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**Case study of Regulatory Co-operation in the context of the International Standard Organization (ISO)**

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**Joining Forces on Global Standards for Better Lives  
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*Delegates are invited to submit their comments by 9 September 2016.*

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## ACRONYMS AND ABBREVIATIONS

ACCSQ	ASEAN Consultative Committee for Standards and Quality
AIDMO	Arab Industrial Development and Mining Organization
ARSO	African Regional Organisation for Standardization
CARICOM	Caribbean Community
CASCO	Committee on conformity assessment
CROSQ	CARICOM Regional Organisation for Standards and Quality
CD	Committee Draft
CEN	European Committee for Standardization
COPANT	Pan-American Standards Commission
COPOLCO	Committee on consumer policy
DEVCO	Committee on developing country matters
DIS	Draft International Standard
EAC	East African Community
EASC	Euro-Asian Council for Standardization, Metrology and Certification
ECOWAS	Economic Community of West African States
FDIS	Final Draft International Standard
GA	General Assembly
GATT	General Agreement on Tariffs and Trade
GCC	Gulf Cooperation Council
GSO	GCC Standardization Organisation
ICAO	International Civil Aviation Organization
IO	international organisation
IEC	International Electrotechnical Commission
IGO	inter-governmental organisation

IRC	international regulatory cooperation
ISA	International Standardization Association
ISO	International Organization for Standardization
ISO/CS	ISO Central secretariat
ITU	International Telecommunication Union
IWA	International Workshop Agreement
JCGM	Joint Committee for Guides in Metrology
JTC	Joint Technical Committee
KPI	Key performance indicators
MoU	Memorandum of Understanding
NATO	North Atlantic Treaty Organization
NGO	non-governmental organisation
NMC	national mirror committee
NSB	national standards body
OECD	Organisation for Economic Co-operation and Development
OBP	Online Browsing Platform
OIML	International Organization for legal Metrology
PAS	Publicly Available Specification
PASC	Pacific Area Standards Congress
PC	Project Committee
PDC	Policy Development Committees
SADC	Southern African Development Community
SARSO	South Asian Regional Standards Organization
SC	Sub-committee
TBT	Technical Barriers to Trade
TMB	Technical Management Board

TR	Technical Report
TC	Technical Committee
TS	Technical specification
UNECE	United Nations Economic Commission for Europe
UNCED	United Nations Conference on Environment and Development
UPU	Universal Postal Union
WG	Working Group
WSC	World Standards Cooperation
WTO	World Trade Organization

The International Organization for Standardization (ISO) is a non-governmental organisation made up of national standards bodies, comprising both public and private entities. 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 a wide range of global challenges. This case study describes ISO, its structure, governance and processes, and how it supports international regulatory co-operation through the global application of its standards.

## **INTRODUCTION: THE RELEVANCE OF ISO FOR INTERNATIONAL REGULATORY CO-OPERATION**

1. The International Organization for Standardization (ISO) is a non-governmental organisation (NGO) with its headquarters, the ISO Central Secretariat (ISO/CS), based in Geneva, Switzerland. It is a membership network of 163 national standards bodies (NSBs) as of June 2016, comprising both public and private entities. ISO develops voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges. Given that the International Standards and other deliverables that it produces are all voluntary, ISO does not consider itself to be a regulator in the traditional sense. However, when governments and industries choose to use ISO standards, this can have the effect of promoting cooperation between countries, facilitating trade, and creating *de facto* rules and best practices at the international level, which can be considered as promoting international regulatory cooperation (IRC). This case study explores the specificities of ISO and describes how it supports IRC – the context in which it takes place, its main characteristics, its impacts, successes and challenges.

2. ISO is not a traditional international organisation (IO). It is not an inter-governmental organisation (IGO), since it is not treaty-based, but it is not a “traditional NGO” either. Its hybrid nature is confirmed by ISO’s status in Switzerland: it is considered as a “quasi-governmental organisation” defined as in-between an intergovernmental organisation and a classic NGO<sup>1</sup>. This divide between “IO” and “NGO” is increasingly criticized by scholars, who underline that the two categories merely exist in legal theory and do not facilitate the understanding of today’s more complex international institutional landscape. Scholars still struggle to agree on a terminology to name such organisations and, besides “IO” and “NGO” (or “international NGO”), ISO can also be referred to as a “hybrid organisation” (Lagrange, 2013), “transnational regulatory organisation” (Abbott, 2014), “international private standard-setting organisation” (OECD, 2016) or “private standard-setting institution” (Benvenisti, 2012). What makes ISO unique in comparison to other NGOs is the fact that it is structurally organized as a federation, with the

1. Swiss Confederation, 2006. ISO is not the only organisation that does not fit into the traditional categories. In February 2016, six organisations, including ISO, were recognized as “Quasi-governmental international organisations” by the Swiss government: International Air Transport Association (IATA), International Electrotechnical Commission (IEC), World Conservation Union (IUCN), Airline Telecommunications and Information Services (SITA), World Anti-Doping Agency (WADA). Eight “Other international bodies” have an agreement giving them a specific status in Switzerland (Swiss Confederation, 2016): Drugs for Neglected Diseases Initiative (DNDi), Foundation for Innovative New Diagnostics (FIND), Global Alliance for Improved Nutrition (GAIN), Geneva International Centre for Humanitarian Demining (GICHD), Centre for Humanitarian Dialogue (HD Centre), International Olympic Committee (IOC), Medicines for Malaria Venture (MMV), World Economic Forum (WEF). Such hybrid organisations also exist in other countries, for example: Interpol in France, the International Organisation of Securities Commissions (IOSCO) in Spain, the International Air Transport Association (IATA) in Canada.

ISO members as the key actors for all core activities of the organization (for example, the technical committees that develop standards are composed of representatives of the ISO members). ISO is therefore a heavily decentralized and very member-driven organization<sup>2</sup>.

3. According to the OECD (2016), ISO is classified as an international private standard-setting organisation, and is considered relevant to the international regulatory cooperation project for several reasons (Abbott, 2014; s. also: OECD, 2013b):

- ISO standards help to improve economic efficiency and facilitate international trade: it is often said that “a day without standards is inconceivable” (IEC, ISO, ITU, 1998) and one of ISO’s priority objectives in its five-year strategic plan is that its Standards are used everywhere (*ISO, 2015a*);
- ISO Standards complement public policy: according to ISO, “ISO standards draw on international expertise and experience and are therefore a vital resource for governments when developing public policy”<sup>3</sup>. In 2014, ISO developed two online platforms<sup>4</sup> and a brochure (ISO/IEC, 2014) to help governments use standards in support of their technical regulations;
- Traditional IOs rely on ISO standards: for example, the Agreement on Technical Barriers to Trade (TBT Agreement) of the World Trade Organization (WTO) requires states to use international standards when they enact domestic technical regulations (if such international standards exist). Additionally, ISO cooperates with over 700 international actors relying on the ISO system to develop International Standards and recognizing ISO as an international forum to develop technical solutions to global challenges. Some scholars go further, and argue that ISO Standards are international standards in the meaning of the TBT Agreement<sup>5</sup>, thus recognizing ISO’s Standards as a source of International Law and “hardening” them (Dupendant, 2014; Lanfranchi, 2006).
- ISO is a public-private collaboration: Formally, ISO is a Swiss private association, but its members are both public and private entities, depending of the structure of standardization in each country. Furthermore, ISO standards can be seen as informal agreements between countries, given the almost global membership of ISO.

4. OECD (2013a) makes it clear that “IRC is not restricted to its strict equivalence with international legal obligations, but also includes non-binding agreements and voluntary approaches”. What’s more, according to OECD (2016), the IRC-mechanisms most frequently used by IOs are non-binding instruments, and few IOs are involved in the downstream activities of enforcement or dispute settlement. In this way, ISO fits well within this definition, despite the fact that its standards are voluntary and not associated with any kind of centralized enforcement mechanisms.

2. The decentralised structure of ISO is very similar to that of the OIML. See OIML Case Study.

3. ISO website: [www.iso.org/iso/home/standards/benefitsofstandards.htm](http://www.iso.org/iso/home/standards/benefitsofstandards.htm).

4. “Using and referencing ISO and IEC standards to support public policy” ([www.iso.org/sites/policy/](http://www.iso.org/sites/policy/)); “CASCO. Conformity Assessment tools to support public policy” ([www.iso.org/sites/cascoregulators/index.html](http://www.iso.org/sites/cascoregulators/index.html)).

5. 2nd Triennial review of the operation and implementation of the Agreement on Technical Barriers to Trade, Annex 4, Decision of the committee on principles for the development of International Standards, guides and recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement, G/TBT/9, 13 November 2000.

## THE CONTEXT OF THE REGULATORY COOPERATION

### A short history of the development of ISO<sup>6</sup>

5. It is a common saying that standardization is “as old as the hills”. Indeed, even before the word standardization existed, a “*de facto* standardization” was used going as far back as Antiquity, for example in the field of construction. “Modern standardization” appeared in the 19<sup>th</sup> Century with industrialization. At the end of the 19<sup>th</sup> Century, and the very beginning of Globalization, the need for standards became international. The development of international communication networks was fostered by the creation of international unions such as the International Telecommunication Union<sup>7</sup> (ITU) in 1865. The International Electrotechnical Commission (IEC), created in 1906<sup>8</sup>, was the first international organisation entirely devoted to standardization. It was followed by the creation in 1930 of the International Standardization Association (ISA), which was the first international standardizing body with general competence. After World War II, the ISA was dissolved and a new organisation was created to take its place – ISO, founded on 23 February 1947.

6. ISO grew rapidly in the mid 1960’s. The opening of national markets revealed the prevalence of technical barriers to trade (until then hidden by tariffs), and the need for international standards to facilitate trade. The development of International Standards for freight containers in the 1960s is one important example of ISO standards contributing to the development of the global market (Box 1). At the same time, the adoption of the International System of Units facilitated technical dialogue at the international level and the development of new technologies required the rapid development of new standards. These changes in international context led to changes in the way standards were developed – until this point, international standardization had consisted mainly of the harmonization of existing national standards, but this increasingly shifted towards the direct development of standards at international level. At ISO, this change was reflected in a change of vocabulary: the result of ISO’s technical work, initially called a “recommendation”, took its current name of “international standard” in 1971. As stressed by the former Secretary-General Olle Sturen in 1975,

*« [a]s long as ISO published only Recommendations... ISO was hardly anything more than a federation of national bodies. With the publication of the ISO results as International Standards and the extension of the ISO contacts with intergovernmental organizations engaged in the harmonization of technical regulations in which reference could be made to ISO standards, ISO has started... to be directly involved in the international community – as an international specialized agency. » (ISO, 1997:60).*

#### **Box 1. The contribution of ISO standards to globalization – the case of freight containers**

Over the years, ISO standards have given important contributions to the world economy in many areas. One of the most significant examples is the international standardization of freight containers, considered a key enabling factor of globalization.

Nobel-prize winner economist Paul Krugman (2009) noted that: “The ability to ship things long distances fairly cheaply has been there since the steamship and the railroad. What was the big bottleneck was getting things on and off the ships. A large part of the costs of international trade was taking the cargo off the ship, sorting it out, and dealing with the pilferage that always took place along the way. So, the first big thing that changed was the introduction of the container.”

6. To learn more about ISO’s history: [www.iso.org/iso/home/about/the\\_iso\\_story.htm](http://www.iso.org/iso/home/about/the_iso_story.htm).

7. For more information on ITU’s history, s. ITU’s website: [www.itu.int/en/history/Pages/home.aspx](http://www.itu.int/en/history/Pages/home.aspx).

8. For more information on IEC’s history, s. IEC’s website: [www.iec.ch/about/history/](http://www.iec.ch/about/history/).

**Box 1. The contribution of ISO standards to globalization – the case of freight containers (cont.)**

ISO TC 104 “Freight Containers” was established in 1961 and the first series of ISO standards in this area was published in 1968. International standardization was indeed a critical factor for the development of the world transportation infrastructure that we know today, facilitating a coordinated effort of players as diverse as cargo, railway and truck transportation companies; public authorities responsible for transportation in many countries; along with port and railway operators. Something that no company or country could have ever achieved alone.

The outcome was phenomenal. Malcom Mc Lean,<sup>1</sup> the pioneer of intermodal transportation, once said:<sup>2</sup> “I talked to an old London dockhand some time back. He allowed as how in 1970 it took 108 guys about five days to unload a timber ship. Then came containerization. The comparable task today takes eight folks one day. That is, a 98.5% reduction in man-days, from 540 total to just eight.”

As noted in the ISO TC 104 business plan “today, the vast majority, in excess of 90%, of world trade in non-bulk goods, moves in ISO freight containers”.

1. Malcolm McLean is the visionary American businessman who brought to life the concept of intermodal transportation, based on the shipping container – i.e. the possibility of uploading and offloading freight from different vectors (ship, train, truck) in a seamless way. By providing a royalty free license to ISO of his patented designs (re: container dimensions and corner fittings) he gave a fundamental contribution to the development of containerisation.
2. Time Magazine, Asia, 22 May 2000.

7. An important milestone in the ISO history, marking the extension of the scope of ISO work from the technical/engineering domains to processes of general nature and management/organizational matters, was the publication in 1987 of the famous ISO 9001. ISO 9001, “Quality systems - Model for quality assurance in design, development, production, installation and servicing”<sup>9</sup> tackles the need for internationally-recognized quality management standards, for instance to help companies to assess the quality management of their suppliers and be able to get their supplies from other companies around the world. This ISO standard has been implemented by millions of organization worldwide. Another important milestone was the establishment of ISO/TC 207 “Environmental management” which focuses on finding technical solutions to ensure the protection of the environment. This committee was created in response to requests from the United Nations Conference on Environment and Development (UNCED), known as the Earth Summit, in its Rio de Janeiro declaration (1992).

**Area where ISO is operating and intended objectives of the regulatory cooperation**

8. The purpose of ISO is broadly defined in Article 2 of its Statutes and “shall be to promote the development of standardization and related activities in the world with a view to facilitating international exchange of goods and services and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity.”

9. ISO defines standardization as the “activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context”.<sup>10</sup> Nevertheless, standardization is not an easy notion to explain and it is often misunderstood and misrepresented. It is easier to have a pragmatic approach to it, as illustrated by this

9. The 2015 edition of ISO 9001 is entitled “Quality management systems – Requirements”.

10. ISO/IEC Guide 2:2004:4.

message from the Presidents of IEC and ISO and the Secretary-General of ITU on the occasion of World Standards Day in 1998:

While we normally don't think about standards unless their absence causes inconvenience, it would be extremely difficult in fact to imagine daily life without standards. Take any scenario, and you will be amazed just how many standards support that aspect of daily life. From the moment you wake, throughout the day, standards in some form are helping to shape your day, to make it easier, more comfortable, safer, and simply more convenient. Imagine, for example, not being able to withdraw money from an automated telling machine (ATM) because your bank card is too big to fit in the slot; imagine batteries that will not fit any of your electrical equipment; stores without barcodes to quantify and price stocks of goods; imagine Internet sites without standardized domain names. The truth is that a day without standards is inconceivable. (IEC, ISO, ITU, 1998)

10. Characteristics of goods produced by different companies in diverse countries do not spontaneously match and, even if they do, the “*de facto* standard” might be imposed by the dominant market player and jeopardise competition. ISO offers a forum for all stakeholders to develop and agree on common standards so that technical requirements are harmonized worldwide and contribute to an open and safe world market.

