→ Why?

To facilitate a harmonized approach and buy-in among all stakeholders for the use of standards to assist policy-making and the development of TRs.

→ What?

Identification of those who will be affected by, or perceive themselves to be affected by, government policies and regulations, so that their needs and expectations (and concerns) can be taken into consideration.

Typical stakeholders can include, for example (in addition to the NSB itself):

- Policymakers and regulators
- Consumer organizations
- Industry, trade and/or service sector associations (including SME associations)
- Academia
- Users (for example contractors, utility companies, private or public sector purchasing/ procurement organizations, exporters, etc.)
- The national accreditation body (or, in its absence, the focal point for national accreditation)
- The national metrology institute
- Testing laboratories (for example medical, food testing, or environmental laboratories)
- Inspection agencies (for example import inspection agencies)
- Product, system, or personnel certification bodies operating in the country
- Market surveillance bodies
- Representatives of regional and international trading partners.

→ Who?

Depending on the pre-existing human and financial resources available within the NSB, this could be assigned to a specific department or person or could potentially be outsourced to a consultant knowledgeable in typical NQI structures.

→ How?

It is expected that the NSB will conduct desk-based research[58] into the various stakeholders and whether or not these are organized in a formal way (for example through industry associations, consumer associations, and CA body associations). The stakeholder groups are likely to be very similar (if not identical) to those applicable also to the NSB. The NSB should communicate its intentions in an open and transparent way, explaining the purpose of the exercise, and start to build support and consensus for the idea of standards-based policy-making and regulation.

→ Challenges and mitigation measures

If the various stakeholder groups are not organized in a formal way, then it might be necessary to reach out to a representative sample of such stakeholders on an individual basis to obtain further information including their key priorities. One way to do this could be using the information contained in membership lists of the NSB's TCs. The NSB TCs should ideally already include a broad spectrum of relevant stakeholders, or by inviting participation via the NSB's Website or newsletters. Another source of information could be TC business plans, where these exist.

58 The development of an NSS can also assist in the identification of key stakeholders and their roles and responsibilities. For more information see: https://www.iso.org/publication/PUB100450.html.

Step 1.3 Verify linkages with NQP (if any) and other QI Institutions

→ Intended outcome

Confirmation of the formal basis for the NQI (including any existing NQP). Understanding of the relationships and key interactions of the NSB within the NQI, the need to establish formal links with other institutions and/or to develop or update the NQP.

→ Why?

To avoid potentially conflicting or overlapping activities and facilitate the most efficient use of resources.

→ What?

Verification of the formal role of the NSB within the NQI, and its relationship with other NQI institutions.

→ Who?

This can be achieved by designating someone within the NSB to conduct the initial research, over a relatively short time-period.

→ How?

If there is a NQP, this would include much of the information required, particularly if it has been developed as part of a consensus-building process among all relevant interested parties. The NSB should check to make sure that the NQP is still valid and relevant; if not then it may be appropriate to initiate a revision.

→ Challenges and mitigation measures

If there is no NQP, then the NSB should verify the extent to which the roles, responsibilities and interactions between the various NQI actors are described by other means, and (either in parallel or at a later stage) this could then be used to stimulate the development of a formal NQP, with the NSB taking a key role.

Step 1.4 Identify current roles and responsibilities for TRs

→ Intended outcome

Identification of the various regulatory bodies in the country, together with their areas of responsibility and authority.

→ Why?

To start the ball rolling towards potential collaboration.

→ What?

Understand who are the key regulators with whom the NSB needs to interact.

→ Who?

Depending on the human and financial resources available this could be assigned to a specific department or person within the NSB or could potentially be outsourced to a consultant knowledgeable in the national regulatory structure.

→ How?

Information about the regulatory bodies may sometimes require only a short Internet search; in other cases, it might be necessary to undertake more detailed research.

Regulatory bodies are typically either part of, or assigned by the following government ministries, among others:

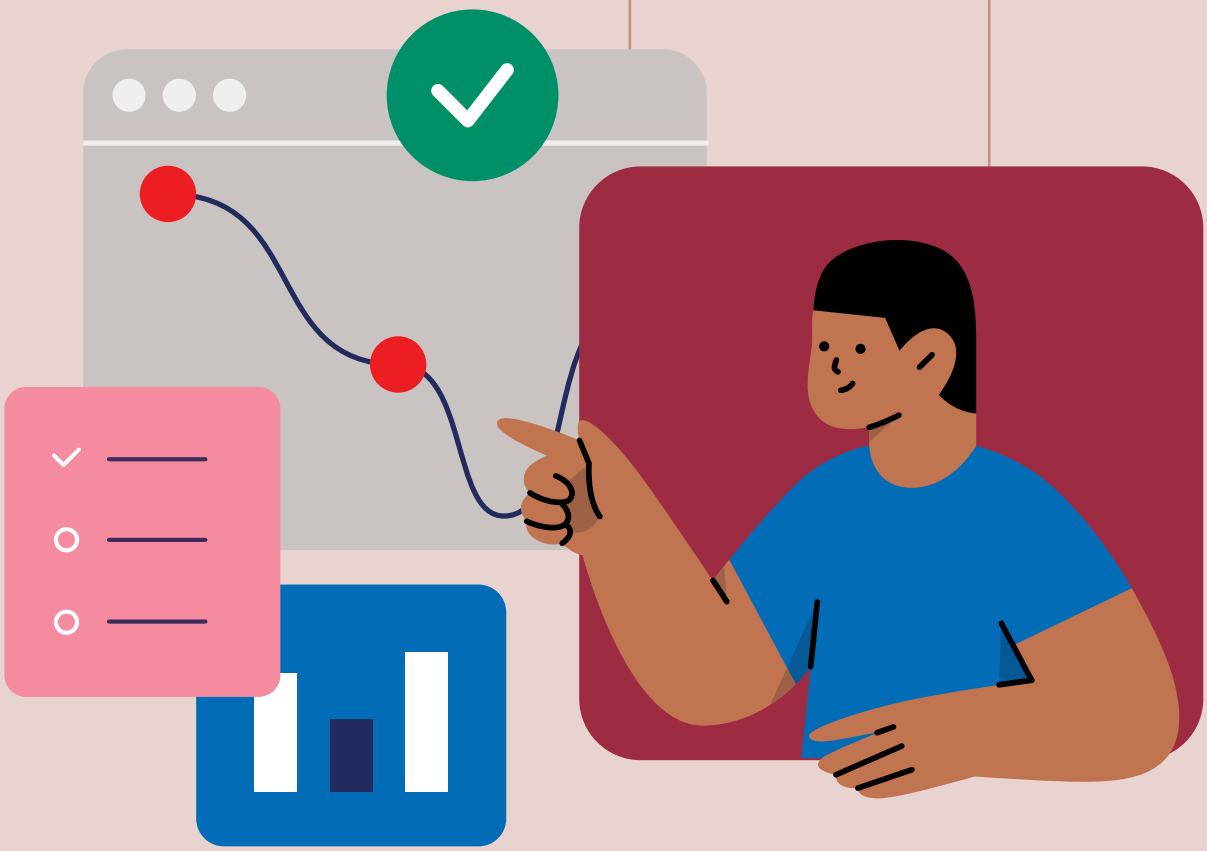
- Trade and Industry (or equivalent)
- Agriculture and/or fisheries
- Health
- Defence
- Environment/energy/water
- Finance
- Public works
- Transport.

Although the specific designations and responsibilities may vary from one country to another, the overall focus of different regulatory objectives are likely to be very similar.

→ Challenges and mitigation measures

If there is no readily accessible single source of information (such as a government Website), then it might be appropriate to engage with the highest levels within government, industry associations and other NSB stakeholders to determine what regulations (and, by inference, regulators) are relevant for the products and services they provide, and gradually build up a picture of the regulatory landscape.

Stage 2
Conduct a gap analysis



The main objective of Stage 2 is to understand where there is a need for greater collaboration and/or clarification of roles and responsibilities between the NSB and policymakers/regulators.

By definition, a gap analysis is a comparison between the desired state and the current (actual) situation. The desired state (from the NSB's perspective) is that government uses the NSB's voluntary standards to their maximum potential in order to support the effective and efficient development and deployment of its public policies.

Prior to the initial drafting of an action plan by the NSB (Stage 3), it is vital that the actual state of affairs is clearly identified. Part of this would have already been done (at the strategic level in Stage 1), particularly in terms of the institutions involved and their overall approach to policy-making and TRs.

Stage 2 aims to make a more detailed analysis that will allow the NSB to define the key areas in which to focus limited resources to ensure they have the biggest impact.

Steps:

- 2.1 Identify the current approach to standards by regulators
- 2.2 Review standards portfolio that is available to support public policy
- 2.3 Review CA capabilities
- 2.4 Review market surveillance capabilities
- 2.5 Identify priority policy areas for the NSB

Step 2.1 Identify the current approach to standards by regulators

→ Intended outcome

Understanding of the different approaches to development of TRs that are adopted by the various regulatory bodies in the country (see the intended outcomes from Step 1.4).

→ Why?

To understand the multitude of TRs that are typically in force, to serve as a basis for suggestions on how their development might be improved by the use of standards, or by less onerous standards-based policy options.

→ What?

Identify the current, valid, TRs, including their generic field of application, responsible regulatory authority, date of publication and reference to any national, regional or International Standards. Obtain information about the extent to which GRP is adopted by the (often numerous) regulatory bodies in the country.

→ Who?

This task is more laborious than it is technically challenging, so it can be assigned to relatively junior NSB personnel, or outsourced, with appropriate guidance and direction from NSB management.

→ How?

This step involves significant time and effort to make a detailed stocktaking exercise of the regulatory landscape, and the ways in which TRs developed by the various regulatory bodies currently refer to or make use of international, regional and national standards. This will typically be done by desk-based research, and much will depend on the availability of national databases, and/or databases managed by each government department or regulatory body. In the absence of a national database, NSBs should use the outputs from Step 1.4) i.e. Identify current roles and responsibilities for TRs, to identify specific regulations issued by each of the regulatory bodies.

→ Challenges and mitigation measures

If there is no specific mention of the approaches taken by the regulators (for example on their Websites or other publications), the NSB could use a sample-based approach, and look at some specific recent examples of published regulations. Care should be taken, however, not to be stalled at this stage by going into too much detail regarding individual TRs.

Depending on the size of the country and its approach to regulation, there are likely to be a vast number of TRs in force. Therefore it will be necessary to make an initial prioritization to focus only on those that are relevant to key government policy areas (as identified in Step 1.1). That is, identify key government policy areas, structure and departments, or to take a sample of regulations issued by each regulatory body for a specific topic, in order to reach a better understanding of the challenges and how to mitigate them.

