International Regulatory Co-operation and International Organisations

The Case of ASTM International

OECD

International Regulatory Co-operation
and International Organisations

The Case of ASTM International

Please cite this publication as:
OECD (2021), International Regulatory Co-operation and International Organisations: The Case of ASTM International, OECD.

Photo credits: Cover illustration © Jeffrey Fisher.

Preface

At its core, ASTM International is about collaboration to improve lives and make the world better. We are extraordinarily privileged to be involved in the International Organizations (IO Partnership) Initiative, steered by the OECD and bringing together a diverse group of international organisations (IOs) to share information, discuss best practices, and promote greater awareness and understanding of how IOs encourage and support international regulatory co-operation. Building on this work – and joined by ASTM International leadership and members – I am delighted to welcome and introduce this OECD case study of ASTM International as an international organisation.

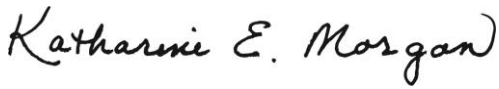
ASTM International is a non-governmental organisation with a global reach and broad societal impact. We bring people together to unite in purpose and develop trusted standards and technical solutions driven by research, data, and science-based decisions. The ASTM International standards development process is designed in accordance with the principles of openness, transparency, impartiality, consensus, effectiveness, relevance, coherence, and inclusion of developing countries. Our approach is noteworthy in that it empowers individuals from any stakeholder category and governments from anywhere in the world to participate directly as equals in an open, balanced and consensus-based manner.

In recent years, we have expanded our collaborative approach to bring together the innovation and standards communities in several emerging technology areas. By engaging the research community, we learned that aligning research plans with standardisation development drives solutions, harnesses technology, and brings innovations to market more efficiently to the benefit of society.

Supported in part by our involvement in the IO Partnership, ASTM International has coordination and collaboration mechanisms in place with many other IOs, some of which are discussed further in this case study. As ASTM International approaches the 125th anniversary of its founding, I hope this brief case study is not only a useful reference for experts in and students of regulatory policy but also that it helps promote

the principle that there are multiple paths to the same destination. As I write this, ASTM International is looking to the future, nurturing our relationships as well as seeking and establishing new collaboration partnerships.

As the recent global pandemic has taught us, humanity does not face a shortage of challenges in the 21st century. Resilient partnerships and collaboration are more important than ever. Together, we can learn from each other and we can leverage our respective strengths to solve global challenges, seize current and emerging opportunities, and build together on everyone's behalf to maximise our impact and make the world better.



Katharine Morgan

President, ASTM International

Foreword

This study builds on OECD long-standing work on regulatory policy and governance, as set out in the OECD 2012 Recommendation of the Council on Regulatory Policy and Governance. It was developed as part of OECD work on international regulatory co-operation (IRC) (Principle 12 of the Recommendation), within the Partnership of International Organisations for Effective International Rulemaking (IO Partnership). It is part of a series started in 2014 that provides detailed overviews of the structure, governance, instruments and processes of international organisations (IOs) in support of international rule-making and standard-setting.

To date, the series includes the cases of the OECD, the International Maritime Organization (IMO), the Food and Agriculture Organization of the United Nations (FAO), the International Organization for Standardization (ISO), the International Organization of Legal Metrology (OIML), the World Health Organization (WHO), the UN Economic Commission for Europe (UNECE), the World Trade Organization (WTO), the Bureau International des Poids et Mesures (BIPM) and the Organization for Animal Health (OIE). The case studies complement broader analytical work conducted by the IO partnership that compares the governance modalities and rule-making processes of 50 IOs, annual meetings and technical discussions within five working groups. The work on international regulatory co-operation by IOs is conducted under the auspices of the OECD Regulatory Policy Committee, whose mandate is to assist both members and non-members in building and strengthening capacity for regulatory quality and regulatory reform.

This report was approved by the OECD Regulatory Policy Committee on 30 April 2021 and prepared for publication by the OECD Secretariat.