11. Like a lot of other IOs, the scope of ISO's activities has expanded over the years (OECD, 2016). One of the primary objects of standardization is to rationalize production through the adoption of common standards to “simplify, unify and specify”. This allows the removal of unnecessary or duplicative manufacturing in favour of the “best” products, and promotes the interchangeability of spare parts, especially at the international level. Thus, the material scope of standardization was initially confined to the industrial sector. It has since expanded considerably and today encompasses many other sectors, related to management, services, health, environment and more. This shift can be traced back to the 1970's, when ISO started to include quality requirements in standards. Later standards further evolved to focus not only on the quality of the *outputs* of production, but on the *production system* itself. Hence, standardization not only aims to rationalize production, but also to increase production quality, including in terms of sustainable development or environmental considerations. What's more, this sort of technical cooperation can only be achieved if the experts developing the standards use a common terminology, which is why ISO also develops so-called “fundamental standards” in areas such as units and measurement, a domain also covered by other IOs, in particular OIML<sup>11</sup>.

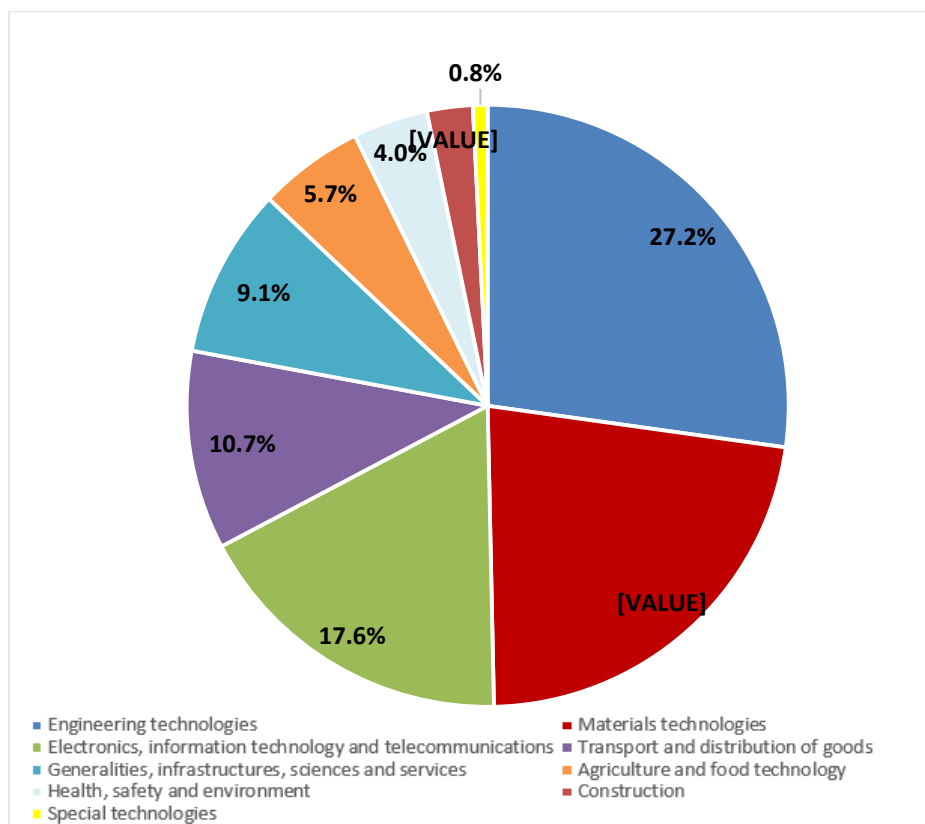
12. As of the beginning of 2016, ISO had published more than 20 500 International Standards and related documents, covering almost every part of daily life and a wide variety of sectors<sup>12</sup>, including agriculture, construction, mechanical engineering, manufacturing, distribution, transport, healthcare, information and communication technologies, the environment, energy, safety and security, quality management, and services<sup>13</sup> (Figure 1).

11. See Case study.

12. To learn more about standards, s. the section “ISO Standards in Action” on the ISO's Website: [www.iso.org/iso/home/news\\_index/iso-in-action.htm](http://www.iso.org/iso/home/news_index/iso-in-action.htm).

13. For the list of the existing Technical Committees and the area they cover, s. ISO's Website: [www.iso.org/iso/home/standards\\_development/list\\_of\\_iso\\_technical\\_committees.htm](http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees.htm).

Figure 1. Portfolio of ISO publications



Source: ISO in Figures 2015.

13. This wide range of International Standards is used by both private sector companies looking for technical solutions and public sector authorities as an input to technical regulations and in support of other public policy objectives (Box 2).

**Box 2. ISO standards and public policy**

ISO standards are voluntary. There is no obligation for ISO's Members to adopt them nationally or for a State to make them mandatory by referencing them in legislation, nor any obligation for any private person to conform to them. Nevertheless, International Standards and public policy often share similar objectives, such as enhancing economic competitiveness and efficiency, and facilitating international trade. Moreover, the use of ISO International Standards in technical regulations is consistent with the obligations of WTO members to reduce technical barriers to trade. For all of these reasons, ISO standards can be useful tools for supporting public policy initiatives, including legislation or technical regulations, and also other kinds of public policy decisions or actions such as in public procurement, incentive systems, or awareness campaigns. A reference to an International Standard in a public policy document can take a number of forms:

**Box 2. ISO standards and public policy (cont.)**

- It can be **direct** - the international Standard is directly quoted within a legal text using its identification number and title;
- It can be **indirect** - a list of standards deemed suitable by the regulator is compiled and published as an official information source external to the regulatory text;
- It can be **dated** - only a particular edition of a standard is used;
- It can be **undated** – the latest edition of the standard in question is used.

Depending on the form of the reference, the use of the referenced International Standard can be made **mandatory** or **optional**.

It is important to underline that using ISO International Standards in legislation does not imply any delegation of power to ISO or any of its members. Regulators still have the power to change or update their legislation at any time or to delete a reference if the standard loses its validity for the relevant legislation.

## **Landscape of international and domestic regulatory actors in this area and IO position in that landscape**

### *International, regional and domestic standardization bodies*

14. Although ISO is the world’s largest developer of voluntary International Standards and the international organisation entirely devoted to standardisation that deals with the broadest range of topics, it is not the only international standards-setting body. On the contrary, international standardization is a crowded field. Already in 1977, the ISO/CS underlined in the first edition of the *Directory of international standardizing bodies* that “there is a large variety of international organisations as far as their memberships, legal status, nature and scope of activities are concerned. In addition, ad hoc or continuous relations between organisations and their subsidiarity bodies considerably complicate the international infrastructure of standardization as at present constituted” (ISO, 1977). At the time, the ISO/CS already listed more than 40 bodies involved in international standardization, while recognizing that the list was not comprehensive.

15. Firstly, the IEC, ISO’s “electric sister organisation” (FRONTARD, 1973) should be mentioned. It was created in 1906 and is one of the oldest international organisations. Similar to ISO, it is a Swiss-based association recognized as a quasi-governmental organisation by the Swiss federal government. Secondly, there are many other intergovernmental organisations that also conduct standardization work, such as: the ITU (Telecommunications), the OECD (Fruits and Vegetables), Codex Alimentarius (food safety), the International Civil Aviation Organization (ICAO) (Aviation), the Universal Postal Union (UPU) (Postal Services), the United Nations Economic Commission for Europe (UNECE) (trade), the International Organisation for legal Metrology (OIML) (Metrology), and the North Atlantic Treaty Organization (NATO) (Military equipment). Recent years have also seen the emergence of new actors in standardization, which develop what is sometimes referred to as “private international standards” (ISO, 2010a). Their status and effect on global trade has been the subject of much discussion in a lot of

intergovernmental organisations, especially in the WTO. The number<sup>14</sup> and diversity of these private bodies makes it difficult to generalize about them or to develop a comprehensive understanding of their impact. In addition, standards can also be developed by industry, pioneers or dominant players in a field, or by a consortium of industry. Such standards can also be *de facto* used as ‘international’ standards.

16. Last but not least, almost all regional groupings have their own regional standard-setting bodies: the ASEAN Consultative Committee for Standards and Quality (ACCSQ), the Arab Industrial Development and Mining Organisation (AIDMO), the African Regional Organisation for Standardization (ARSO), the European Committee for Standardization (CEN), the Pan-American Standards Commission (COPANT), the Euro-Asian Council for Standardization, Metrology and Certification (EASC), the Pacific Area Standards Congress (PASC), and the South Asian Regional Standards Organization (SARSO).

### ***Co-operation between ISO and other international standard-setting bodies***

17. ISO cooperates with over 700 international actors<sup>15</sup>, including the UN and its specialized agencies. Regarding the UN, ISO has general consultative status with the UN Economic and Social Council (ECOSOC) and equivalent status with nearly all other bodies and specialized agencies of the UN system. This recognition is the key to ISO’s strong position within the crowded field of international standardization and has been cultivated by the organisation itself – for example, as early as the 1970’s, the ISO Council decided “that ISO should continue to overcome problems of conflict of competence with other international organisations through direct contacts with the latter” (ISO Council Resolution 59/1974 – “LORCO Recommendation 2”). This cooperation also aims to promote standardization, avoid duplication of work and conflicting international standards, take into account the expertise of its international partners, and help build capacity in developing countries to enhance their participation in ISO’s work.

18. Cooperation takes place in different ways and at different levels of governance: ISO can participate in the work of another IO as an observer or “liaison”, depending on the governance arrangement of the IO and ISO’s status in it; while external organisations can participate in ISO’s technical work as liaisons to ISO’s technical committees if they meet the qualification criteria, in accordance with the ISO/IEC Directives<sup>16</sup>. ISO has also created a joint committee with IEC, the ISO/IEC Joint Technical Committee (JTC) 1 on “Information technology”, and participates in joint committees with several other organisations, such as the BIPM in the case of the Joint Committee for Guides in Metrology (JCGM)<sup>17</sup>. Cooperation is sometimes facilitated by a Memorandum of Understanding (MoU) (ISO has 67 MoUs, as of July 2016) providing, notably, for the systematic exchange of information. The most intense cooperation takes place with ITU and IEC, ISO’s sister organisations. Together they created an informal entity, the World Standards Cooperation (WSC)<sup>18</sup>, to promote the worldwide visibility of international consensus-based standardization and related conformity assessment matters, for example, via the creation of a World Standards Day, celebrated each year on October 14<sup>19</sup>.

14. For instance, the International Trade Center (ITC) already took an inventory of over 170 Standards only in the field of sustainable trade: [www.standardsmap.org](http://www.standardsmap.org).

15. For a list of those organisations: [www.iso.org/iso/home/about/organisations\\_in\\_liaison.htm](http://www.iso.org/iso/home/about/organisations_in_liaison.htm)

16. s. below « Participation of non-members ».

17. For more information on the JCGM, s. [www.bipm.org/en/committees/jc/jcgm/](http://www.bipm.org/en/committees/jc/jcgm/).

18. For more information on the World Standards Cooperation, s. the WSC’s website: [www.worldstandardscooperation.org/](http://www.worldstandardscooperation.org/).

19. The World Standards Day was first created by the ISO Council Resolution 33/1978.

19. ISO also has institutional links with regional and sub-regional standards organisations. Eight Organisations have been recognized by the ISO Council: ACCSQ, AIDMO, ARSO, CEN, COPANT, EASC, PASC and SARSO. Such recognition is possible only for regional organisations consisting of national standards bodies, where at least 50% of their members are ISO full or correspondent members and where there is a commitment to endeavour “as a matter of principle to fully rely on and support international standardization, and to use International Standards whenever possible as the basis for its own standards work”<sup>20</sup>. In addition, five organisations are recognized as sub-regional organisations: CARICOM Regional Organisation for Standards and Quality (CROSQ), the East African Community (EAC), The Economic Community of West African States (ECOWAS), GCC Standardization Organisation (GSO) and the Southern African Development Community (SADC)<sup>21</sup>. ISO establishes regular working relations with these recognized organisations, notably by participating in general meetings of the regional organisations, and inviting them to attend ISO General Assemblies as observers.

20. ISO also has agreements with some of these regional organisations, such as AIDMO, COPANT, EASC and PASC. These agreements usually provide for cooperation by correspondence and through mutual representation and allow the adoption by one organisation of available publications from the other organisation under certain conditions. The most extensive cooperation is the one with CEN, under the Vienna Agreement of June 1991<sup>22</sup> (*Agreement on technical co-operation between ISO and CEN*, last revised in September 2001).<sup>23</sup> Specific features of this agreement include the possibility to define an agreed allocation of work and to have parallel approval of standards in ISO and CEN, in order to better meet the special needs of the Single European Market.

- 20. ISO Council Resolution 26/1992 – “Relations with regional standards organisations New policy”.
- 21. ISO Council Resolution 34/2011 – “Sub-regional organisations – Criteria for enhancing collaboration”.
- 22. The cooperation can be trace back 1989 and the agreement on the exchange of technical information between ISO and CEN (called the Lisbon Agreement).
- 23. For more information on the Vienna Agreement, s. ISO’s Website: [www.iso.org/va](http://www.iso.org/va).

## MAIN CHARACTERISTICS OF REGULATORY COOPERATION IN THE CONTEXT OF ISO

### Governance arrangements and operational modalities

21. The hybrid nature of ISO offers an important advantage: the ISO Statutes can be more easily modified by ISO's General Assembly (GA) than an international treaty. This allows ISO to adapt its governance to the changing needs of the world. And indeed, over the years, the ISO Statutes have been amended several times, new organs have been created or dissolved, and new membership categories have been created, notably to facilitate the access of developing countries to the ISO system. The most striking example of reform undertaken by ISO since its creation might be the composition of the Council. In 1947, there were only 11 members sitting on the Council and 5 of them (China, United States, France, United Kingdom and USSR) were permanent members<sup>24</sup>. This historical privilege was removed in 1951 and replaced in 1994 by a more balanced economic and geographic representation of the members on Council.

### *Membership and participation*

22. ISO membership is strictly limited to one national standards body per country, regardless of their legal nature (public or private). Other entities (individuals, companies, IOs, etc.) may participate in the development of ISO standards through their national standards bodies (as stakeholders or experts), or through international organizations (IOs or NGOs) in liaison with ISO committees.

### *Membership*

23. ISO is a network of NSBs with, as of June 2016, 163 members (119 Member bodies, 40 Correspondent members, 4 Subscriber members), ensuring a wide geographic representation<sup>25</sup>.

24. The nature of ISO's members is much more eclectic than other IOs (in particular in comparison with classical IGOs). They can be governmental as well as non-governmental, public or even private. This indifference of ISO toward the legal status of its members preserves the freedom of each country to organize standardization at the domestic level to best suit their needs and as a function of the human and financial resources available. Although ISO's members are not States (like with traditional IGOs), the NSBs that are ISO's members nevertheless represent their countries. According to article 3 of the ISO Statutes, there can only be one member per country and "the member bodies shall be those national standards bodies most broadly representative of standardization in their respective countries". The most representative body is not always a public one. In fact, about 80% of ISO members are governmental or public entities, and the remaining 20% are private or semi-private entities. However, the vast majority of these private bodies have some kind of institutional link (a law or other legal instrument, a contract, a MoU) with their government. Thus, even if these bodies were created by private persons (often engineers), and are organized as private entities (often as national not-for-profit associations or companies), their mission is nevertheless recognized, sometimes implicitly, as having a public interest function. Consequently, they are usually given privileges to pursue their public interest mission, such as fiscal privileges, a monopoly on the label "national standard", or state subventions. The legal instruments regulating these bodies usually give them the authority to represent the country in international standardizing bodies such as ISO.