→ Reference documents/templates

- https://www.forbes.com/sites/waynecrews/2017/08/15/how-many-rules-and-regulations-do-federal-agencies-issue/#:~:text=Looking%20back%2C%20there%20have%20been,play%20at%20year%2Dend%202016.
- US Code of Federal Regulations (CFR); https://ecfr.io/ available from https://www.fda.gov/regulatory-information/fda-rules-and-regulations.
- Example of a regulatory agency Website for specific products, see http://antigo.anvisa.gov.br/cosmetics.

Step 2.2 Review standards portfolio that is available to support public policy

→ Intended outcome

Linkages identified that are needed to support policymakers / regulators; potential for supporting other policy options.

→ Why?

To facilitate a self-assessment by the NSB of its own portfolio of standards and the extent to which this might need to be reformulated to support specific government policy/regulatory objectives.

→ What?

Review the current portfolio of national standards, the date of publication (latest revision) and whether or not these are national adoptions of regional or International Standards.

→ Who?

Depending on the human and financial resources available this task could be assigned to a specific department or person within the NSB as a short-term project or could potentially be outsourced to a consultant knowledgeable in the field of standards and TRs from both the national and international perspectives.

→ How?

The NSB should have a complete database of all its standards, though this may not necessarily be in digital form. The main objective is to verify the extent to which the standards are current, reflect international consensus and how they are (or could be) used to support TRs or other policy initiatives. The first part of this analysis is relatively straightforward; the analysis of the suitability of the standards for use to support TRs or other policy initiatives will, however, need more reflection, and a deeper understanding of the technical content of the standards. It will also depend on the extent to which the NSB has itself published 'mandatory standards' that have traditionally been considered as TRs.

→ Challenges and mitigation measures

Depending on the size of the country there are likely to be a significant number of standards (including 'mandatory standards') that, depending on the resources available to the NSB may or may not have been kept up to date. It could be necessary to make an initial prioritization to focus only on those that are relevant to key government policy areas (as identified in Step 1.1). In any case, it should be possible to identify those standards that have not been reviewed or revised for a significant period of time and – using a relatively small sample – the percentage of standards that are national adoptions of International Standards.

Step 2.3 Review CA capabilities

→ Intended outcome

Actual and potential use of standards as a basis for CA and the demonstration of regulatory compliance.

→ Why?

Governmental and public confidence in a standards-based approach to policy and TRs is closely linked to the availability and choice of procedures for verifying regulatory compliance.

→ What?

Review the availability of CA bodies in the country, and the extent to which regulators require and/or refer to accreditation and the use of International Standards (such as those provided in the ISO/CASCO Toolbox) as a basis for demonstrating compliance with their TRs.

→ Who?

Depending on the human and financial resources available this task could be assigned to a specific department or person within the NSB as a short-term project or could potentially be outsourced to a consultant knowledgeable in the field of standards and CA from both the national and international perspectives.

→ How?

In many economies, the NSB itself has a CAB. This can provide a starting point for the analysis, particularly in small low-income economies where there may be few CA options available.

Most CABs advertise their services in some way, so this can also provide contact information to initiate communications.

Another excellent source of information are the local businesses that have to comply with national, and potentially international, TRs. They will be well aware of the requirements that have to be met when they seek to engage CABs. These stakeholders typically could be expected to participate in the NSB's Board or in its TCs, thereby facilitating communications.

International trading partners (or regional/international organizations) can also provide useful information where there might be a perception that excessive or inappropriate use of CA procedures in the NSB's country have been designed to close the market against fair competition (particularly if the procedures are out of line with international best practice). Equally, national businesses who wish to export their products may experience a lack of suitably recognized local CABs (for example if these do not meet the internationally accepted requirements).

→ Challenges and mitigation measures

If the NSB itself offers CA services, other CABs might be reluctant to provide the NSB with the information requested. In these cases, it might be appropriate to liaise directly with government to source or request the information on the NSB's behalf.

Step 2.4 Review market surveillance capabilities

→ Intended outcome

Actual and potential use of standards as a basis for market surveillance.

→ Why?

International best practice aims for an approach to regulatory compliance that strikes a balance between 'pre-placing on the market' checks and 'post-placing on the market' checks (market surveillance). Market surveillance is therefore an important component to provide confidence that requirements are consistently being met.

→ What?

Verification of the extent of, responsibilities for, and influence of International Standards on market surveillance activities in the country.

→ Who?

Depending on the human and financial resources available, this task could be assigned to a specific department or person within the NSB as a short-term project or could potentially be outsourced to a consultant knowledgeable in the field of TRs and market surveillance.

→ How?

Market surveillance normally comes under the responsibility of the regulatory body that issued the relevant TRs, and it is notoriously difficult to obtain information about market surveillance from sources other than the regulatory body itself. In some cases, CABs might be able to provide inputs if, for example, the MS activities of the regulator or its representative involve product testing or inspection.

→ Challenges and mitigation measures

Many market surveillance activities suffer from chronic underfunding, so they may be non-existent, or triggered by the need to respond to safety-related incidents, rather than being conducted using a systematic risk-based approach. The media and/or consumer associations can therefore be a useful alternative source of information. One excellent example of collaboration between a regulator and the media was the long-term relationship between Inmetro and the popular current-affairs TV programme 'Fantastico' in Brazil, watched by millions of households every Sunday evening, which raised awareness of compliance problems with product samples taken from the market.

→ Resources

https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_guide.pdf.

Step 2.5 Identify priority policy areas for the NSB

→ Intended outcome

Definition of where the NSB should focus its resources.