Acknowledgements

This study was prepared by the OECD Public Governance Directorate under the leadership of Elsa Pilichowski, Director. It was managed and drafted by Camila Saffirio and Marianna Karttunen from the OECD Regulatory Policy Division under the overall direction of Nick Malyshev, Head of the Regulatory Policy Division. This study was developed with significant inputs from ASTM International staff and members, OECD members and other international organisations. Background research was provided by James Correia. The study was prepared for publication by Jennifer Stein.

The study was circulated for comments to the Regulatory Policy Committee and members of the Partnership of International Organisations for Effective International Rulemaking in November 2020 and April 2021.

The authors wish to thank ASTM International staff and members for responses to interviews and several rounds of comments. Special thanks in particular go to Katharine Morgan and Jeff Grove for their vision and support for the project. We are very grateful to Sara Gobbi and Craig Updyke for their extensive inputs throughout the process and for facilitating the preparation of this study. We also thank interviewed ASTM members for their time and insights, namely: Amer Bin Ahmed (Knauf Middle East), Cesar Constantino (Separation Technologies), Franceen Gonzales (WhiteWater West Industries), Ian Mylrea (Stanhope-Seta), Ralph Paroli (National Research Council Canada), Taco van der Maten (Malvern Panalytical). The study also benefitted from inputs from staff of other international organisations, in particular the International Organization for Standardization, the International Electrotechnical Commission and the World Trade Organization.

Table of contents

Tables

Figures

Boxes

Executive summary

There is no longer any doubt that the major policy challenges of the 21st century are of transboundary, even global, magnitude. Fighting climate change and biodiversity loss, ensuring financial stability, and guaranteeing the safety and quality of goods traded globally are but a few of the issues that regulators across the world are required to act upon. International organisations support them by providing the institutional setting to identify best policies and develop common approaches to common challenges. The policy challenges are also increasingly complex and specific, requiring increasingly specialised and diverse actors beyond traditional intergovernmental organisations to support governments in the variety of transboundary challenges they face.

The *Case Study of ASTM International* throws light on a unique actor in this rich and diverse global governance landscape. ASTM International is a private standard-setting organisation that brings together technical experts from across government, academia, industry, as well as producers, users and consumers from over 150 countries, and mobilises their practical experience in developing international standards. The full body of ASTM standards exceeds 12 800, and the organisation is active in over 90 industrial sectors. By analysing its governance arrangements, operational modalities, standard-setting practices and efforts to assure the quality of its standards, as well as its specificities and commonalities with other international actors, this case study helps build the body of knowledge of the Partnership for Effective International Rulemaking. To illustrate the activities of ASTM International, this study provides an overview of standards developed by the organisation in additive manufacturing (3D printing), sustainable aviation fuels, and sustainable construction.

ASTM stands out from traditional international organisations particularly for its open and innovative membership, which comprises over 30 000 individual members. This membership model explains many specificities of the Organisation and aligns with it's ambition to be responsive to the global market and standardisation demands. ASTM International is strongly committee-led and quick to react to emerging areas in need

of standardisation, notably new production technologies. This is facilitated by the participation of technical experts across committees that draw attention to new opportunities for standard development and a streamlined process that enables the creation of new committees and standards.

ASTM International applies a variety of mechanisms and tools to ensure the quality of its standards. Upon reception of proposals for new standards, ASTM International conducts an *ex ante* assessment to determine whether the proposal will generate results in terms of better safety, fit-for-purpose specification and classification, and more efficient testing, and maps the scope of the subject under consideration. The standards development process includes specific efforts to ensure balanced participation from diverse interests and participants and prevent over- representation of certain types of members, such as producers versus consumers or general interest participants. In addition, ASTM International follows national and international guiding principles to ensure due process, inclusiveness and quality. To enable broad participation, the standards development process of ASTM International often integrates tools for remote participation, such as virtual meetings, collaboration areas, and online balloting. These digital tools equipped the organisation to continue its standard-setting activities throughout the COVID-19 pandemic, which led most international organisations to adapt their rulemaking to a newly virtual context.