24. Constitution and Rules of Procedures, July 1947.

25. To see the evolution of ISO membership over the years, s. ISO, Historical record of ISO membership since its creation (1947), [www.iso.org/iso/historical\\_record\\_of\\_iso\\_membership\\_1947\\_to\\_today.pdf](http://www.iso.org/iso/historical_record_of_iso_membership_1947_to_today.pdf).

25. Of course, all ISO members whether public or private, have the same obligations toward ISO, depending of their type of membership. There are three categories of membership in ISO. Each enjoys a different level of access and influence over ISO's system<sup>26</sup>:

- Member bodies: As “full members”, they can participate and vote in ISO technical and policy meetings and may become members of the Council or the TMB, the two main non-plenary governance organs of ISO. They are allowed to sell and adopt ISO International Standards nationally and can participate in all ISO technical committees (TC) as active members (P-members) or observers (O-members).
- Correspondent members and Subscriber members: These categories are similar to the so called “observers”, “associates” or “affiliates” in other IOs. As members with limited rights, *Correspondent members* and *Subscriber members* may attend the GA with no voting rights<sup>27</sup>. Only correspondent members may receive all ISO publications, attend policy<sup>28</sup> and technical meetings<sup>29</sup> as observers, and sell and adopt ISO International Standards nationally. The two status were created in 1964<sup>30</sup> and 1992<sup>31</sup> respectively, to facilitate the participation of developing countries in ISO and were designed as stepping stones on the way to becoming Member bodies. In an effort to further facilitate their transition, the ISO Council has approved a pilot program to exceptionally allow them to actively participate in a maximum of five committees, with full commenting and voting rights, for the period 2014-19.

#### *Participation of non-members*

26. Some actors, other than national standards bodies, can also take part as non-members in ISO activities.

- Individuals or companies: They cannot become ISO members. They can however participate as experts or stakeholders as part of a national delegation or in the national mirror committees of ISO's Members.
- International organisations: There is no general status of observer for other IOs. Nevertheless, some of them are often invited to participate as observers in the annual General Assembly. Moreover, they can become “liaison organisations” with ISO/TCs and participate in the development of ISO International Standards. Applications to become a liaison organisation are approved by the P-members of the relevant TC. Organisations must meet certain criteria in order to become a liaison organisation with an ISO committee, for example, the organisation must be not-for-profit, membership-based, open to members worldwide or over a broad region, and sufficiently representative within the field of the technical work in question. The organisation

26. For more information on the rights, benefits and obligations of ISO's members, see the “ISO membership manual” ([www.iso.org/iso/iso\\_membership\\_manual.pdf](http://www.iso.org/iso/iso_membership_manual.pdf)). To see the list of all ISO members: [www.iso.org/iso/home/about/iso\\_members.htm](http://www.iso.org/iso/home/about/iso_members.htm).

27. s. Article 6.8 of the ISO Statutes.

28. ISO Council Resolution 35/1984 – “*Participation of correspondent members in Council committees*”.

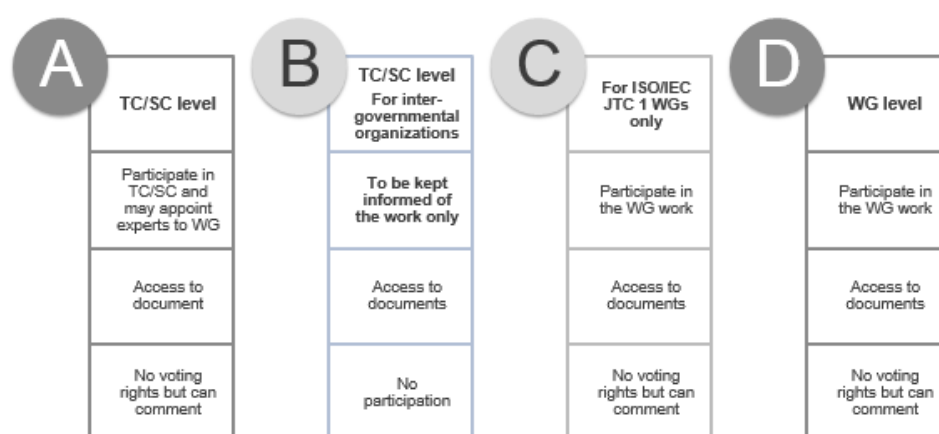
29. ISO Council Resolution 14/1965 – “*Rights of Correspondent Members*”; ISO Council Resolution 24/1967 – “*Correspondent Members*”.

30. ISO Council Resolution 40/1964 – “*DEVCO – Associated bodies and correspondents*”.

31. ISO Council Resolution 30/1992 – “*Third category of ISO membership “subscriber membership”*”.

must accept the policies of ISO, including those related to copyright and the procedures for standards development. To this end, it must have a process for stakeholder engagement and consensus decision-making to develop the input it provides to ISO<sup>32</sup>. There are four categories of liaisons (Figure 2). Category B is reserved for IGOs, although they can also apply in the other categories. In 2015, 702 international organisations (in the broadest sense of the term) were in liaison with ISO committees<sup>33</sup>. For instance, WHO participates in 57 TCs, the OECD in 28, the OIML in 48, UNECE in 74, FAO in 39 and the Codex Alimentarius Commission in 22.<sup>34</sup>

**Figure 2. Categories of liaison organisations**



Source: Based on ISO/IEC Directives Part 1 (7<sup>th</sup> edition, 2016), clause 1.17; [www.iso.org/sites/directives/2016/consolidated/index.xhtml#\\_idTextAnchor094](http://www.iso.org/sites/directives/2016/consolidated/index.xhtml#_idTextAnchor094).

### Structure of the organisation

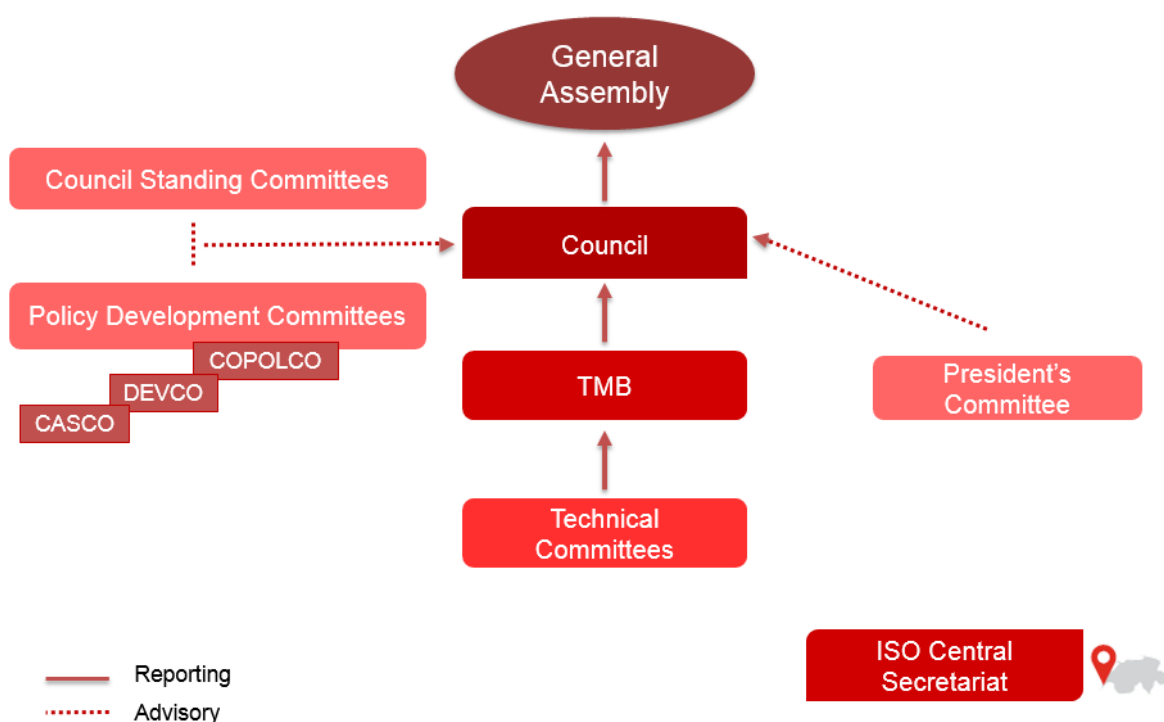
27. At first glance, ISO has a classical governance structure with a supreme plenary organ (the General Assembly), an executive organ (the ISO Council) and a Central Secretariat. However, it does have original features related to the fact that ISO is a decentralized member-driven organisation - for example, the Central Secretariat is a light structure and the technical work does not take place at the ISO/CS in Geneva, but rather in the TCs, with the committee secretariats provided by the ISO members. Given the technical purpose of the organisation and the complexity of the issues that ISO deals with, particular attention is also given to the composition of the governance organs in order to ensure a balance between representativeness and efficiency.

32. ISO/IEC Directives part 1, clause 1.17.1

33. For more information on liaison organisations, s. ISO/IEC Directives, § 1.17.

34. For a full list of the organisations in liaison with ISO's TC, s. [www.iso.org/iso/home/about/organisations\\_in\\_liaison.htm?filter=ALL](http://www.iso.org/iso/home/about/organisations_in_liaison.htm?filter=ALL).

Figure 3. ISO governance structure



Source: Based on [www.iso.org/iso/home/about/about\\_governance.htm](http://www.iso.org/iso/home/about/about_governance.htm).

28. According to Article 5 of the ISO Statutes, the Organisation is composed of Organs (a General Assembly, a Council, a President’s Committee, a Technical Management Board, technical committees, and a Central Secretariat) and Officers (a President, including when serving as President-elect, three Vice-Presidents, a Treasurer, and a Secretary-General).

*The General Assembly (Article 6 of the ISO Statutes)*

29. The GA is the organisation’s ultimate authority. As any supreme organ within an IO, it is plenary and is thus composed of all the members, but also of the ISO Officers. Each Member body, as a full member, has one vote. Correspondent and subscriber members may attend the GA as observers, without voting rights. It meets only once a year in order to adopt the financial and moral statements of the Organisation, elect or appoint the President, the Vice-Presidents, the Council members and the financial auditors of the Organisation’s accounts. It also approves the annual ISO membership fees and the ranking criteria for Council membership. It can also amend its own Rules of Procedure (Article 22.2 of the ISO Statutes) and the Statutes following the procedures laid down in Article 21 of the ISO Statutes.

*The ISO Council (Article 7 of the ISO Statutes)*

30. The ISO Council manages most governance issues in accordance with the policy laid down by the Member bodies, to which it reports every year during the GA. The Council is composed of 20 Member bodies (“full members”)<sup>35</sup>, the ISO Officers and the Chairs of the Policy Development Committees. The composition of the Council aims at ensuring a balance between representativeness and efficiency, as well as a balance between economic and geographic representation. Council members are elected or appointed by the GA using a ranking of ISO Member bodies. The ranking criteria are set by the Council, approved by the GA and are reviewed for confirmation or revision at least every three years<sup>36</sup>. Currently the ranking criteria “reflect the size of the economies of their countries and the degree of their involvement in ISO’s technical work, both quantitatively and qualitatively” and hence take into consideration the financial contribution to the organisation, the number of technical committee secretariats and the number of P-memberships in committees<sup>37</sup>. The GA should also take into account the Member body’s good standing and the background of the nominated Member body representatives. The Council membership should also reflect the geographic and industrial diversity of ISO members.

31. The Council normally meets twice a year<sup>38</sup> and works in between meetings by voting on issues by correspondence. The Council decides on the organisation’s strategy and how this strategy will be implemented (including how to monitor and measure implementation of the strategy). It makes decisions related to the ISO Central Secretariat (its budget, appointment of the Secretary-General and defining the scope of its work), members (new member bodies’ applications, member exclusions), the TMB (it approves the ranking criteria for TMB membership and appoints TMB members), and the Treasurer (appointment). The Council can also establish committees that provide guidance and management on specific issues. In 2016, there are two standing committees<sup>39</sup> advising on financial (Council Standing Committee on Finance) and strategic (Strategy and Policy Committee) matters and three Policy development committees (PDC)<sup>40</sup> providing guidance on conformity assessment (CASCO), consumer issues (COPOLCO) and matters related to developing countries (DEVCO).

*The ISO Officers (Article 5.2 of the ISO Statutes)*

32. There are several ISO Officers: a President (including when serving as President-elect), three Vice-Presidents, a Treasurer, and a Secretary-General. They provide leadership to the members within the scope of their responsibilities and are ISO’s public figures. Like traditional IOs, they must be citizens of a country with an ISO Member body<sup>41</sup>. Since 2012, the ISO Officers form the President’s Committee, which

35. The current Member bodies on Council are: Armenia (SARM), Botswana (BOBS), China (SAC), Czech Republic (UNMZ), Denmark (DS), France (AFNOR), Germany (DIN), Italy (UNI), Japan (JISC), Korea, Republic of (KATS), Mexico (DGN), Norway (SN), Russian Federation (GOST R), Singapore (SPRING SG), Slovenia (SIST), South Africa (SABS), The Former Yugoslav Republic of Macedonia (ISRM), Turkey (TSE), United Kingdom (BSI), United States (ANSI).

36. *Rules of Procedure of the General Assembly*, Clause 2.1.1.

37. For more information on P-Membership, s. *infra* “*Technical Committees*”, s. also General Assembly Resolution 15/2015 – “*Endorsement of ranking criteria for election to Council*”.

38. Although clause 2.4 of the Rules of Procedure of the Council envisage « normally three times each year ».

39. Article 7.6 of the Statutes.

40. Article 7.5 of the Statutes.

41. This is not a formal requirement only for the SG but in practice ISO’s SG always came from a country which had a member body.

advises the Council and reports to it, oversees the implementation of the decisions taken by the Council and the General Assembly<sup>42</sup> and acts as a Nominating Committee. The Officers are also responsible for coordination among the different ISO organs and the Council.

33. Each Officer's mission was clarified in 2012 with the drafting of profiles<sup>43</sup>:

- *The President*<sup>44</sup> is elected for a two or three-year term by the Member bodies, either at the GA or by correspondence, preceded by one year as President-elect. The President chairs the GA, the Council and the President's Committee. He or she can establish *ad hoc* advisory groups upon Council's consent and reviews the performance of the Secretary-General and top-level managers.
- There are three *Vice-Presidents* appointed by the GA for a two-year term: the Vice-President policy who chairs the Strategy and Policy Committee, the Vice-President technical management who chairs the Technical Management Board and the Vice-President finance<sup>45</sup>, who chairs the Council Standing Committee on Finance. These three Vice-Presidents allow coordination among the three main organs reporting to the Council. In addition, the Treasurer acts as trustee for the funds of the Organization and advises Council on all financial matters.
- *The Secretary-General* is the chief executive officer of the Organisation and the head of the Central Secretariat. He or she conducts the affairs of the Organisation on a day-to-day basis and is appointed by the Council for a five-year term of office, renewable once.

34. The President is elected one year before the end of the term of the previous President. During this year the President-elect can attend the meeting as an observer in order to become familiar with ISO and its on-going issues. The same system has been implemented for the first time in 2016 for the Vice-President technical management. The Vice-President elect technical management participates as an observer in at least two TMB meetings and the last President's Committee meeting before taking office. This system allows for more continuity in the work of ISO.

#### *The Central Secretariat (Article 11 of the ISO Statutes)*

35. Because of the heavily decentralized structure of ISO, the role of the ISO/CS is mainly a coordination function, to ensure that all of the components of the ISO system work in a consistent manner. The ISO/CS is located in Geneva and comprises approximately 140 staff members led by the Secretary-General. It supports the work of the political and technical organs of ISO and makes sure that the procedures, especially the procedures on standards development, are respected. The ISO/CS is also responsible for the publication of all ISO deliverables.