→ Why?

The NSB has only limited resources, so it needs to prioritize these in areas that will have the greatest return on investment.

→ What?

The NSB needs to identify its own priorities, aligned as far as possible with the policy objectives of government (who may be directly or indirectly funding the activities of the NSB) by referring to the NSS (if available) or other such strategic documents.

→ Who?

Senior management of the NSB.

→ How?

Using information derived from the results of Stage 1 and Stage 2, Steps 2.1 to 2.4 to select, or develop, specific projects that are compatible with the funding available (including any potential funding or technical assistance from international development agencies).

→ Challenges and mitigation measures

This whole initiative by the NSB can seem like an extremely daunting task, so it needs to be broken down into 'bite-sized chunks'. One strategy might be to develop a pilot project or projects with an engaged government department on a relatively easy or non-controversial topic, in order to provide quick wins and success stories to share with others. These might include, for example:

- Working with a specific regulator to develop or adopt voluntary standards to help replace outdated (and difficult to enforce) prescriptive legislation.
- Developing or adopting voluntary standards to help policymakers to pursue specific new policy objectives.

Stage 3
Build bridges between the NSB and policymakers and regulators

The third stage of the process involves the establishment of an action plan to promote sound and enduring two-way communication channels with the relevant stakeholders identified in Stage 1, with a particular focus on policymakers and regulators, and prioritized according to the results of the gap analysis conducted during Stage 2. It is important to ensure that all are aware of the benefits to be achieved by using International Standards as an effective and efficient way of implementing policy and supporting TRs.

Steps:

- 3.1 Build awareness within the NSB about benefits of collaborating with policymakers and regulators and assign responsibilities for coordination
- 3.2 Build awareness within government about the role of the NSB
- 3.3 Explain to policymakers and regulators about the important role of voluntary standards

Step 3.1 Build awareness within the NSB about benefits of collaborating with policymakers and regulators and assign responsibilities for coordination

→ Intended outcome

Buy-in from personnel at all levels of the NSB, and clear definition of roles and responsibilities, for coordination with policymakers and regulators at the strategic, management and operational levels.

→ Why?

To ensure that there is a consistent understanding within the NSB of the contributions that can be made by voluntary standards, and that the responsibilities and authorities for communicating with the various levels of government are defined.

→ What?

Promote an understanding of the various approaches to policy-making using international, regional and national standards as an alternative to the development of regulatory solutions.

Ensure that the relevant people in the NSB are knowledgeable about the need for GRP, including the role of voluntary standards and 'mandatory' standards.

→ Who?

Depending on the size of the NSB and the resources available, the coordination of this task can be assigned as follows:

- A specific director with responsibility for government affairs (either by assigning an existing director to carry out this role, or by recruiting someone to fill a new position). This may or may not be integrated with the international relations function of the NSB.
- A steering committee (possibly including other stakeholders).

NOTE: Senior personnel within the NSB should be not only technically proficient in standards-making, but also competent to engage in dialogue with governments, legislators and regulators.

→ How?

Provide training or other awareness-building activities to all relevant NSB personnel (including, as appropriate, board members and members of the NSB's TCs) to cover the main topics that are addressed elsewhere in the document. The focus should be on trying to look at standards from the policymakers' and regulators' perspectives, and how to overcome potential obstacles to collaboration.

→ Challenges and mitigation measures

NSB personnel need to be aware of and be able to deal with legitimate criticisms of the standards-development process that may undermine policymakers' and regulators' confidence; notably any imbalances in the representation in TCs (such as potential over-representation of product suppliers and under-representation of product-using businesses, consumers, trade unions, environmental groups and others). With these considerations in mind, NSBs can persuade their standards-development committee members (and their employers) that collaboration with policymakers and regulators can add value to their work because the standards will command greater confidence in trade, procurement and placing of products and services on the market. This in turn may increase the incentive to employers and stakeholders to take part in the standards-making process, and thus create a virtuous circle.

Step 3.2 Build awareness within government about the role of the NSB

→ Intended outcome

Communication strategy developed and potential 'champions' at high levels of government identified.

→ Why?

This is probably one of the most important steps in the whole process of engagement with policymakers and regulators, in order to create a critical mass of support for the NSB's role within government.

→ What?

This step aims to 'put the NSB in the hearts and minds of policymakers and regulators', in advance of Step 3.3 which is aimed at building awareness of the specific contributions that can be made by voluntary standards.

→ Who?

This initiative should be a consolidated effort led by senior management of the NSB (coordinator for government affairs – see Step 3.1), with support from board members, staff at all levels, and stakeholder representatives from TCs. The NSB should consider appointing to its board people with experience in dealing with governments and legislatures if that is not already the case.

→ How?

It is important that the NSB develop a communications strategy and implementation plan. A typical strategy includes ***what*** the communications intend to achieve (objectives), ***who*** the NSB needs to engage with as a priority (audiences), ***what*** these audiences need to hear (key messages), and broadly ***how*** the NSB will communicate with them (communications channels).

The NSB should aim initially at the easy targets and quick wins, by cultivating and expanding on its relations with individuals in government who have already understood the role of the NSB and have traditionally been sympathetic towards it. The NSB should maintain regular contact with these 'champions', equipping them with evidence to support the case for standards-based policy-making within their sphere of influence.

It is also important to engage with other influencer groups, and particularly to cultivate relationships with consumers, trade unions, environmental organizations and other members of civil society that consider standards-based regulations helpful to their interests. This is to gain their acceptance, their involvement and their agreement to lobby governments and legislatures.