The ASTM International Review of Standards Procedure creates a framework for the systematic review of individual standards within five years of approval, to ensure that they remain fit for purpose. It also provides a pathway for balloting on their re-approval, revision or withdrawal. To maximise the coverage of its standard-setting activities and reduce duplication, ASTM International engages in a variety of co-ordination initiatives with other IOs active in its sphere of operation.

Still, like all IOs, ASTM International faces challenges to ensure the effectiveness, impact and relevance of its standards. Fostering the active engagement of members throughout the standard-setting process is central to ensure their quality and relevance, but can prove challenging, particularly when dealing with so many different players. Furthermore, the focus on a diverse membership has left little space for an active stakeholder engagement strategy to garner further viewpoints beyond the ASTM membership. In addition, while regular review is well embedded into the standardisation process, the large volume of standards developed and the fast-paced evolution of the areas involved call for efforts to ensure that standards remain relevant and fit for purpose.

Acronyms and abbreviations

ACCSQ	ASEAN Consultative Committee for Standards and Quality
AFNOR	French Standardization Association (*Association Française de Normalisation*)
AIDMO	Arab Industrial Development and Mining Organisation
ANSI	American National Standards Institute
APEC	Asia Pacific Economic Cooperation
ASSP	American Society of Safety Professionals
BSI	British Standards Institution
CAP	Conformity assessment procedure
CARICOM	Caribbean Common Market
CPSC	Consumer Product Safety Commission, United States
CSA	Canadian Standards Association
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardization
CIS	Interstate Council for Standardization, Metrology and Certification, serves the Commonwealth of Independent States
COPANT	Pan American Standards Commission
COT	Committee on Standards (ASTM International)
COTCO	Committee on Technical Committee Operations (ASTM International)

COP	Committee on Publications (ASTM International)
CROSQ	CARICOM's Regional Organization for Standards and Quality
DIN	German Institute for Standardization
EASC	Euro-Asian Council for Standardization, Metrology and Certification
EN	European Standard
ETSI	European Telecommunications Standards Institute
GSO	Gulf Cooperation Council Standardization Organization
IAEA	International Atomic Energy Agency
IATA	International Air Transport Association
IATM	International Association for Testing Materials
ICAO	International Civil Aviation Organization
ICONTEC	Colombian National Institute of Technical Regulations and Certification (*Instituto Colombiano de Normas Técnicas y Certificación*)
IEC	International Electrotechnical Commission
IO	International organisation
IGOs	Inter-governmental organisations
IMDRF	International Medical Device Regulators Forum
ISEA	International Safety Equipment Association
ISO	International Organization for Standardization
ITU	International Telecommunications Union
JARUS	Joint Authorities for Rulemaking of Unmanned Systems
MoU	Memorandum of Understanding
NATO	North Atlantic Treaty Organization
NFPA	National Fire Protection Association, United States
NIJ	National Institute of Justice, United States
NOCSA	National Operating Committee on Standards for Athletic Equipment, United States
OECD	Organisation for Economic Co-operation and Development
OIML	International Organisation for Legal Metrology
PASC	Pacific Area Standards Congress

PPE	Personal protective equipment
PSDO	Partner Standards Development Organization
SADC	Southern African Development Community
SAF	Sustainable aviation fuels
SARSO	South Asian Regional Standards Organization
SCC	Standards Council of Canada
SCSC	APEC Sub-Committee on Standards and Conformance
SDO	Standard Development Organisation
SPS	Sanitary and Phytosanitary
STANAGs	Standardization Agreements, NATO
TBT	Technical Barriers to Trade
UNECE	United National Economic Commission for Europe
UNFCCC	United Nations Framework Convention on Climate Change
UNIDO	United Nations Industrial Development Organization
WCO	World Customs Organization
WHO	World Health Organization
WMO	World Meteorological Organization
WTO	World Trade Organization

Introduction

ASTM International is a not-for-profit private standard-setting body headquartered near Philadelphia, Pennsylvania, United States, active in areas spanning over 90 industrial sectors, and counting today more than 12 800 active standards. A number of special features of ASTM International provide interesting perspectives about international standard-setting in various aspects:

- The standards-development process followed by ASTM International balances the interests of different participants distinguishing between producers, users, consumers, and general interest (representatives of interests such as government and academia) that work to deliver standards by reaching consensus on common ground.
- ASTM International's membership structure and standard-development process promote open participation. Its membership surpasses 30 000 individuals and organisations from over 150 countries, contrasting with the small-sized secretariat of ASTM International. This results in a strong reliance on the members of technical experts to develop the technical content of standards actively in response to market needs.
- Remote participation tools are commonly integrated into the regular standard-development process of ASTM international, facilitating the engagement of members globally, optimising staff and supporting flexibility in participation and contributions to the process.
- ASTM International's bottom-up approach to standard development and a streamlined process allow the organisation to facilitate standard-setting action in new market areas, including through the creation of new technical committees and standards.
- In recent years ASTM International has launched several initiatives with a view to bridging the gap between technological innovation and technical standardisation notably around key emerging production technologies. This is facilitated by the participation of technical experts across committees that

support the organisation's focus on science and technical quality raising attention to new opportunities for standard-development.

- ASTM International operates in a variety of areas with a mandate that is close to or at times overlaps with a number of national, regional and international actors. To avoid inefficiencies and unnecessary duplication of effort and to promote technical alignment, it co-ordinates closely with various actors, including through the development of joint standards – in selected areas – with organisations such as ISO and IEC, and co-operation with traditional IGOs.

ASTM International is an international private standard-setting organisation differing in a number of aspects from typical international organisations (IOs) (OECD, 2016[1]). Such private standard-setting organisations can be defined as international bodies established under domestic law and not by a treaty, which differentiates them from traditional intergovernmental organisations (IGOs). Their main activity is to produce international standards and members may be non-governmental organisations, private bodies, or governmental agencies, and at times individual members. The category includes a broad variety of IOs with different governance models, for instance in relation to their profit or not-for-profit nature or to the membership composition.

This study of ASTM International's standard-setting and governance practices contributes to the OECD's analytical work on international rulemaking with the perspective of an atypical form of IO, all the more relevant in light of the increasing reliance on the deliverables produced by international private standard-setting organisations. Standard-development organisations are commonly referred to as private regulators and, while standards are voluntary, they can support international regulatory co-operation (IRC) between countries and promote global regulatory convergence (OECD, 2013[2]). They help regulators draw on international expertise and facilitate trade by reducing specification and conformity assessment costs (OECD, 2017[3]). Still, systematic consideration of international standards when developing and applying domestic regulations requires assurance about their quality, accessibility, and public interest orientations.

This OECD case study is based on its expertise in the field of the rulemaking and standard-setting practices of international organisations (IOs), as part of a broader priority for the work of the OECD Regulatory Policy Committee on IRC. It is situated within the broader context of the Partnership of International Organisations for Effective International Rule-Making (IO Partnership) spearheaded by the OECD. This provides a structured framework for mutual learning on effective international rule-making among over 50 IOs and their constituencies, through regular exchange of information and practices and the development of analytical work.

This case study provides a draft report on the standard-setting practices and related governance mechanisms of ASTM International. It describes how ASTM International supports IRC – the context in which this takes place, its main characteristics, its impact, as well as areas of progress and challenges. It builds on interviews conducted by the OECD with ASTM staff and selected Members, as well as on desk research on information specifically provided by ASTM International and publicly available information. ASTM staff provided comments that are reflected in this draft report. The final case study will be shared with members of the IO Partnership during its 8th Annual Meeting to be held in 2021.

Box 1. Definitions of key terms

The definitions of the key terms are used for the purpose of this case study and are without prejudice to the meaning of these terms in individual organisations of the IO Partnership, including the OECD, as well as in their respective members:

There is no agreed definition of "**international organisation**". The academic literature acknowledges the diversity of IOs and offers several classifications based on functions, membership or purpose (OECD, 2016[1]) For the purpose of the IO Partnership, the term has been defined broadly to encompass a variety of organisations regardless of their mandate, sector, legal attributes or nature, engaged in normative activities, i.e. the development and management of "rules". These organisations share three critical features: 1) they generate international instruments, be they legal, policy or technical instruments; 2) they rely on a secretariat; and 3) they are international in that they involve "representatives" from several countries. For the present report, the term of "international organisation" refers to an organisation composed of its members and supported by a permanent secretariat.