42. Article 8 of ISO Statutes.

43. Subsequently amended under Council Resolutions 18/2013 and 25/2014.

44. Article 12 of ISO Statutes.

45. Article 14 of ISO Statutes.

*The Technical Management Board (Article 9 of the ISO Statutes)*

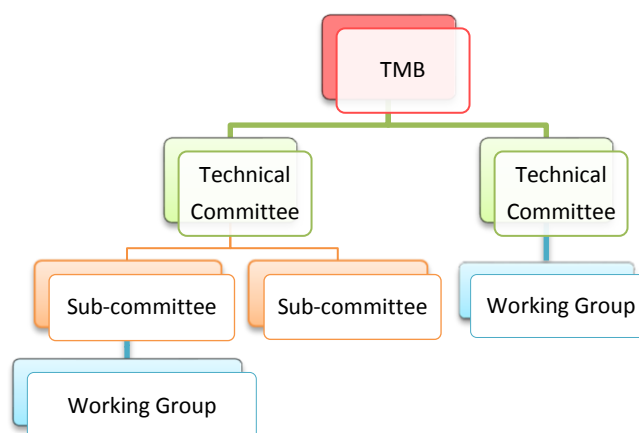
36. The TMB manages the technical work of ISO. The TMB is composed of 15 Members<sup>46</sup> appointed or elected by the ISO Council according to a ranking system, which should reflect the “responsibility and productivity within the technical committee structure”<sup>47</sup>, as well as the geographic and industrial diversity of ISO members, the Member body’s good standing and the background of the nominated Member body representatives. The TMB holds three meetings a year. Between meetings decisions are made by correspondence using the electronic balloting system. Acting as a coordinator for ISO’s technical work, it approves the establishment and dissolution of TCs, defines their titles and scopes, appoints committee chairs, coordinates the overall coherence of the technical bodies (merging of TCs<sup>48</sup>, assigning new fields of work to new or existing TCs, *etc.*), and monitors and assesses their performance<sup>49</sup>. In addition, the TMB is responsible for the review and revision of the ISO/IEC Directives – the rules and procedures for standards development.

*The Technical Committees (Article 10 of the ISO Statutes and ISO/IEC Directive, clause 1.5)*

37. The decentralized structure of ISO is one of its specific features. The technical work takes place within TCs, whose secretariats are provided by ISO’s members, and managed and coordinated by the TMB (Figure 4). The meetings of TCs and their Sub-committees (SC) take place all around the world. For example, in 2015, 37 Member bodies provided the administrative and technical services for the secretariats of 3535 technical bodies, comprising 238 TCs, 521 SCs, 2625 working groups (WG) and 151 *ad hoc* study groups. These services involve a full-time staff equivalent to 500 persons. 2468 technical meetings were held in 50 different countries with an average of 23 technical meetings each working day of the year somewhere in the world (ISO, 2016a). TCs/SCs are open bodies: each Member body (full member) interested in the subject-matter dealt with by an established TC/SC can become an active member (P-member) or an observer (O-member), depending on how much that member wants to get involved in the work of the committee. Correspondent members may register as observers, but without commenting or voting rights. As previously highlighted, since 2014, as part of a pilot project approved by the ISO Council, correspondent and subscriber members may participate as full P-Members in a maximum of 5 TC/SCs.

- 46. The current TMB members are: ABNT (Brazil), AFNOR (France), ANSI (USA), BSI (United Kingdom), DIN (Germany), DSM (Malaysia), GOST (Russian Federation), JISC (Japan), KATS (Republic of Korea), SA (Australia), SABS (South Africa), SAC (China), SIS (Sweden), SFS (Finland), SNV (Switzerland).
- 47. Rules of Procedures of the Council, Clause 4.1.
- 48. Often the criteria for the merger of several TC is the fact that they have identical stakeholders.
- 49. s. *infra* “Assessment of the impact and success of regulatory cooperation”.

Figure 4. Technical management of ISO



Source: Author.

38. As already mentioned, TCs are established and dissolved by the TMB. Each TC is responsible for the development of standards within a pre-defined subject field (delimited by its scope). A proposal for a new field of work may come from a national body, a TC/SC, a PDC, the TMB, the SG, a certification body or another organisation. A new TC can only be established if 2/3 of the voting ISO Member bodies (full members) are in favour and at least 5 of them commit to participate actively. The TMB might also decide to assign the work to an existing TC or to create a Project Committee (PC) for a single project, not falling within the scope of an existing TC. A PC is usually dissolved once it publishes its standard. TCs can establish subcommittees (SCs) by a 2/3 majority decision of the P-members of the TC, and this decision needs to be ratified by the TMB. The secretariat of a TC is allocated to a Member body by the TMB and the secretariat of a SC by the parent TC. TCs and SCs can also establish WGs (*ISO/IEC Directives Part 1*, clause 2.4) where the experts come together to draft the standards (s. *infra* “Form of IRC”).

39. Each TC/SC is chaired, for a maximum of 9 years, by an expert in the field<sup>50</sup>. Working groups are chaired by convenors<sup>51</sup> and each project is led by a Project leader<sup>52</sup>. Chairs<sup>53</sup> and Secretariats<sup>54</sup> must act in an international capacity, hence a Chair cannot serve concurrently as the delegate of a national body in his or her own committee. Chairs, Project leaders, Secretaries and Conveners must remain neutral, act as facilitators to reach consensus among the experts/ISO members, and not try to influence the work of the committee<sup>55</sup>. In 2016, the role of Chair-elect was introduced to ensure more continuity in the leadership of

50. In the case of a TC, the Chair is nominated by the Member body holding the TC secretariat and is approved by the TMB. In the case of a SC, the Chair is nominated by the Member body holding the SC secretariat and approved by the TC (by a 2/3 majority decision of voting P-Members).

51. *ISO/IEC Directives Part 1*, clause 1.12.

52. *ISO/IEC Directives Part 1*, clause 2.1.8.

53. *ISO/IEC Directives Part 1*, clause 1.8.2.

54. *ISO/IEC Directives Part 1*, clause 1.9.2.

55. To better understand the role of the different people leading the technical work : ISO, 2015b; *ISO/IEC Directives Part 1*, Annex SQ “Selection criteria for people leading the technical work”; Annex SS.2 “Tips for Convenors and Project Leaders when proposing to skip the CD stage”; Annex SS.3 “Tips for committee Chairs and Secretaries”.

the TC/SCs and to “provide the new chair elected an opportunity to learn before taking over as chair of a committee”<sup>56</sup>.

### *Decision-making process*

40. Consensus is the key principle underlying decision-making in the ISO system and it is one of the main tasks of ISO committee leaders to be able to build consensus, and to recognize when consensus has been achieved. Of course, there are also many instances, particularly with regard to the progress of the technical work, where the ISO/IEC Directives set out specific criteria for approval of decisions (for example simple majority vote or 2/3 majority vote), and decision-making processes also vary slightly amongst the various governance bodies, depending on their functions and working methods, as described below.

41. Except for amendments to the Statutes that require a “super Majority” of three-fourths of the Member bodies, decisions at the GA and Council meetings are taken by a simple majority vote of the members.<sup>57</sup> The decisions of the TMB adopted by correspondence are taken by a 2/3 majority or by relative majority in case of proposals with multiple alternatives. During meetings, “every effort shall be made to reach consensus”<sup>58</sup> and most decisions are taken without a formal vote. Moreover in the Council and the TMB, members are supposed to represent the interests of the ISO community as a whole, and not take into consideration their national interests.<sup>59</sup>

42. In the three Policy development committees, decision-making processes are diverse. Decisions are taken in COPOLCO by consensus except in cases of formal votes on Guides (this latter case follows the process outlined in the ISO/IEC Directives). CASCO, on the other hand, functions much more like a TC, following the ISO/IEC Directives in its procedures. DEVCO’s Resolutions are taken by consensus (without voting) to soften the distinction between P and O-members, given the fact that a lot of developing countries are O-members.

43. In the technical work, the decision making process must ensure a wide acceptance of the content of the standard, with an International Standard requiring a “double layer of consensus”, firstly among the experts (in the WG), and secondly among the Member bodies (at the TC/SC level and Publication stage). In the ISO System, consensus is defined as a “general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments”.<sup>60</sup> It is the responsibility of the conveners (preparatory stage) or the Chair of the TC/SC (committee stage) to assess if consensus has been reached and to decide to move forward to the next step, in cases where no formal vote is required. Secondly, for stages where a vote is required, the approval criteria are set to reflect a wide acceptance among the ISO members. For instance, an International Standard is approved only if a two-thirds majority of voting P-members of the TC/SC is in favour and not more than one-quarter of the voting ISO members cast a negative vote.

56. *ISO/IEC Directives Part 1, clause 1.8.1.*

57. Rules of Procedure of the General Assembly, clause 1.8, Rules of Procedures of the Council, Clause 2.11.

58. TMB Working procedure, clause 4.

59. Rules of Procedure of the Council, clause 2.7; Rules of Procedure of the TMB, clause 3.

60. *ISO/IEC Guide 2:2004.*

44. Hence, a standard is approved by the members that actively participate in the development of the standard and whose stakeholders have the market need for the standard, i.e. the P-members, but can nevertheless be blocked by a minority of ISO Member bodies (full members). These two combined parameters ensure that the published standard is well accepted on an international level. Moreover, Member bodies have recourse to an appeals mechanism if they feel strongly that ISO rules and procedures have not been correctly applied or if there could be serious negative consequences as a result of a committee's actions or inactions (in particular when they are not "in the best interests of international trade and commerce, or such public factors as safety, health or environment")<sup>61</sup>.

45. Additionally, in the technical field, negative votes must be technically justified to be valid. If no justification statement is provided, the negative vote is not registered. This requirement ensures a more constructive vote and facilitates the attempts to resolve negative votes and achieve consensus. Secretaries must take all comments into account or give a justification for why they reject a comment.

46. Both on the political and technical field, votes can be cast by correspondence, using an online balloting system. It is also sometimes possible to take part in meetings via WebEx. This facilitates the participation of all, especially developing country members and stakeholders, who cannot always afford the travel expenses. As far as ISO governance bodies are concerned, the GA and the Council adopt most of their decisions during meetings, while the TMB adopts around 100 decisions per year by correspondence. In the technical committees, a large majority of decisions are taken by correspondence. With an average of 7500 votes per year, the online balloting system is a key resource for facilitating decision-making in ISO and fostering the most widespread participation possible.

### ***Budget and dedicated staff***

47. The decentralised structure of ISO has a direct impact on the financing of ISO and its technical work. The resources of ISO do not only come from membership fees and are not only managed by the ISO/CS – for example, the financial and material resources provided and managed by the members hosting the committee secretariats form a significant contribution to the ISO system. Additionally, ISO also gets some resources from the sale of standards.

### ***Dedicated staff***

48. In 2015 over 137 people were working full time for the ISO/CS in Geneva. But this is just the tip of the iceberg since, as underlined, ISO is a decentralised organisation and relies strongly on its members, especially to conduct the technical work: in 2015, 37 Member bodies provided the administrative and technical services for the secretariats of 3535 technical bodies. These services involve a full-time staff equivalent to 500 persons. In addition, thousands of experts participate in the development of standards and in ISO meetings. On average 23 meetings were held somewhere in the world each working day of the year (ISO, 2016a).

### ***Budget***

49. The business model of ISO is one of the specific features of the organisation. Given the decentralized structure of ISO, it is important to distinguish the budget of ISO/CS from the budget of the members and the costs of running the TCs. The administrative work involved in running a TC is financed

61. *ISO/IEC Directives Part 1*, clause 5.1.2.

by the member providing the secretariat.<sup>62</sup> Costs of TC meetings are often financed by the member hosting the meeting (sometimes with sponsorship from local industry/stakeholders). The financing arrangement of each TC/SC depends on the business model of the member hosting the secretariat, especially whether it is a public or private body, and the subject dealt with by the TC/SC. In addition, working group experts, stakeholders in national mirror committees and national delegates participating in ISO meetings on a voluntary basis must pay for their own travel expenses and the time they give to the ISO system (most often, they are funded by the company/organisation they represent). Hence, it is hard to evaluate how much the overall system costs, notably because the contributions of members, experts and stakeholders are material/intellectual rather than financial.

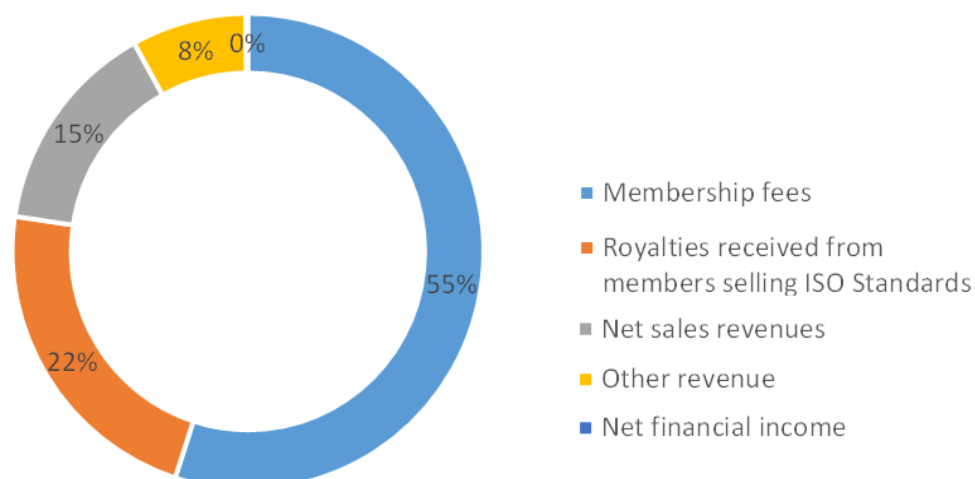
50. The budget of the ISO/CS is more formal and is presented each year in the annual report. The ISO/CS is mainly funded by its members (Figure 5). The membership fees of each member depend on the number of allocated units and the value of the unit. The monetary value of the subscription unit is set up every year by the GA to ensure there is adequate revenue from ISO membership fees to cover ISO Central Secretariat operations. The number of subscription units per member reflects its economic activity. Since 2014, the index has been reviewed on a triennial basis to ensure the responsiveness of the index to significant changes in the economic situation of the Member bodies or in the world economy. In addition, in order to contain the financial influence of the biggest contributors, no Member body pays more than 8% of the total budget and no member pays less than five units. The largest contributors are the members of group 1 in the ranking for Council elections – currently these are AFNOR (France), ANSI (United States), BSI (United Kingdom), DIN (Germany), JISC (Japan) SAC (China) – and they pay the same amount of membership fees. Correspondent members pay a fixed amount of two units and subscriber members pay a fixed amount of one-half of a unit.

51. In addition to their fees, the members also pay voluntary contributions to the “Funds-in-Trust” (FiT) devoted to the financing of the Action Plan for developing countries. The action plan for developing countries and other specific projects are also funded by external donors. Finally, the ISO/CS is also financed by the sale of standards. This commercial activity of ISO does not conflict with the fact that ISO remains not for profit – ISO is, from a formal point of view, a not for profit association under Swiss law, and so are the majority of its members. The sale of standards only aims to support the activities of the Central Secretariat and the development of International Standards.

62. For more information s. *ISO/IEC Directives Part 1*, annex D, Resources of secretariats and qualifications of secretaries.

Figure 5. 2015 revenue breakdown by source

## 2015 revenue breakdown by source



Source: ISO Annual Report 2015, [www.iso.org/iso/annual\\_report\\_2015.pdf](http://www.iso.org/iso/annual_report_2015.pdf).