→ Challenges and mitigation measures

If there is support for the NSB only at the working level within public administration, then NSBs should work with the officials concerned to bring the benefits to the attention of their superiors at every opportunity.

If there is a new reformist administration keen to promote a change of approach to policy-making and regulation, with greater emphasis on the use of voluntary standards, there may be resistance from those at the working level both in government and within the NSB. While ministers have some ability to decide and direct what happens, true buy-in throughout the administration depends on persuasion and building consensus. The NSB's communications strategy and plan should not therefore focus exclusively on the highest levels of government; awareness-building can often be better achieved at the lower levels, by showing that rather than being "a threat" to regulators, the NSB can actually make their jobs easier, and the results obtained more effective.

→ Resources

An excellent example of a communications strategy, together with a toolkit for its implementation can be found here – https://www.health.org.uk/publications/communications-in-health-care-improvement-a-toolkit.

Step 3.3 Explain to policymakers and regulators about the important role of voluntary standards

→ Intended outcome

Greater awareness among policymakers and regulators on the advantages of using national, regional and International Standards to support their activities.

→ Why?

Help policymakers and regulators understand the advantages of developing and using goals-oriented, voluntary standards-based legislation and then assist them to make what may be a radical and quite possibly difficult change in their approach.

→ What?

The overall message to transmit to policymakers and regulators should be based on publications such as ISO and IEC's document[59] *International Standards for policymakers*, adapted to the local (national) context.

→ Who?

Everyone in the NSB and connected with it should be considered as a potential ambassador to promote the use of voluntary standards by governments and regulators to support their policy objectives.

→ How?

This step should build on the communications plan, developed as part of Step 3.2, to promote awareness-building activities aimed at all levels of government, covering the main topics that are addressed elsewhere in the document. The guidance in the ISO publication[60] *National Standardization Strategies* can also be useful here, and in particular Section A.3.4 ("Key messages to governmental agencies and public authorities").

→ Challenges and mitigation measures

It is important in promoting voluntary and consensus-developed standards that NSBs start from an acknowledgement of national legislative traditions and build up support for a change of approach gradually. It may be appropriate to facilitate visits for government officials to their peers in other countries, who have had good experiences with the use of voluntary standards, so that these success stories can be taken back for sharing and to encourage the process of change. It is also important to ensure that standards-based policy and regulations appear on the agenda of ministerial visits and participation in regional events.

59 Available at https://www.iso.org/publication/PUB100359.html.
60 Available at https://www.iso.org/publication/PUB100450.html .

Stage 4
Establish a plan for future NSB collaboration with policymakers and regulators

Once the appropriate bridges have been built with policymakers and regulators (Stage 3), it is not uncommon for the person in charge to be removed or reassigned and the whole process has to begin again. It is therefore vital to institutionalize the collaboration to sustain the relationships over the long term. The aim of Stage 4 is to ensure that the NSB has prioritized and budgeted for both short-term and long-term plans. These should be based on inputs from all the previous stages and focus on achieving agreed 'SMART' objectives (Specific, Measurable, Achievable, Relevant, and Timely).

Steps:

- 4.1 Establish long-term collaboration mechanisms for the NSB with policymakers and regulators
- 4.2 Develop plans to ensure an ongoing constructive relationship between the NSB, policymakers and developers of TRs
- 4.3 Advocate the plan among involved institutions

Step 4.1 Establish long-term collaboration mechanisms for the NSB with policymakers and regulators

→ Intended outcome

Defined responsibilities/authorities for collaboration with specific policymakers and regulatory bodies.

→ Why?

To ensure that long-term collaboration does not depend on the actions of individuals in the respective organizations, which could result in early initiatives gradually fading out over time.

→ What?

Define the nature of meetings and other interactions; decide who needs to be involved and regular communications procedures, including mechanisms and means of ensuring that these are followed.

→ Who?

This would be an appropriate point at which to establish a formal long-term oversight group, led by senior management of the NSB, but including government policymakers, regulators and other stakeholders. If the country has an NQP with its own steering committee, then it might be appropriate to establish this oversight group as a sub-group within that committee.

→ How?

Effective collaboration needs to take place at three levels, as follows:

- **Strategic level:** to ensure that the overarching NSB strategy and policy documents are conducive to collaborating with the policymakers and sufficient resources are allocated for this collaboration.
- **Management level:** to ensure that the strategy is implemented by establishing channels of communication with policymakers, for example through a designated department in the NSB that manages policy relations with government bodies/regional bodies and then transfers this information to the relevant parties.
- **Process level:** to ensure that the various NSB staff members and TCs follow the agreed upon procedures and guidelines to ensure collaboration with policymakers and regulators, and that regulators can contribute actively to the standards-development processes, as appropriate.

In establishing these cooperation mechanisms, it is important to:

- Emphasise why the NSB and the government believe standardization is valuable in general and specifically to the process of policy-making and TR.
- Be clear about the strengths, weakness, opportunities and threats that standards-based TRs represent.
- Identify the rhythms and annual/multi-annual cycles of legislation, regulation and standards-making; prepare programs of meetings and reporting to fit in with these.