In line with this definition, the term "international organisation" used in the IO Partnership, including in the upcoming *Compendium of International Organisations' Practices* (OECD, 2021 forthcoming[4]), covers three broad categories of entities (OECD, 2016[1]) (OECD, 2019[5]):

- ***Intergovernmental organisations (IGOs)*** are classical IOs created by "a treaty or other instrument governed by international law and poss[ess] [their] own international legal personality" (International Law Commission, 2011[6]). Their full members are primarily states and, in some cases, other IGOs or even non-governmental actors. Some may have universal

membership. Others limit membership using a number of criteria, such as geographical location or shared values.

- **Trans-governmental networks (TGNs)** differ from IGOs by their membership, legal basis, and the nature of their decisions. They typically involve specialised units of national governments (principally ministries and regulatory agencies), but also nongovernmental actors such as private sector organisations or technical experts. They are established by voluntary agreements among regulators and generally described as "networks" because of their "loosely-structured, peer-to-peer ties" (Raustiala, 2002[7]). They make non-legally binding decisions and usually rely on member agencies to implement decisions within their respective jurisdictions.
- **International private standard-setting organisations** are generally international bodies established under domestic law and not by a treaty, which differentiates them from traditional IGOs. Their main activity is to produce international technical standards. It is however worth noting that this category gathers quite a variety of IOs with different governance models, be it in relation to the profit or not for profit nature of the IO or to the membership of the organisation (OECD, 2016[1]).

To encompass the broad range of legal and policy documents adopted by international organisations as part of their normative activity, this document uses the broad term of **international instruments**. These cover legally binding requirements that are meant to be directly binding on members and non-legally binding requirements that may in some cases be given binding value through transposition in domestic legislation or recognition in international legal instruments; and statements of intent or guidance (OECD, 2016[1]). This broad notion therefore covers e.g. treaties, legally binding decisions, non-legally binding recommendations, model treaties or laws, declarations, voluntary technical standards, statements of intent or any other guidance.

Technical standards are voluntary instruments developed "in response to a need in a particular area expressed by stakeholders through a bottom up approach" (OECD, 2016[1]). Technical standards can be developed domestically, by national standards bodies, or internationally (or regionally), by international (or regional) bodies. They can also be developed by private bodies. Technical standards may then be referenced or incorporated by States within their domestic legislation (the World Trade Organisation Agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary (SPS) Measures strongly encourage WTO members to base their domestic regulations on international

standards which can be developed by different kinds of international bodies) and/or used voluntarily by private actors to meet market expectations.

1. See, e.g. Appellate Body Report in US – Tuna II and Panel Report in Australia – Tobacco Plain Packaging (currently under appeal). The TBT Committee decision on the six Principles for the Development of International Standards, Guides and Recommendations (G/TBT/9, 13 November 2000, para. 20 and Annex 4) also played an important role for clarifying the meaning of "international standard" under the TBT Agreement (see e.g. Appellate Body Report in US – Tuna II, paras. 370-379 and 382, 384, and 394). The TBT Agreement refers to "relevant" international standards; the term relevant has been addressed by the Appellate Body in EC-Sardines. For further discussion on the "Six Principles", see pp. 80-81.
Source: (OECD, 2016[1]) (OECD/WTO, 2019[8]) and (OECD, 2021 forthcoming[4]).

1 The context of regulatory co-operation

A short history of the development of ASTM International

The origins of ASTM International can be traced back to 1898, when seventy members of International Association for Testing Materials (IATM) met in Philadelphia to form the American Section of the organisation (ASTM International, 1998[9]). The American Section's first technical committee on steel initiated a series of discussions around testing and material standards for the railroad industry, approving its first Standard on Structural Steel for Bridges in 1901. In 1902, the American Section decided to rename the organisation the American Society for Testing Materials. In its early years, the organisation institutionalised its standard development process. The "Procedures Governing the Adoption of Standard Specifications", agreed in 1908, set out the key features that govern its standard development today: a consensus-driven process with balanced representation of manufacturers, users, and general interest participants. Initially, ASTM standards focused primarily on the steel, railroad, and cement industries. By the 1920s, it had over 100 technical committees and more than 1 500 members based mostly in the North-East of the United States.