52. It is important to underline that the ISO/CS does not have a monopoly on the sale of ISO standards. On the contrary, in line with ISO's decentralized approach, ISO's distribution strategy relies primarily on ISO members, who can sell ISO deliverables in different forms (subscriptions, standards collections, etc.) in order to meet with the specific needs of the standards users in their territories. The "ISO Webstore" run by the ISO/CS offers visibility for International Standards and overcomes the fact that some ISO members do not have an online store, do not have the capacity, or are not allowed to run commercial activities. When they sell ISO standards, Member bodies (full members) and correspondent members<sup>63</sup> – subscribers are not allowed to sale ISO Standards – have to pay royalties. In 2014, it was estimated that over 70% of ISO Standards were sold by the members.

53. Member bodies and correspondent members can also adopt ISO standards nationally, meaning that they publish a national normative document based on an ISO standard or endorse it as having the same status as a national standard. Besides being a fundamental right of the ISO members, national adoption fosters a wide dissemination of ISO standards, especially when the national adoption translates the standard into a language other than the official languages of ISO. Once a member has adopted the standard nationally, ISO does not get any royalties on its sale. Considering that there is no obligation for members to report on their national adoption activity and sales to the ISO/CS, it is impossible to know how many nationally adopted standards are sold and used.

54. This copyright and commercial policy is set out in the so called "ISO POCOSA" (Policy for the distribution of ISO Publications and the Protection of ISO's Copyright), which is compliant to competition laws in a significant number of countries. In particular, there is no fixed price for ISO standards worldwide, but POCOSA gives members the responsibility to determine the price of each ISO standard they sell.

63. Moreover they are allowed to outsource the distribution of standards to commercial distributors.

*Business model of ISO*

55. ISO’s business model is often challenged. In particular, pressure exists to have standards available for free, especially when they have been referenced in legislation. Since its creation, ISO has adapted its business model to the challenges and needs of its stakeholders. An assessment of the business model by the ISO Council, including some pilot projects, was made in 2015. Significant changes have already been made, like the Online Browsing Platform (OBP)<sup>64</sup> created in 2012 to provide easy access to publications, including free access to selected parts of standards. However, free standards represent a major risk for the ISO system, including for a significant part of its membership, whose budget depends on the sale of standards. Also, the current model allows ISO partial financial independence – any one member or stakeholder alone cannot influence the system, and it does not rely too much on public funds.

**Forms of regulatory cooperation provided by ISO to its members**

56. Among the forms of IRC identified by the OECD in its reports (OECD, 2016), ISO essentially offers only one – standards. Of course, it could be argued that through its governance bodies and through its various programs to help build capacity in developing countries, ISO also offers a forum for exchange of information and experiences. Nevertheless, ISO’s main activity is the development of standards and this homogeneity of products clearly distinguishes ISO from other types of IOs studied by the OECD (2016). What’s more, this homogeneity of IRC-mechanisms allows for systematic and homogeneous processes and is, without doubt, one of the main reasons behind the success of ISO standards as a mechanism for IRC.

57. It is important to note that ISO focuses only on the upstream activities of rule-making (design) and is not involved in the downstream activities. In particular, ISO does not conduct any conformity assessment (Box 3) – this is performed by external certification bodies. Therefore, a company or organisation cannot be certified by ISO and CASCO does not deliver conformity certificates, but only develops policies and standards related to conformity assessment.

**Box 3. ISO Standards and conformity assessment**

Conformity assessment is a demonstration that a product, service, person or system meets specified requirements, which are usually contained in a standard. The main conformity assessment techniques include assessment, auditing, evaluation, examination, inspection and testing. Testing (resulting in a test report) is the most common type of conformity assessment. However, these techniques can be combined to form conformity assessment schemes, and lead to certification. There are different types of certification that products with product certification and management system certification being the most common. A claim of conformity can be first-party (self-declaration, also called supplier’s declaration), second-party (purchaser’s declaration) or third-party (certification). Peer review is also sometimes used to ascertain conformity. ISO has the “neutrality principle” which means that ISO standards cannot mandate one form of conformity assessment in preference to another. It is therefore the market (or customer) that decides if first party, second party, or third party is most appropriate.

Conformity assessment has a number of important benefits – it provides consumers and other stakeholders with added confidence and helps regulators to ensure that health, safety or environmental conditions are met, especially when a standard is made mandatory through legislation.

In the field of conformity assessment, ISO works closely with a large number of international associations including the International Electrotechnical Commission (IEC) and the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

64. Website of the OBP: [www.iso.org/obp/ui/](http://www.iso.org/obp/ui/).

### *Characteristics of ISO's deliverables*

58. All ISO deliverables are:

- Voluntary: there is no obligation for the members to adopt and implement them nationally and no obligation for individuals or organisations to use them or comply with them.
- Consensus-based: all deliverables are adopted through consensus, with different sorts of deliverables reflecting different levels of consensus among different actors. The most advanced deliverable is the International Standard, being based on the “double layer of consensus”, first among the experts (Working group), and secondly among the members (at the TC level).

59. The voluntary nature of ISO deliverables must be slightly qualified concerning the role of international standards. As already mentioned, ISO standards are widely considered by scholars to fall under the category of ‘international standards’ recognized by the WTO’s TBT Agreement as contributing to the removal of technical barriers to trade. According to article 2.4 of the TBT Agreement, States have the obligation to “use them, or the relevant parts of them, as a basis for their technical regulations”. Hence, while international standards are not compulsory, they are a convenient and efficient tool for States that want to enact technical regulations, but whose domestic regulatory power is limited due to their obligations as WTO members. Thus many scholars argue that the TBT agreement “hardens” the international standards falling under its scope and at the same time gives a degree of international public authority to ISO. It is therefore not surprising that, at the time of the negotiation of the TBT agreement of 1979 under the General Agreement on Tariffs and Trade (GATT), GATT members referred to ISO as “Professional groups (...) of a quasi-public Character” (GATT, 1969).

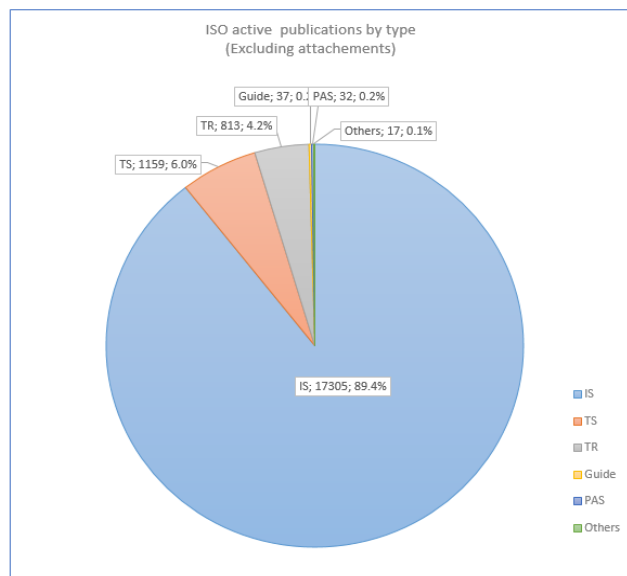
60. Standards development mainly takes place in the TCs. But some deliverables may be developed by PDCs or groups reporting to the TMB<sup>65</sup>. Some deliverables are also prepared in cooperation with the IEC (ISO/IEC Joint committees/groups). The homogeneity of the procedures followed by the many TCs hosted by ISO members around the world is ensured through common processes detailed in the ISO/IEC Directives Part 1. ISO also has rules and procedures in place to ensure editorial alignment and quality, which are outlined in the *ISO/IEC Directives, Part 2 — Principles and rules for the structure and drafting of ISO and IEC documents*. Furthermore, all documents are formatted by the ISO/CS at multiple stages during the document’s development and every committee has a designated ‘Editorial programme manager’ at the ISO/CS to provide them with editorial advice.

### *Typology of ISO's deliverables*

61. ISO’s main deliverables are International Standards, but ISO also develops other deliverables (Figure 6). These deliverables do not differ much from International Standards, as the procedures for their development are very similar. The main difference lies in the level of consensus represented by the deliverable – intermediate deliverables (Technical Specifications and Publicly Available Specifications) and International Workshop agreements (IWA) reflect a weaker level of technical consensus than an International Standard. These deliverables may be published when, for example, the market needs a solution rapidly, but the technology is not mature enough to be embodied in an International Standard. Only the technical report (TR) can be seen as another form of IRC, namely data collection.

65. It was the case for the famous ISO 26000:2010 – “Guidance on social responsibility”.

**Figure 6. Portfolio of ISO Deliverables**



Notes: IS: International Standard; TS: Technical Specification; TR: Technical Report; PAS: Publicly Available Specification; Others: Other publications (like IWA, TTA & R : IWA: International Workshop Agreement, TTA: Technology Trends Assessment or R: Recommendation).

Source: ISO Project Management Database.

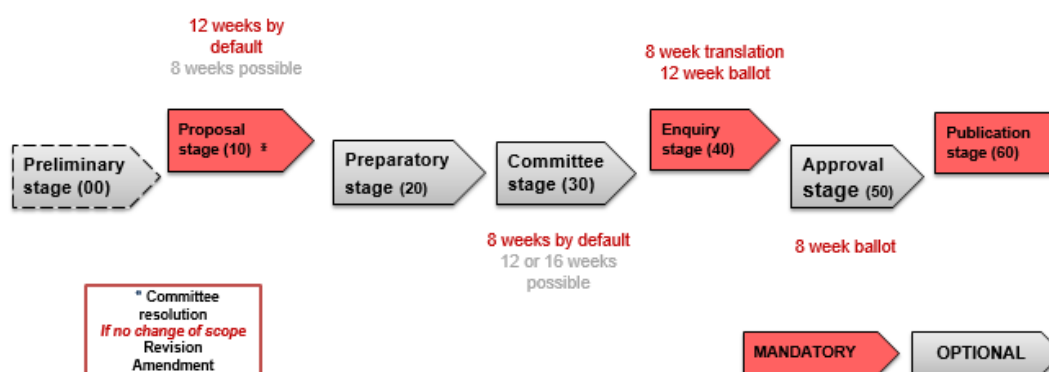
*International standards*

62. ISO’s main deliverables are International Standards<sup>66</sup>. International Standards are developed through a three to seven-stage-procedure, each stage reflecting a consensus that becomes stronger as the procedure goes forward (Box 4).

66. The current denomination for the results of ISO’s technical work was introduced in 1971 (before, ISO’s publications were named “Recommendations”).

## Box 4. The stages of standards development

## The stages of standards development



**Preliminary stage (ISO/IEC Directives Part 1, clause 2.2):** The preliminary stage is used when the subject matter is not sufficiently mature to be processed as a standard (for example, because it deals with new technology), but still needs to be introduced into the work programme of a TC/SC, allowing for further study of emerging needs and more time to develop a detailed proposal. Preliminary work items must progress to the proposal stage within three years or be automatically deleted from the programme of work.

**Proposal stage (ISO/IEC Directives Part 1, clause 2.3):** A new work item proposal within the scope of an existing TC/SC may be made by a national body, the secretariat of that TC/SC, another TC/SC, a liaison organisation, the TMB or one of its advisory groups, or the Secretary-General. The proposal is circulated to all the members of the TC/SC for a 12 week ballot and is accepted by a simple majority of the voting P-members of the TC/SC providing that at least 4 or 5 P-members (depending on the size of the TC/SC) commit to participate actively in the development of the standard.

**Preparatory stage (ISO/IEC Directives Part 1, clause 2.4) (also called working group stage) (optional):**  
**Consensus among the experts:** Experts nominated by the P-Members participating in the work develop a *working draft*. This stage is optional, and may or may not be used depending on whether there is an existing draft (for example a national standard) and on the quality of this draft. The experts must be aware of the national point of view but they do not represent their country. Instead, they act in a personal capacity to input their know-how<sup>67</sup>. Working groups are led by a convenor appointed by the parent committee<sup>68</sup>. Once there is a consensus among the experts on a final working draft, it is circulated as a first *committee draft* (CD) to all members of the TC/SC. If the draft developed by the WG is of a high quality and there is strong consensus amongst the experts, the committee can also decide to register it directly as a *Draft international standard* (DIS), skipping the CD stage.

**Committee Stage (ISO/IEC Directives Part 1, clause 2.5) (optional):**  
**Consensus among the members of the TC/SC:** All members of the TC/SC can send written comments on the *committee draft* (CD). Depending on the comments and the consensus surrounding the CD, the CD is either discussed at a TC/SC meeting, revised, and the new CD circulated, or else it is registered directly for the enquiry stage. Consideration of successive drafts continues until all technical issues have been resolved and consensus of the P-members of the TC/SC has been obtained. The CD is then sent to the ISO/CS for registration as a DIS, editorial formatting and circulation.

**Enquiry stage (ISO/IEC Directives Part 1, clause 2.6):**  
**Consensus among ISO members:** The DIS is circulated by the ISO/CS to all ISO Member bodies for a 12-week ballot. Positive votes can be accompanied by editorial or technical comments. Negative votes must be justified with technical reasons. For example, the member may indicate that the acceptance of specified technical modifications will change its negative vote to one of approval. A

67. ISO/IEC Directives Part 1, clause 1.12.1.

68. ISO/IEC Directives Part 1, clause 1.12.1.

DIS is approved if a two-thirds majority of voting P-members of the TC/SC are in favour and not more than one-quarter of the total number of votes cast are negative. When the approval criteria are not met, the Chair of the TC/SC can circulate a revised enquiry draft for voting, a revised committee draft for comments, or decide to discuss the enquiry draft and comments at the next meeting. If the criteria are met, the project can either be published as an International Standard or, if many changes are required given the comments received on the DIS, the project can be submitted to the Member bodies as a *Final Draft International Standard* (FDIS) for final approval. At this stage, the experts of the working group participate in the review of the comments and contribute to the editorial changes.

**Approval stage (ISO/IEC Directives Part 1, clause 2.6) (optional): Consensus among ISO members:** The *Final Draft International Standard* (FDIS) is distributed to all ISO Member bodies for an 8-week ballot. Members cannot submit comments if their vote is positive. Negative votes must be justified with technical reasons. An FDIS is approved if a 2/3 majority of the P-members of the TC/SC voting are in favour and not more than one-quarter of the total number of votes cast are negative. If the criteria are met, the FDIS proceeds to publication as an international standard. If not, the TC/SC can decide to submit a new CD, DIS or FDIS.

**Publication stage (ISO/IEC Directives Part 1, clause 2.8):** The International standard is published by the ISO/CS – it is made available on the ISO webstore for purchase, and distributed to the ISO members for national sale or adoption.

Source: Based on ISO/IEC Directives Part 1, Clauses 2.1-2.8, [www.iso.org/sites/directives/2016/consolidated/index.xhtml#\\_idTextAnchor108](http://www.iso.org/sites/directives/2016/consolidated/index.xhtml#_idTextAnchor108).

### *Other normative deliverables*

63. ISO also develops some “intermediate deliverables”. If it appears from the beginning that there is an urgent need for a technical document but that the development of a standard will take too long, a TC/SC can decide to develop a different kind of deliverable that can be published more quickly. A TC/SC may also decide to publish an alternative deliverable if, during the course of the development of an International Standard, the required level of consensus cannot be achieved.