→ Challenges and mitigation measures

When addressing TR, everyone might not agree about whether or not there is a need for TR, or if it might be possible to achieve the policy objectives by other less onerous means. Through their regular contacts with stakeholders, NSBs can help to build consensus, and encourage the stakeholders to lobby government and legislators in an organized way, deciding what precise means of approach are most effective, given national traditions, procedures and practices. In other circumstances it may be more a case of getting stakeholders to respond to proposals from the government or the legislature for change. For example, this could occur due to a government response to proposals for TR from a regional body, such as the European Union or the Mercosur countries (Argentina, Brazil, Paraguay, and Uruguay).

Governments need either to establish consultation mechanisms on proposals for TR or if they do already exist, NSBs need to check that they include all of their stakeholders and, if they do not, help governments make the necessary changes and extensions to include them.

NSBs need to consider whether their established standard-making and other fora can be used as part of the consultation process e.g. by developing an agreed position between stakeholders, encouraging them to ask for meetings with government to promote them and, where appropriate, offering to host consultation meetings between ministers or officials and stakeholders.

Step 4.2 Develop plans to ensure an ongoing constructive relationship between the NSBs, policymakers and developers of TRs

→ Intended outcome

Clearly defined responsibilities, authorities, budgets and priorities.

→ Why?

To build on the early initiatives, and ensure that the relationship is an enduring one, with adequate funding for the NSB.

→ What?

A sound implementation plan typically needs to address the '5W 2H's' associated with the initiative: *who, what, when, where, why* and (crucially for the NSB), *how* and *how much*?

The plan needs to be realistic and include measurable objectives and milestones.

→ Who?

The initiative for the development of the plan should come from senior management of the NSB, but it should consider inputs from policymakers and other stakeholders.

→ How?

Those involved in developing the plan should identify:

- Quick wins – actions that can have a short-term impact (implemented over the course of 1 –3 years), with minimal additional investment by the NSB in terms of resources or infrastructure.
- Longer term actions (3 – 5+ years), that might require more significant expenditure in, for example, ICT, as well as additional administrative personnel for coordination and support for the NSB's TCs.

The long-term implementation plan should not necessarily try to include details of all potential policy objectives and collaborative activities. Instead, it should draw up a list of current issues and likely future developments to which standards are relevant, and generic problems they can help to solve, when called upon to do so. Priorities can then be assigned to the various short and long-term actions, with emphasis on those that are most appropriate for the national/regional context at the time. Yearly workplans by sector or functions should be prepared and used, and regular (yearly) updates on progress and achievements produced and circulated.

The plans need to be supported with careful, robust costings, and if possible, cost/benefit analyses together with specific examples of the benefits that standards can bring in the fields of trade, public procurement and public protection.

→ Challenges and mitigation measures

Securing sources of funding for standards-development activities is a constant challenge. It is important for all stakeholders to recognize that while most NSBs are not-for-profit, they are not charitable institutions so they have to recover their costs from somewhere. If standards are to provide cost-effective solutions for policymakers and regulators it may be appropriate for the NSB to solicit financial support from these sources for the services it provides if it is not already doing so.

In the case of low-income economies, some financial support might be also available from international funding agencies, interested to help the country become more active in international markets or to further other policy objectives that may have international repercussions, such as those related to the UN SDGs. This, should not, however, be considered in the longer term; the NSB should be able to become financially self-sufficient.

Step 4.3 Advocate the plan among involved institutions

→ Intended outcome

Obtain buy-in from all relevant interested parties.

→ Why?

To ensure long-term success by marshalling support for a standards-based approach to policy-making and TR development.

→ What?

Build support for the collaboration between the NSB and policymakers with all relevant institutions and interested parties.

→ Who?

NSB senior management.

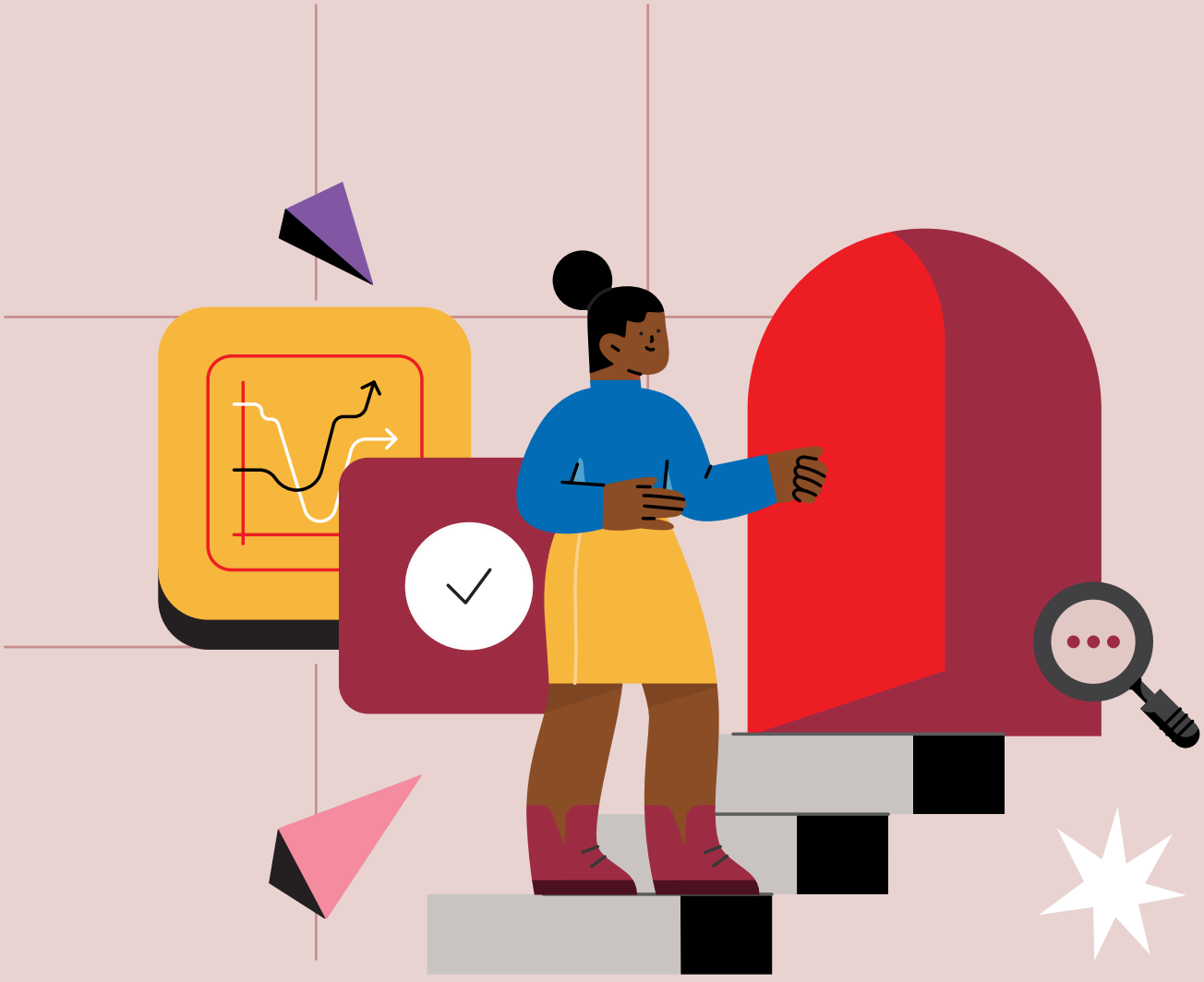
→ How?