- A Publicly Available Specification (PAS)<sup>69</sup> is a normative document representing the consensus within a working group. Nevertheless, a PAS must be approved by the committee concerned. A simple majority of the P-members voting is sufficient. Competing PAS offering different technical solutions are possible provided that they do not conflict with existing International Standards.
- A technical specification (TS)<sup>70</sup> is a normative document reflecting the technical consensus within a TC/SC. The adoption of a TS requires a two-thirds majority vote of the P-members voting of the TC/SC. Competing technical specifications offering different technical solutions are possible provided that they do not conflict with existing International Standards.

### *Guides*

64. Guides are drafted by PDCs, such as COPOLCO<sup>71</sup>, or by committees or groups established by and operating under the TMB. A number of Guides are jointly developed between ISO and IEC and then

69. *ISO/IEC Directives Part 1*, clause 3.2.

70. *ISO/IEC Directives Part 1*, clause 3.1.

71. CASCO no longer develops Guides and is in the process of converting any remaining Guides into other deliverables.

published as ISO/IEC Guides. As of August 2016, ISO has 11 ISO Guides and 22 ISO/IEC Guides in its catalogue.

65. A Guide provides guidance on matters related to international standardization, especially to standards writers on how to deal with specific issues when drafting standards, or to national standards bodies on how to deal with issues specific to standardization principles. Many of these issues cover broad topics and are therefore of interest to a wide range of ISO committees – for example, guidance on how to take account of sustainability in the drafting of standards<sup>72</sup>, or methods of regional or national adoption of standards<sup>73</sup>.

66. The adoption of a Guide follows a specific procedure<sup>74</sup>. After consensus has been obtained in the group preparing the Guide, the draft is disseminated to all ISO member bodies for a four-month enquiry vote as a DIS. A draft Guide is approved if not more than 1/4 of the votes cast by the ISO member bodies is negative. In the case of ISO/IEC Guides, the acceptance criteria have to be met in both organisations independently. If the acceptance criteria are met, the Guide is published without being subject to an additional approval vote as an FDIS.

67. Some Guides are available for free and can be downloaded via the ISO website<sup>75</sup>.

#### *International Workshop Agreement (IWA)*

68. An IWA is not drafted through the TC process but follows a specific procedure based on a workshop format<sup>76</sup>. Unlike International Standards, the proposal for an IWA may come from any source and stakeholders may directly participate in an IWA without having to go through a national delegation. An IWA can be produced on any topic, provided that it does not conflict with the scope of an existing International Standard. Since it can be published in less than 12 months, it can address a rapidly emerging market need or public policy requirement. IWAs are often developed in cooperation with an external organisation that initiates the Workshop and wants to benefit from ISO's expertise and network. Moreover, the ISO brand gives international recognition and credibility to the work. An IWA must be reviewed every three years and cannot exist for more than six years. At the end of that period, the IWA is withdrawn or converted into another ISO deliverable. IWAs can be used as precursors to International Standards.

#### *Technical Reports (TR)*

69. ISO also publishes Technical Reports (TRs)<sup>77</sup>. TRs are not normative documents, but informative documents containing data of a different kind from that which is normally published as an International Standard (for example data obtained from a survey). TRs are published after their adoption by a simple majority vote of P-members voting in the concerned committee. TRs are generally published in support of other deliverables (such as International Standards), and every TR must clearly explain its relationship to normative aspects of the subject which are, or will be, dealt with in International Standards.

72. ISO Guide 82.

73. ISO/IEC Guide 21.

74. *ISO/IEC Directives Part 1*, Annex A.

75. s. ISO's website: [www.iso.org/guides](http://www.iso.org/guides).

76. *ISO/IEC Directives Part 1*, Annex SI.

77. *ISO/IEC Directives Part 1*, clause 3.3.

## ENSURING REGULATORY QUALITY

70. The procedures in place at ISO to ensure the quality of its International Standards are the consequences of its special context. Firstly, as already underlined, ISO is not a traditional IO and ISO standards are not mandatory. ISO had to gain its legitimacy and reputation through the development of high-quality standards, with quality being assured by ISO's robust procedures contained in the ISO/IEC Directives that are reviewed every year and amended, if needed.

71. Secondly, ISO follows a Code of Ethics<sup>78</sup>, published in 2004. As stated in the Code itself, "ISO and its members recognize that it is imperative to conduct activities in an ethical manner that deserves the confidence of all parties involved in standardization and of the general public." The Code defines the specific provisions that ISO members and all of ISO's organisational entities must follow to ensure the ISO standards development process be open, transparent and impartial, to promote ISO standards and associated good practices for conformity assessment, to ensure ISO's integrity and to take into account the needs of developing countries. "Each ISO member and each of ISO's organizational entities, including its technical and governance bodies and central supporting functions, are expected to act in accordance with this Code and to promote adherence to the values of ISO by other organizations and individuals engaged in standardization".

72. Thirdly, ISO benefits from legal instruments that set requirements for standards development and governance practice for international standard-setting organisations. These kind of instruments are rare in international law. As emphasised by scholars, there are few legal instruments that apply directly to IOs, subjecting them to principles of good governance or human rights and offering them guidance on how to act in a way that is consistent with the values of the international community<sup>79</sup>. ISO's legal context, however, places a number of constraints on it that helps it to ensure better quality procedures and products. First of all, as a Swiss-based NGO, ISO is subject to domestic law. Then, in addition, there are two international instruments that can guide ISO in the development of its standards:

- ISO adheres to the principles outlined in the "Code of good practice for the preparation, adoption and application of standards" in Annex 3 of the TBT Agreement – for example public consultation, transparency, and international cooperation (although this code is meant for national standard setting bodies, i.e. ISO's members, rather than for international standards settings bodies).
- ISO also applies the six WTO TBT "principles for the development of international standards, guides and recommendations"<sup>80</sup> as guidance for its own procedures. These principles were enacted by the TBT committee "to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries" (WTO, 2000), given the legal effect of international standards within the TBT agreement and their impact on the global market.

78. [www.iso.org/iso/codeethics\\_2004.pdf](http://www.iso.org/iso/codeethics_2004.pdf).

79. s. for instance the conference organized by the University Paris 1 – Panthéon – Sorbonne at the OECD under the provocative title « Are IO really subject to law ? » (« La droit et la pratique: les organisations internationales sont-elles vraiment soumises au droit? »): [www.univ-paris1.fr/fileadmin/IREDIES/colloques/AfficheForumOCDE300914.pdf](http://www.univ-paris1.fr/fileadmin/IREDIES/colloques/AfficheForumOCDE300914.pdf)

80. Annex 4 to the 2nd triennial review of the WTO TBT Agreement.

73. As already mentioned, the homogeneity of ISO's products also makes it easier to develop systematic approaches and processes and to ensure their quality. Compliance with these procedures is ensured through transparency<sup>81</sup> (Principle B) and the procedure for appeals<sup>82</sup>.

74. Ultimately, in the ISO system, achieving "quality" standards means developing standards that are relevant, coherent, and represent the 'state of the art'. Ensuring regulatory quality for ISO standards therefore means controlling for:

- Relevance: standards must respond to a market need and be globally relevant (be able to be applied in all countries around the world), which is ensured by a wide participation of stakeholders and members.
- Coherence: Given the technical nature of the issues dealt with by ISO standards, it is important to ensure coherence among ISO's many International Standards, and also with international standards developed by other international standards-setters – standards should not contain conflicting information.
- State of the art: ISO has a review mechanism to make sure that its International Standards stay up-to-date and that they are withdrawn if they become obsolete.

### **Ensuring the relevance of ISO standards**

#### *Market relevance*

75. ISO only develops standards for which there is a clear market requirement. Indeed, standardization needs to be effective and relevant in order to facilitate trade and prevent the creation of unnecessary trade barriers. This implies that a new standard must respond to a market need, that it is developed in a timely manner to tackle this need, and that it is globally relevant to offer a technical solution that is applicable worldwide.

76. It is not the responsibility of ISO to assess or determine what the market needs – this responsibility falls to the ISO members. The ISO model uses a "bottom-up" approach to ensure the market relevance of proposed International Standards, with over 90% of proposals for new standards coming directly from the ISO members, via their national stakeholders. Once a proposal is received, the procedure to approve it (either as a new field of work (establishment of a TC/SC) or a new work item (new standard) ensures that ISO only begins work if there is a clear need.

77. First of all, any proposal for a new field of work or a new work item must be adequately detailed and justified and so is similar to an ex-ante impact analysis. It should suggest a programme of work, mention any existing work in the field (including by other national, regional or international organisations), explain how any conflict or duplication will be minimized, list the countries where there might be a particular interest for the work undertaken, and identify the possible affected stakeholders. Similar justifications are required for proposals for a new standard (a new work item proposal). The ISO/CS

81. ISO ensure full transparency of the technical work to the participants (members and liaison organisations). For the public at large, transparency can only happen within the constraints of ISO's copyright policy and the data protection of the participants to the technical work. Nevertheless, TMB documents are accessible online. International Standards and FDIS can be purchased online.

82. ISO/IEC Directives Part 1, Clause 5.

ensures that the proposal is properly developed and provides sufficient information to support informed decision making by the ISO members.

78. Indeed, a new standard can only be developed if a majority of the members of a TC/SC are in favour and if 4 or 5 members (depending on the size of the committee) commit to actively participate and nominate experts to develop the draft. Before taking the decision on whether to approve a proposal and participate in the work, NSBs must consult their stakeholders in the relevant sector to determine if they have an interest in the proposed work. This ensures that new work begins only if it responds to a market need and if there are available resources for its development. The requirements for the establishment of a new field of work (TC/SC) are even stricter, since a 2/3 majority of ISO members and the commitment of at least 5 of them to participate actively are required.

79. To be market relevant a standard must be published when the market needs it. Therefore, one of ISO's main concerns is to make the standards development process as timely as possible (which in practice often means offering possibilities to speed up development times). When a proposed new project is approved, the TC must choose a standards development track: Accelerated standards development track (up to 24 months to publication), Default standards development track (up to 36 months) or Enlarged standards development track (up to 48 months) and it must establish target dates for the completion of each step in the standards development process. The TC secretariats have the responsibility of reviewing the target dates in order "to confirm that projects are still market relevant and in cases in which they are found to be no longer required, or if the likely completion date is going to be too late, thus causing market players to adopt an alternative solution, the projects shall be cancelled"<sup>83</sup>. A TC may amend target dates if more time is needed, however the TMB automatically cancels "all work items which have been on the work programme for more than 5 years and have not reached the approval stage". Moreover, since 2003, if the target date for DIS or publication is exceeded, the committee must decide within 6 months to either submit the DIS or FDIS, publish an intermediate deliverable or delete the work item. An extension up to 9 months for the total project duration is possible upon the authorization of the TMB, providing that there is strong interest from stakeholders to continue<sup>84</sup>.

### *The engagement of Stakeholders*

80. The active participation of stakeholders is one of the main features and strengths of the ISO system and is a central element of what some scholars call "technical democracy". In the famous ISO 26000 on social responsibility, a stakeholder is defined as an "individual or group that has an interest in any decision or activity of an organisation" (clause 2.20). In the ISO system, this refers to the participation of individuals, companies, NGOs, etc., that are brought together by the ISO members and must work towards building consensus.

81. Indeed, stakeholders are not directly engaged by ISO, but through ISO's members and its liaison organisations. While stakeholder engagement is an obligation for ISO members, they are free to determine *how* this engagement takes place and to organize the participation of stakeholders as they wish, in whatever way best suits their national context. Nevertheless, ISO offers extensive guidance to its members on best practices for stakeholder engagement (ISO, 2010b; ISO, 2010c) and this has long been a priority subject for the TMB.

82. Usually the participation of stakeholders takes place through public consultations and/or through national mirror committees (NMCs), which are technical committees at the national level, composed of all

83. ISO/IEC Directives Part 1, clause 2.1.6.1.

84. ISO/IEC Directives Part 1, clause 2.1.6.

categories of national stakeholders, and that mirror the work of the international TC. The national stakeholders in the NMC develop a consensus position at the national level, which can then be defended by the NSB at the international level.

83. Historically, standardization at ISO is the result of a consensus among experts, originally mostly engineers from industry. The diversification of stakeholder engagement can be traced back to the 1960's and the first participation of consumers in international standardization. In 1964, the ISO Council encouraged member bodies to “work in close liaison with consumers’ organisations in their own countries” and to “associate representatives of the consumers’ organisations to the preparation of the meeting [of ISO] and invite them to co-operate in forming their national delegation”<sup>85</sup>. Revealing of this important shift, ISO/TC 73 “Marks indicating conformity with standards” was renamed “Consumer questions” in 1966<sup>86</sup>. In 1977, the Council committee on consumer policy (COPOLCO) was created<sup>87</sup>.

84. In 2005, ISO embarked on the development of ISO 26000 on social responsibility using a ‘special procedure’ and multi-stakeholder approach that ended up drawing attention to the fact that not all of the six stakeholder categories deemed necessary for the development of this new standard were equally represented in ISO’s traditional working groups and in the national mirror committees of its members. This ‘special procedure’ is described in the introduction of the standard:

85. “ISO 26000 was prepared by ISO/TMB Working Group on Social Responsibility. This International Standard was developed using a multi-stakeholder approach involving experts from more than 90 countries and 40 international or broadly-based regional organizations involved in different aspects of social responsibility. These experts were from six different stakeholder groups: consumers; government; industry; labour; non-governmental organizations (NGOs); and service, support, research, academics and others. In addition, specific provision was made to achieve a balance between developing and developed countries as well as a gender balance in drafting groups. Although efforts were made to ensure balanced participation of all the stakeholder groups, a full and equitable balance of stakeholders was constrained by various factors, including the availability of resources and the need for English language skills.” (ISO 26000:2010:V).

86. To address this issue and to foster a true multi-stakeholder approach to standardization whilst ensuring its impartiality (Principle D of the TBT committee), ISO published two brochures on stakeholder engagement for NSBs (ISO, 2010c) and liaison organisations (ISO, 2010b) and created seven stakeholder categories: Industry and commerce, Government<sup>88</sup>, Consumers, Labour, Academic and research bodies, Standards application and Non-governmental organisation<sup>89</sup>.

87. ISO’s members are supposed to engage all relevant categories of stakeholders to build the national position. To help NSBs in identifying the relevant stakeholders, form 4 for New work item proposals was modified in 2015 (Table 1), requiring the proposer to give additional details on what kind of stakeholders are relevant to the proposal and why. In addition, when NSBs register their experts as members of ISO working groups, they must indicate to which stakeholder category each expert belongs.

85. ISO Council Resolution 48/1964 – “*National and International Consumer’s Organisations Liaisons*”.

86. ISO Council Resolution 44/1966 – “*ISO/TC 73 New title Scope*”.

87. ISO Council Resolution 19/1977 – “*COPCO Creation Terms of reference Participation*”.

88. This category includes “international and regional treaty organisations and agencies; national government and local government departments and agencies, and all bodies that have a legally recognized regulatory function” (ISO, TMB, *TMB Communiqué*, n°41, July 2012, p. 7).

89. ISO TMB Resolution 75/2012 - “*TMB Ad Hoc group on Stakeholder categories*”.

The convenor of the WG is then supposed to ensure a balance of interest and representation of all relevant stakeholder categories and is encouraged to issue a new call for experts in case of imbalance.

**Table 1. Extract of Form 4 for New work item proposal**

Please fill out the relevant parts of the table below to identify relevant affected stakeholder categories and how they will each benefit from or be impacted by the proposed deliverable(s).		
	<b>Benefits/impacts</b>	<b>Examples of organisations/companies to be contacted</b>
<b>Industry and commerce – large industry</b>	Click here to enter text.	Click here to enter text.
<b>Industry and commerce – SMEs</b>	Click here to enter text.	Click here to enter text.
<b>Government</b>	Click here to enter text.	Click here to enter text.
<b>Consumers</b>	Click here to enter text.	Click here to enter text.
<b>Labour</b>	Click here to enter text.	Click here to enter text.
<b>Academic and research bodies</b>	Click here to enter text.	Click here to enter text.
<b>Standards application businesses</b>	Click here to enter text.	Click here to enter text.
<b>Non-governmental organisations</b>	Click here to enter text.	Click here to enter text.
<b>Other (please specify)</b>	Click here to enter text.	Click here to enter text.