Undertake a public consultation with copies of the plan being sent to all stakeholders for comment, and courtesy communications to opposite numbers in international and regional standards bodies as well as key figures in national or regional legislatures.

→ Challenges and mitigation measures

Particular attention should be paid to the views of those stakeholders who had limited opportunities to take part in earlier stages of the process, particularly if they are not supportive of the plans for greater contributions from voluntary standards. It may be appropriate to see whether it might be desirable to make some modifications to what is being proposed or to make a final attempt to bring them on board. The latter is an important consideration because they are likely to have their own lines of communication to government and it is not a good idea for governments to be hearing conflicting messages from different interested parties.

Stage 5
Implement, monitor and evaluate the plan



Circumstances change, so in order to ensure effective and sustainable collaboration, it is vital that the implementation of the plan be monitored, evaluated and, if necessary, changes made to the plan. At no time was this more apparent than in 2020, when the COVID-19 pandemic radically changed government approaches to policy-making and regulation on an unprecedented level, requiring rapid responses from all concerned.

Steps:

- 5.1 Obtain endorsement from government body
- 5.2 Conduct workshops at the relevant levels
- 5.3 Establish mechanisms for review and ongoing dialogue with policymakers and regulators

Step 5.1 Obtain endorsement from government body

→ Intended outcome

High-level support for collaboration between the NSB and policymakers/regulators.

→ Why?

To provide visibility and credibility to the initiative and ensure its long-term viability.

→ What?

The agreement, memorandum of understanding or other instrument (be it a new document or an existing one with extended scope) should be formally approved by a minister and the head of the NSB.

→ Who?

Senior management of the NSB (coordination).

→ How?

The NSB should make its recommendation to government about its own and its stakeholders' preferred approach to policy-making and the development of TRs, and how to consult and involve stakeholders in the process. There are likely to be exchanges and rounds of negotiations between the government bodies and the NSB before an agreed position is finalized. Stakeholders should be kept informed, and their opinions sought on any significant additions or amendments.

→ Challenges and mitigation measures

The most satisfactory consultation and collaboration mechanisms in the production of sound policies and good regulation are likely to emerge by a process of iteration between government, legislatures, the NSB and other stakeholders. If the early steps have not been carried out by a systematic, consensus-building approach, this final hurdle of obtaining formal approval from government can take a significant amount of time.

Step 5.2 Conduct workshops at the relevant levels

→ Intended outcome

Sound working relationship established between the NSB and policymakers/regulators.

→ Why?

To ensure that the collaboration is effectively understood and deployed at all levels in the various collaborating organizations and is made known to other interested parties.

→ What?

Informative face-to-face or virtual workshops to explain the new or enhanced involvement of the NSB in policy-making and TR.

→ Who?

Senior management of the NSB (coordination).

→ How?

By summarizing the approaches and agreements made and emphasising the benefits to all concerned using the arguments presented earlier.

Together with the workshop invitations it is advisable to inform potential participants about the background to and objectives of the workshop. This will help to put the workshop in its proper context, and, if the invitation is signed by someone at a high level of government (for example a minister), will encourage participation (particularly if the minister is to participate in the workshop in some way).

→ Challenges and mitigation measures

Bringing together all the relevant people at the same time and the same place is always a challenge. Good communication ahead of time, and the provision of appropriate funding is particularly important for SMEs and consumers, who may not be organized into formal, well-funded associations, and are therefore more difficult to reach. Consideration could be given to holding separate workshops for individual stakeholder groups and/or conducting workshops in geographic locations other than the capital city. If the workshops are to be conducted virtually, then these could be recorded, for viewing at a later date, although this does limit the possibilities for questions or other interactions.