Source: ISO, Form 4 “New work item proposal”, [www.iso.org/iso/home/standards\\_development/resources-for-technical-work/forms-agendas-letters.htm](http://www.iso.org/iso/home/standards_development/resources-for-technical-work/forms-agendas-letters.htm).

88. It should be noted that ISO relies entirely on its members to engage stakeholders. Of course, this situation can prevent the participation of stakeholders if their NSB is not an ISO member or not a P-member in the relevant committee. However, this situation is rather theoretical, since NSBs usually participate in technical works in which their stakeholders have an interest, and stakeholders can also participate through liaison organisation, if they meet the criteria.

*Global relevance*<sup>90</sup>

89. In order to facilitate international trade, international standards must be globally relevant. Indeed, an international standard can only contribute to the removal of technical barriers to trade if the technical solution embodied in the standard can be used everywhere on the planet. In cases where unique international solutions are not possible, International Standards may present options to accommodate legitimate and essential market differences, where justified. What’s more, International Standards “should not distort the global market, have adverse effects on fair competition” or “give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s” (WTO, 2000). This impartiality and relevance can only be achieved by the widest possible participation of all ISO members and of all categories of stakeholders. This requirement is also directly linked to the “openness” principle of the TBT committee.

*The participation of all members*

90. The participation of all relevant ISO Member bodies is seen as a major factor in supporting global relevance. Indeed, the openness of an international standardizing body is one of the TBT principles (principle C) and implies the possibility for the relevant bodies of all countries to participate at every stage of the standards development process. ISO membership is open to one national standardization body per

90. For more information on ISO’s global relevance policy, s. [www.iso.org/iso/home/standards\\_development/governance\\_of\\_technical\\_work.htm](http://www.iso.org/iso/home/standards_development/governance_of_technical_work.htm).

country and the Member bodies “have the right to participate in the work of technical committees and subcommittees”.<sup>91</sup> They can actively participate in all the procedures: making proposals for new fields of work (new TC/SC) or for new work items, sending experts, submitting comments and voting. Any Member body can host the secretariat of a TC/SC, provided that it has sufficient resources.

91. Usually, members participate in ISO, its governance and the development of its standards because they, or their stakeholders, have a concrete stake in the outcomes, i.e. the published standards. All the more so as WTO members have the legal obligation to “play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations”.<sup>92</sup>

92. ISO is nevertheless concerned about achieving good *quality* of participation by members, and not simply about getting the maximum number of countries involved. Therefore, ISO has a number of processes in place to both encourage greater participation by members, but also to make sure they fulfil their obligations as members. For example, P-members (participating members) of a TC/SC must cast a vote (positive, negative or abstention) on all matters formally submitted for voting within the committee. When a P-Member has been persistently inactive or “has failed to vote on over 20% (and at least 2) of the questions formally submitted for voting” over a year, the P-member is reminded of its obligation and is automatically downgraded to O-member (observer) status if it persists in its behaviour. The member may regain P-membership of the committee after 12 months.<sup>93</sup> The aim of this procedure is not just to ensure an active participation of the member but to push them to assess if their P-membership still makes sense and to systematically consult their stakeholders.

93. Furthermore, these voting procedures ensure a constructive participation by members, since negative votes on draft standards must be justified with a technical reason in order to be counted. This ensures the efficiency of the system and helps in resolving negative votes and reaching consensus.

#### *The participation of developing countries*

94. ISO recognizes that increased and effective participation of developing countries is essential to ensure<sup>94</sup> the global relevance of ISO standards, and that ISO members from developing countries need specific assistance to increase their participation in international standardization and to fully exploit the value of standards in support of their countries’ development.

95. The general framework describing the ISO commitment to this very important area is the Action Plan for Developing Countries (APDC). The APDC covers a five-year timeframe and is aligned with the ISO Strategy, which complements by specifying objectives and actions to be undertaken by ISO to meet the needs and expectations of its developing country members. The APDC was first introduced in 2005 and has now reached its third edition (APDC 2016-2020).

96. In the framework of the APDC 2011-2015, a total of 717 activities were undertaken (including trainings, technical assistance projects and sponsored participations in ISO TC/SC meetings), involving over 19’000 participants from 122 ISO members from developing countries – with total expenditures close to 12 million CHF (and an annual volume between 5 and 10% of the total budget of the Organization).

91. *ISO/IEC Directives* Part 1, clause 1.7.1.

92. Article 2.6 of the TBT agreement.

93. *ISO/IEC Directives Part 1*, clause 1.7.4.

94. ISO Strategic Plan 2011-2015, Objective 3

97. ISO's APDC 2016-2020<sup>95</sup> has an ambitious overarching goal (or "impact"): i.e., to "*Contribute to economic development, social progress and the protection of the environment in developing countries*", in line with the United Nations Sustainable Development Goals. ISO contributes to the programme's impact through its specific competencies, primarily by helping to strengthen the national quality infrastructure (NQI)<sup>96</sup> of developing countries. In addition, by launching new International Standards projects or supporting developing countries' participation in projects that address sustainable development issues of particular importance for them.

98. ISO can help the development of solid and effective NQIs by strengthening its members in developing countries. The APDC 2016-2020 identifies five main areas of improvement for these ISO members, set as outcomes of the programme. A combination of technical assistance and training activities are then implemented by ISO/CS adjusting the specific objectives through an annual member needs assessment survey, and using resources provided by ISO itself as well as by a number of development agencies which recognize the important role of standardization for sustainable development.

99. The importance of developing countries' participation in international standardization and the consideration of their specific needs was recognized by ISO at a much earlier stage.

100. The ISO Committee on developing country matters (DEVCO) was established in 1961, to provide a dedicated forum to identify the specific needs of developing countries in standardization matters and to recommend actions to meet them. In 1964, ISO created the membership category of 'Correspondent member' in order to make ISO membership more accessible for developing countries and subsequently, in 1994, created the category of 'Subscriber member' to further lower barriers to ISO membership. Originally, these two alternate membership categories were supposed to be temporary – however, economic development dynamic did not meet its promise, and many members maintained these levels of membership.

101. In an effort to allow them to participate in the fields that are of particular importance for their economies and to further facilitate the transition from correspondent or subscriber to full member, the ISO Council approved a pilot program in 2013<sup>97</sup> for two years, renewed for four more years in 2015<sup>98</sup> to exceptionally allow these members to actively participate in a maximum of 5 committees, with full commenting and voting rights. The programme includes specific training and allows correspondent or subscriber members to benefit of the sponsorships available to cover the costs of developing countries' participation in TC/SC meetings (up to three meetings per year).

102. Members from developed countries are also encouraged to help build capacity in developing countries via the ISO 'twinning' programme<sup>99</sup>. A twinning arrangement is a partnership between a developed and a developing country ISO member, wherein the developed country member helps the developing country member to achieve specific goals. Twinning is possible at every level: P-member,

95. The latest action plan is available online: [www.iso.org/iso/home/store/publication\\_item.htm?pid=PUB100374](http://www.iso.org/iso/home/store/publication_item.htm?pid=PUB100374).

96. The national quality infrastructure (NQI) is a country's institutional framework – involving public and private institutions – that establishes and implements the practice of standardization, including conformity assessment services, metrology and accreditation. The NQI is an essential for the country's economic and social development and environmental protection

97. ISO Council Resolution 3/2013 – "*Increased member participation*".

98. ISO Council Resolution 22/2015 – "*Assessment of the new rights pilot project*".

99. To learn more about twinning at ISO: ISO, *Guidance on Twinning in ISO standards development activities. Increasing the participation of developing country members*, April 2013, [www.iso.org/iso/pub100341.pdf](http://www.iso.org/iso/pub100341.pdf).

convenor, secretariat, or chair<sup>100</sup>. The exact content of the twinning arrangement is up to the members involved. The TMB is currently working on a plan to strengthen the twinning programme.

103. It is useful to underline that 76% of the ISO members are from developing countries, and that the “developing countries” category is broader in ISO than in the UN system, since the ISO list is based on the UN list of Member States of the Group of 77, plus ISO members in the UN Eastern European Group of countries that asked to be added<sup>101</sup>.

104. The existence of a dedicated forum such as the DEVCO committee, the consideration of the instances of developing countries at the strategic and operational levels and the capacity building and technical assistance programmes, allow ISO to consider itself fully compliant with the “Development dimension” (Principle F of the TBT principles).

#### **Box 5. A successful twinning example**

ASI (Austria) and ESA (Ethiopia) entered into a twinning arrangement at P-member level that provides for training, simulation, and exchange of information and helps ESA to build capacity in order to use the ISO IT-tools properly (access to the online system, registration, casting votes, etc.) and to follow ISO working methods (support in engaging stakeholders, alerts for commenting and voting on time). ASI also shared information with ESA about positions that may be of interest to Ethiopia with regards to the country’s economic priorities.

### **Ensuring coherence of international standards**

105. As already mentioned, standardization is a crowded field. The more organisations that conduct standardization work, the more risk there is that international standards are not consistent, or even contradict each other. The situation undermines the main objective of trade facilitation, since market players do not know which standards they should rely on. Furthermore, even if several international standards are consistent, their existence implies a duplication of effort and hence is more costly. What’s more, ensuring the coherence of international standards through cooperation and coordination is required by the TBT principles (Principle E).

106. Firstly, ISO ensures the coherence of its own standards. Even if the technical work is decentralized, its overall management is assured by the TMB, which is responsible for the coherence of the TCs and their work programmes. For example, the TMB can merge several TCs/SCs if it is found that their scopes and stakeholders overlap. TCs/SCs working in related fields are also obliged to establish and maintain liaisons and follow each other’s work, and a request for an internal liaison (i.e. between two ISO committees) cannot be refused. Committees are also encouraged to maintain liaisons with TCs/SCs responsible for basic aspects of standardisation (e.g. terminology, graphical symbols). This liaison status allows a TC/SC to send observers to follow the work of another TC/SC, including the right to participate in meetings and submit written comments on drafts. This internal liaison mechanism is especially important for horizontal fields, such as environmental issues.

107. Secondly, ISO ensures the coherence of its work with other international organisations, and in particular with other international standards-setting bodies. This coherence is facilitated by the participation of other organisations in ISO’s TCs/SCs, by the participation of ISO (or ISO’s TCs/SCs) in

100. *ISO/IEC Directives Part 1*.

101. The ISO list of developing countries at ISO is available online: [www.iso.org/iso/home/about/iso-and-developing-countries/developing-countries-in-iso-by-region.htm](http://www.iso.org/iso/home/about/iso-and-developing-countries/developing-countries-in-iso-by-region.htm).

the technical work of other organisations, and by the creation of joint committees. As already mentioned, the most extensive cooperation takes place with IEC and ITU. The three “sister organisations” exchange their new work items every month in order to better coordinate the work and avoid duplication of effort and overlaps. Furthermore, ISO and IEC share the same procedures for standards development.

**Ensuring that standards remain state of the art**

***Systematic Review***

108. Once an International Standard has been published, circumstances (and technologies in particular), might evolve, making the standard obsolete. Therefore, the TBT committee has recommended that standards development organisations “put in place procedures aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective for various reasons” (principle D). At ISO, this is done via the process of ‘Systematic Review’. The systematic review of a deliverable can be initiated by a TC, by an NSB, by the ISO/CS or the Secretary-General. Table 2 shows the maximum time that can elapse before a systematic review takes place, but committees can choose to launch a review much earlier, if they believe it necessary.

**Table 2. Timing of systematic reviews**

Deliverable	Max. elapsed time before systematic review	Max. number of times deliverable may be confirmed	Max. life
International Standard	5 years	Not limited	Not limited
Technical Specification	3 years	Once recommended	6 years recommended
Publicly Available Specification	3 years — no default action by ISO Central Secretariat	Once	6 years (If not converted after this period, the deliverable is proposed for withdrawal)
Technical Report	Not specified	Not specified	Not limited

Source: ISO/IEC Directives Part 1.

109. The systematic review of a deliverable can result in its confirmation, revision, withdrawal or conversion to another form of deliverable. A standard can only be confirmed or amended if it is used in at least 5 countries (otherwise it is deemed to no longer be ‘international’). If a revision seems necessary, the standard is registered as an approved work item and follows the usual procedure for standards development (except that there is no minimum number of P-members required for revision). If results of the systematic review reveal that the standard is not widely used, it will be proposed for withdrawal via a ballot sent to all ISO members for a 20-week vote (members can object to the withdrawal if they feel the standard is still needed).

110. Although the process of systematic review is robust, its key weakness is that it relies on the quality and quantity of replies by ISO members. If few members reply to the systematic review ballot, or if they have not done sufficient stakeholder consultation to find out about the national use of the standard in question, the results of the review may not be accurate. Member participation in systematic review ballots (i.e. the number of countries that reply) has frequently been quite low and this has been identified by the TMB as an improvement area for ISO. For this reason, the rules around systematic review were changed in 2016, making it an obligation for P-members in a committee to vote on all systematic review ballots for deliverables within that committee.

### *Monitoring of the Implementation of Standards*

111. The voluntary nature of ISO standards makes it difficult to track and monitor their implementation. Even for the standards that are certifiable (those containing requirements), certification is only a voluntary step (Box 3). ISO, as a standards developing organisation, does not perform certification and therefore organisations wishing to get certified to an ISO standard must use an independent certification body, of which there are many – this means that ISO does not have information on the number of certificates issued to its standards. What's more, a claim of conformity can also be done through self-declaration (Box 3). In any case, simply assessing the implementation of, or the compliance with, a standard is not necessarily meaningful, since standards offer technical solutions that can be used for numerous different reasons by companies, organisations or public institutions.

112. Nevertheless, in order to get an idea of the impact and success of its management standards, ISO conducts a survey every year of accredited certification bodies, requesting that they report the number of valid certificates they have issued to specified ISO standards (such as ISO 9001 and ISO 14001). The results are reported for each country, each year, and also by industry. As participation in the survey is voluntary, there is some variability in the number of certificates from year to year<sup>102</sup>, however the survey gives a good idea of the market penetration of ISO management standards.

102. To see the results of the last survey, s.: [www.iso.org/iso/iso-survey](http://www.iso.org/iso/iso-survey).

## ASSESSMENT OF THE IMPACT AND SUCCESS OF REGULATORY COOPERATION THROUGH ISO

113. Given the decentralized structure of ISO, the voluntary nature of its standards and the diffuse character of standardization, it is not easy to assess the impact and success of ISO standards. What's more, the impact of a standard also depends on a number of external factors, especially social and economic ones. Nevertheless, studies and indicators show the benefits of standards and the success of ISO and ISO has developed some of its own indicators in order to assess its performance and impact and constantly improve its processes.

### Benefits of Standards

114. The role of standards and their impact on economy and society have been studied for a long time. In the mainstream view of economists<sup>103</sup>, standards are seen as contributing to public welfare by:

- *Improving economic efficiency*: Ensuring interchangeability of parts and supporting variety reduction, standards drive economies of scale. Enabling compatibility and interoperability, standards allow the establishment and exploitation of *network effects (or positive externalities)*, fostering the development of markets for materials and product components, as well as for complementary products
- *Limiting market failures*: Reducing the *information asymmetry* between buyers and producers through information, measurement and minimum quality standards, the latter contribute to improve the functioning of markets – increasing customer choice and promoting fair competition, allowing vendors of higher quality goods to better express their value proposition. Quality, safety and environmental standards help to contrast directly, or in combination with regulations, *negative externalities* (such as health, safety or environmental impact of products and processes)
- *Promoting trade*: Facilitating access to markets (through the harmonization of requirements and conformity assessment practices), reducing transaction costs (through reliable information about material and product characteristics and performances), and facilitating the establishment and operation of (global) supply chain networks.

115. The contribution of international standards to trade has been clearly recognized by the international community for a long time: during the 1970's the members of the GATT approved the Standards Code (1979) which later evolved into the WTO's TBT Agreement (1995) – agreements within which international standards play a very important role.

116. Considering the benefits of ISO standards, examples such as those of Freight Containers (TC 104), and Quality and Environmental Management (TC 176 and TC 207) have already been given (Box 1). Other important examples of extremely successful ISO standards include: those for Cranes (developed by TC 96), which have contributed to improving the operations and enhancing the safety of Cranes worldwide; those for Food Safety (developed by TC 34 and particularly its SC 17), which help companies from all countries to meet customer and public authority requirements; and standards supporting digital media (developed by the ISO MPEG group, ISO/IEC JTC 1/SC 29/WG11), which have made a

103. A valuable description of the role of standards in economic theory is given in the World Trade Report 2005, *Trade, standards and the WTO*

fundamental contribution to the usability and dissemination of digital media, and are today implemented, literally, in *billions* of devices.

117. Whilst standardizers are generally quite certain that their work generates considerable benefits for organizations, markets and society, substantiating and quantifying the real-world value of consensus-based standards is a challenge. Nevertheless, ISO has continuously made an effort to do so – even as early as the 1960s, the ISO Committee on standardization principles (ISO/STACO – no longer active) was carrying out significant analysis on this topic.

118. In more recent times, from 2000 onward, significant efforts have been dedicated to this topic and many research studies have been published<sup>104</sup>. They range from analysis of the macro-economic impact of standards on national economies and international trade, to sector-based analysis, case studies covering businesses and industry sectors, and specific company case studies.

119. Macroeconomic studies focus on evaluating the contribution of standardization to the economic performance of countries, considering indicators such as GDP growth and productivity increase. In summary, these studies indicate a positive correlation between the increase in the stock of standards, and GDP and productivity growth of a country.

120. A landmark study was undertaken in Germany and published in the year 2000. Commissioned by DIN, the German standards body, the study was conducted by the Technical University (TU) Dresden and the Fraunhofer Institute for Systems and Innovation Research, Karlsruhe. The authors of the macroeconomic section of the study, Prof. K. Blind, Dr. A. Jungmittag and Dr. A. Mangelsdorf, used advanced econometric methods to examine German macroeconomic growth between 1961 and 1996 (the analysis was extended to 2006 in a revised version of the study published in 2011). According to their methodology<sup>105</sup>, benefits of standardization for economic growth derive primarily from the contribution of standards to the dissemination of technological knowledge among as many companies as possible. The result of the analysis indicated that the contribution of standards to German GDP growth had its maximum impact throughout the 1970s (1.8% in the period 1971-1976 and 1.2% for 1976-1980) and, after German reunification (1990), the value stabilized at 0.7% - 0.8%.

121. Several studies conducted in other countries in following years and using comparable approaches reached similar conclusions (UK 2005 updated in 2015, Australia in 2006 updated in 2014; Canada in 2007 updated in 2015; France in 2009 and New Zealand in 2011).

122. Another approach was used by France in a study published by AFNOR, the French standards body, in 2016<sup>106</sup>. In this study the performance, e.g. in terms of total revenues and export sales, of companies of various sizes and sectors engaged in standardization (a sample of 2,099 companies), was compared with that of French enterprises (in general) of comparable sizes and sectors. The results show that companies participating in standardization achieve a significantly higher average annual growth rate

104. More detailed information can be found on the section of the ISO website dedicated to the benefit of standards: [www.iso.org/iso/benefits\\_of\\_standards.html](http://www.iso.org/iso/benefits_of_standards.html)

105. The authors followed R. Solow's economic growth model, according to which economic output can be described by three determinants: an increase in capital (e.g. machinery and infrastructure), an increase in labor, and technical progress (a qualitative component – referred to as “total factor productivity”, or TFP). They assumed that TFP can be described both in terms of generation of new knowledge and dissemination of knowledge, and have identified as proxy variables to represent these factors: the number of patents and number of technology license payments (generation of knowledge); and the stock of German standards (dissemination of knowledge).

106. [www.eurogip.fr/images/pdf/Etude%20impact%20economique%20de%20la%20normalisation.pdf](http://www.eurogip.fr/images/pdf/Etude%20impact%20economique%20de%20la%20normalisation.pdf)

(4% compared with 3.3%), and a consistently superior performances in relation to all the indicators analysed.

123. Other significant research efforts have been dedicated to addressing the microeconomic side. In particular, ISO itself has developed a Methodology<sup>107</sup> which provides a systematic approach for assessing the quantitative *contribution of standards to the creation of value* by an individual organisation. The methodology also provides guidance on how to analyse the qualitative contribution of standards to company operations, and to maximise the value contributed by standards.

124. Since 2010, ISO and its members have applied the ISO Methodology, developing about 40 company case studies in more than 20 countries, from all the regions of the world. A variety of sectors have been covered, including agri-food production, chemicals, building construction and construction materials, electrical appliances, electrical power transmission, food retail and logistics, heating, ventilation and air conditioning, industrial automation equipment, information and telecommunication, pipes and piping systems, shipbuilding, and water supply.

125. Three main types of benefits from standards have been identified and quantified, concerning:

- *Streamlining of internal operations*: achieved by reducing the time needed to perform specific activities in the various business functions, decreasing waste, reducing procurement costs and increasing productivity.
- *Process improvement and scaling-up operations*: a number of case studies provide examples where standards served as the basis for innovating business processes, allowing companies to expand their suppliers' network or to introduce and manage new product lines effectively. In other instances, standards helped mitigate the risk to companies of introducing new products.
- *Entering or even creating new markets*: in some cases, standards have been used as the basis for developing new products, getting access to new markets (both domestic and export), supporting the market uptake of products, and in special cases, creating new markets.

126. These case studies consistently report that the contribution of standards to the gross profit of companies ranges between 0.15% and 5% of the annual sales revenues. In exceptional cases, when companies were able to use standards as a means to create new markets (e.g. by positioning themselves as technology leaders and convincing larger companies to license from them technologies based on standards mastered by the company) the impact of standards far exceeded these figures, with a contribution to gross profit of up to 33% of their annual revenue.

127. Finally, it is worth noting that a similar approach has been developed to assess the social and environmental benefits of standards. A set of pilot case studies has already been developed by ISO and NSBs, and this activity should significantly evolve in the future.

### **Assessment of ISO's success**

128. It is very difficult (or even impossible) to perform a quantitative assessment of the uptake and impact of ISO standards, due largely to the decentralised nature of the organisation and the voluntary nature of the standards themselves. Nevertheless, there are a number of indicators that demonstrate the success of ISO and the dynamism of the system.

107. [www.iso.org/iso/pub100344.pdf](http://www.iso.org/iso/pub100344.pdf).

### ***The growth in ISO membership and broad involvement in ISO work***

129. The fact that ISO's membership has grown considerably since it was founded and that it covers most of the world is a testament to the attractiveness of the organisation. In 1947, there were only 26 founding members: Australia, Austria, Belgium, Brazil, Canada, Chile, China, Czechoslovakia, Denmark, Finland, France, Hungary, India, Israel, Italy, Mexico, Netherlands, New Zealand, Norway, Poland, South Africa, Sweden, Switzerland, United Kingdom, USA, USSR. In 2016, membership has grown to encompass 163 countries (119 Member bodies, 40 Correspondent members, 4 Subscriber members)<sup>108</sup>.

130. In addition to the ISO members, over 700 international actors also participate in ISO's work. The intense participation of stakeholders through liaisons and ISO members is possibly the best proof that stakeholders view ISO in a positive light and see material benefits from being involved with ISO and using its standards – after all, they must finance their own participation in the standards development process.

131. In 2015, 75754 people were involved in the ISO system. These experts, coming from 163 national standards bodies, participated in the work of 3535 technical bodies. Together they developed 1505 International Standards, bringing the total number of ISO Standards to 21133. 756 new work items were registered and sales figures increased (probably largely supported by the publication of new editions of ISO 9001 and ISO 14001). The ISO Survey also showed an increase in the number of the certifications to ISO management system standards. What's more, an external survey commissioned by ISO showed an improvement in customer satisfaction from the ISO members, standards users as well as standards developers. The Global NGO Barometer, undertaken by WIN/Gallup International Association, shows a great awareness and a good opinion of ISO around the world.

### ***Performance and satisfaction indicators***

132. ISO conducts surveys, internally or externally, after each event – be it the GA or a training course – to assess its success and the satisfaction of the participants, to address any problems and to make improvements for the future. ISO also continuously gathers data on all aspects of the standards development process, member performance and the ISO/CS's performance, and is currently working to develop specific performance indicators to assess its progress in the implementation of its 2016-2020 strategic plan.

### ***Strategy implementation and Key Performance Indicators (KPIs)***

133. Since 2005, ISO has published a five-year strategic plan developed through a broad consultation process involving its members – many of which, in turn, use this opportunity to engage in dialogue with national stakeholders, capturing their views and requirements, which are then consolidated into a national position submitted to ISO. The five-year ISO strategic plan is then complemented by an annual implementation plan and a set of key performance indicators (KPIs), used by Council and by the bodies reporting to Council to monitor progress on a regular basis and to evaluate results (at intermediate and final stages).

134. The approaches adopted to implement the strategic plan and the specific set of KPIs used to measure its implementation have changed over time, reflecting the evolution of the organisation's objectives, the evaluation of past experiences and the direction given by the governance bodies.

108. To see the evolution of ISO membership over the years: ISO, Historical record of ISO membership since its creation (1947), [www.iso.org/iso/historical\\_record\\_of\\_iso\\_membership\\_1947\\_to\\_today.pdf](http://www.iso.org/iso/historical_record_of_iso_membership_1947_to_today.pdf).

135. The latest approach to strategy implementation (2016) comprises seven strategic programmes linked to key elements of the strategic plan (the ‘ISO Strategy: 2016-2020’<sup>109</sup>): Standards development, Stakeholder engagement, Development and training, Marketing and communication, Information technology services, Conformity assessment, and IPR protection. For each strategic programme, objectives are specified (up to five), and each of them is linked to a specific indicator. For example, the first objective of the Standards development programme is “Ensure the high-quality of ISO deliverables” and the associated KPI is “editorial quality” (determined on the basis of the number of errors detected, and their impact on the corresponding ISO publications).

136. The Council Strategy and Policy Committee is responsible for monitoring the implementation of the ISO Strategy 2016-2020 (through the KPIs and qualitative information) and making regular progress reports to Council. Since 2016 is the first year that this new approach using ‘strategic directions’ is being implemented, no results are available, as yet.

#### *TMB Dashboard*

137. Given its extensive use of IT tools for standards development, ISO is able to automatically collect a lot of data on standards development processes, sectoral trends/new fields of work, the performance of the TCs, cooperation with liaisons and partner organisations, and the voting performance of the members. This data is compiled once a year for review by the TMB in what is referred to as ‘the TMB dashboard’. The TMB analyses the data, comparing the actual figures to the yearly targets set for various items and identifies any trends or problematic areas requiring action. The kind of actions taken as a result vary depending on the problem at hand. In some cases, the TMB may decide that the rules and processes for standards development (the ISO/IEC Directives Part 1) need to be modified to achieve a certain result. For other cases, the TMB may undertake a larger project involving members of the technical community and the ISO/CS, for example, to improve the effectiveness and efficiency of project management for standards development and reduce the average development time for standards. The TMB uses the information in the dashboard to identify where members may need assistance, where processes can be improved and to evaluate the progress being made in the technical work.

138. For example, one of the statistics that is regularly monitored in the dashboard is the average development time for an International Standard, from its proposal to its publication (in 2015, this was 33.4 months). It is ISO’s goal to publish standards in as timely a manner as possible (i.e. when the market needs them). Therefore, over the last few years the TMB has worked to revise the rules and procedures for standards development to allow more flexibility for committees to skip certain stages (CD and FDIS) and to speed up development, under certain circumstances. However, dashboard statistics have shown that the average development time is not decreasing as much as anticipated, is not meeting the yearly targets set, and that the new flexible options are not as widely used by committees as hoped. As a response, the TMB concluded that it is project management that must be improved and launched in 2016 a major initiative to improve ‘project management for standards development’. Together with the IEC, ISO held a workshop in April 2016 with Chairs, Secretaries, Convenors, programme managers and members of the technical boards of both organizations to discuss best practices and cultural change. This project is ongoing and its impact will be monitored, at least in part, by the key statistics on standards development included in the TMB dashboard every June.

109. The latest version, approved by the ISO General Assembly 2015 and covering the timeframe 2016-2020, is available here: [www.iso.org/iso/iso\\_strategy\\_2016-2020.pdf](http://www.iso.org/iso/iso_strategy_2016-2020.pdf).

## CONCLUSION

139. Overall, the story of ISO, and of its contribution to IRC, is one of success. Created in 1947 by a group of engineers, ISO has become one of the leading and most widely recognised and respected providers of international standards in the world. At the time, both the structure and processes of ISO were avant-garde: participation of the public and private sectors, involvement of a wide range of stakeholders, bottom-up approaches to ensure market relevance – these features have been in place at ISO almost since its creation in 1947, way before it became fashionable or common in other IOs or at the domestic level. What's more, the specific structure of ISO as a private association offers a lot of flexibility to adapt quickly to today's challenges. One of the most recent examples is how ISO took advantage of new technologies (especially IT tools), integrated them into its processes and thereby facilitated and enhanced the participation of its members and stakeholders. Indeed, the ISO model today could provide a model for other IOs to follow, and also for transnational networks that have been emerging over the last decade (OECD, 2014: 27).

140. One of the main factors of ISO's success as a contributor to enhanced IRC identified in this case study is the homogeneity of the ISO deliverables and process. This homogeneity is made possible because ISO's only business is standardization and all of its products are developed using more or less the same procedures and rules. This enables ISO to more easily ensure it produces high-quality products and to continually monitor and improve its standards development process.

141. Of course ISO also faces some challenges. Firstly, the active participation of members and stakeholders is crucial to ensuring a fair and balanced system and the global relevance of the International Standards produced. Because of the decentralized nature of the system, it is difficult to effectively monitor stakeholder engagement and ISO is continually looking for ways to improve this key aspect of its work. Secondly, the business model of ISO is often criticized, as some argue that standards, and in particular those that are referenced in regulations, should be available for free. The fact that ISO standards are not free-of-charge could be an impediment to its contribution to IRC if States choose not to reference international standards for fear of violations of copyright or criticisms for restricting access to information. However, the process of continual improvement that figures prominently in many of its own management system standards is also central to the ISO story and ISO is committed to regularly reviewing its processes, revising them as necessary, and working together with its members to increase the profile of the organisation and its impact in the international arena. In this vein, in 2016 the Council launched a review of all of ISO's governance structures to assess their effectiveness and efficiency in the face of today's challenges. As far as IRC is concerned, ISO hopes to further strengthen its contribution and impact, and to continue to provide States and other international actors with consensus-based solutions to support their businesses and public policies.

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