Step 5.3 Establish mechanisms for review and ongoing dialogue with policymakers and regulators

→ Intended outcome

An established schedule for review meetings and revision of collaboration mechanisms.

→ Why?

To ensure effective long-term implementation and improvement of the collaboration over time, and to adapt as necessary to keep pace with changes in the national priorities and international context under which it was initially developed.

→ What?

Review of progress, monitoring of objectives and milestones and recommendations for corrective actions or improvements.

→ Who?

Collaboration oversight group.

→ How?

The NSB should collate the available data, and prepare a report (with proposals), to be circulated to participants in good time ahead of the meeting.

→ Challenges and mitigation measures

There may be stipulations in the procedures of regional or international negotiations on TR that these must be conducted on a confidential basis. This combined with, for example, majority decision-making procedures and tight negotiating procedure deadlines will make it difficult to keep stakeholders fully involved. The consultation procedures may need to be re-appraised in the light of such experiences.

13. Conclusion

This document provides a framework for the NSBs to advocate for the development of better practices for public policy and regulation through greater use of International Standards.
It is designed to equip NSBs to engage proactively with policymakers and regulators. It is based on the premise that a better understanding of where International Standards interact with economic and other objectives can assist policymakers and regulators in being even more effective.

Contact us

For further information and support to engage with policymakers on standards, trade and public policy, contact us at: capacity@iso.org

About ISO

ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 170* national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.

ISO has published more than 25 000* International Standards and related documents covering almost every industry, from technology to food safety, to agriculture and healthcare.

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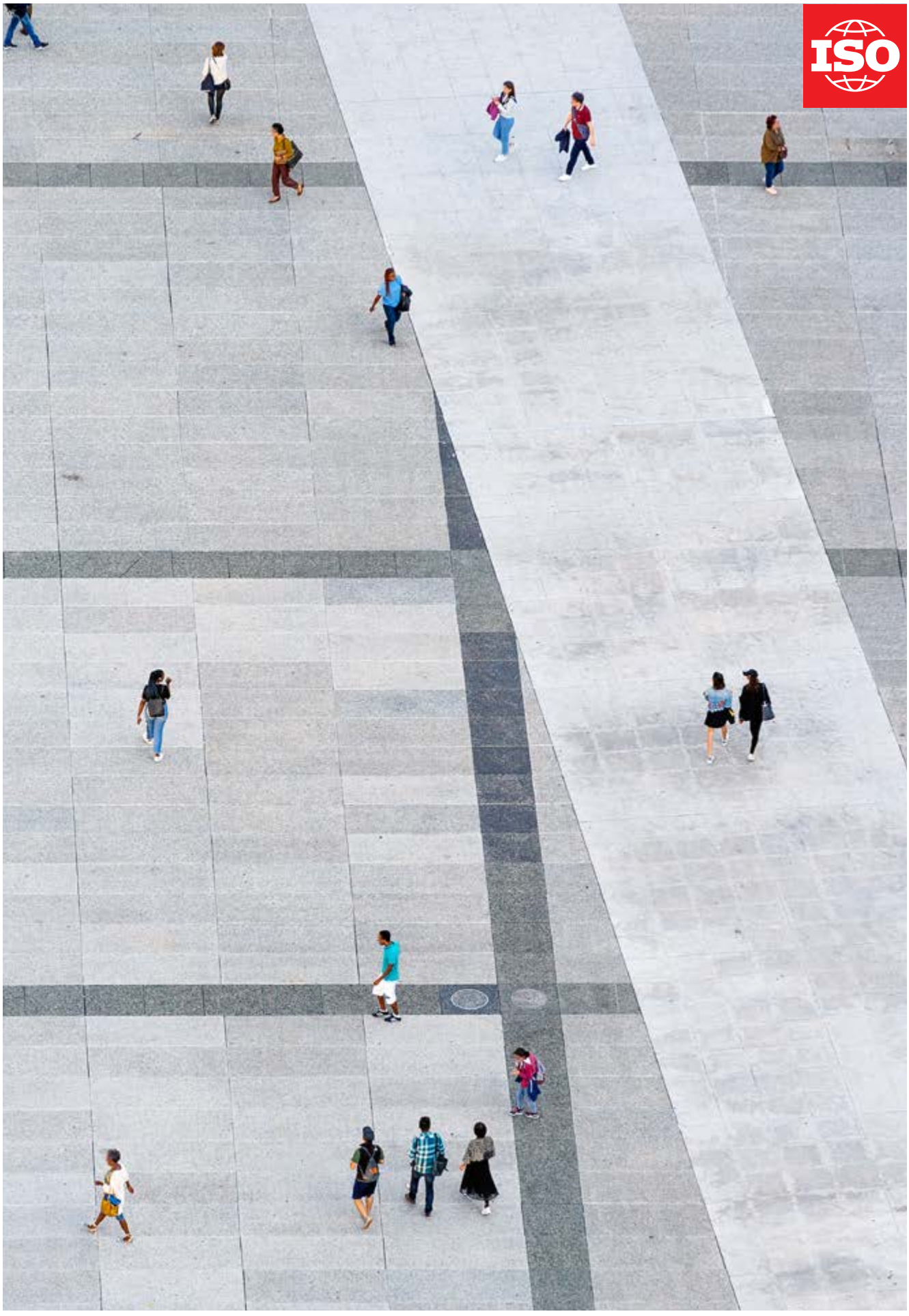

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ISBN 978-92-67-11329-6

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