The expansion of ASTM into new areas closely parallels the path of United States industrial and economic development, a country where standards development is sector-based and market-led. In 1942, the organisation introduced emergency standards to support WWII efforts. It later benefited from the recognition of its standards for public procurement, particularly in the defence sector through the 1952 Defence Standardization Act. ASTM standards on building codes and construction played a central role in the post-war growth of American cities and suburbs. In 1961, the organisation was again renamed, becoming the American Society for Testing and Materials, underscoring the focus on the development of standardised material specifications as well as test methods. In the following years, the organisation

expanded beyond industrial standards and into the markets for consumer products and environmental standards.

Globalisation and technological innovation compelled ASTM to increase its international outreach efforts. This involved establishing offices outside of the United States, promoting the participation of international technical experts and interested parties in its rule-making processes, and collaborating with national and international standard-setting bodies. In 2001, with a membership of individuals from over 100 countries and nearly 40% of standards distributed outside the US, ASTM changed its name to ASTM International to reflect its position as a standards development organisation with worldwide participation and acceptance. To date, the global distribution of ASTM standards is above 50%.

Areas in which ASTM International is operating and intended objectives of regulatory co-operation through ASTM standards

(OECD, 2019[5]) highlights the wide range of instruments with external normative value adopted by international organisations, most of which are non-legally binding. Among them, "international technical standards are voluntary instruments developed in response to a need in a particular area expressed by stakeholders through a bottom-up approach" (OECD, 2016[1]). They may be incorporated by states within their domestic legislation and/or implemented directly by private actors, on the basis of their technical quality and relevance. Although there is no definition of international standards universally recognised across international organisations, to support WTO member state governments' implementation of the WTO Agreements on Technical Barriers to Trade (TBT) and pursuit of greater regulatory alignment to minimise technical barriers to trade,[1] in 2000 the WTO TBT Committee issued a set of six principles for development of international standards. The six principles and procedures are to be observed when international standards, guides and recommendations (WTO, 2000[10]).

The purpose of ASTM is defined in its Charter of Incorporation, which states that "the corporation is formed for the development of standards on characteristics and performance of materials, products, systems, and services; and the promotion of related knowledge" (ASTM International, 1902[11]). ASTM International defines a standard as "a document that has been developed and established within the consensus principles of the Society and that meets the approval requirements of ASTM procedures and regulations" (ASTM International, 2019[12]). While all ASTM standards are developed following the same approval procedure, the organisation recognises six types of standards based on needs and usage as decided by the

technical committees. These include test methods, specifications, guides, practices, classifications, and terminology. The term “standard” serves in ASTM International as a nominative adjective in the title of documents containing such standards, to connote specified consensus and approval.

The subjects encompassed for standardisation by ASTM International are broad. As of 2020, the organisation had published nearly 13 000 active standards spanning over 90 industrial sectors, including Oil and Gas, Environment (Water, Air and Land), Buildings and Construction, Plastics, Medical Devices, Personal Protective Equipment (PPE), Life Sciences/Nanotechnology, Alternative Energy (Solar, Geothermal and Hydropower), Aviation, Additive Manufacturing, and Robotics/Exoskeletons.

Voluntary standards, such as ASTM standards, can provide input for domestic policy-makers and regulators when designing measures to advance their policy objectives. This is particularly evident for technical regulations, and for the co-ordination of approaches among peers with similar goals. Recognition of international standards is one of the primary approaches available for countries to embed international considerations within domestic rule-making (OECD, 2013[2]). International standards are a central dimension of regulatory alignment, enabling the alignment of technical specifications of products as well. Their use has been promoted by the WTO TBT and SPS Agreements, which strongly encourage members to use them as the basis for their measures (OECD/WTO, 2019[8]). There are several different methods through which to reference an international standard in primary or secondary legislation, for its voluntary or mandatory use (OECD/ISO, 2016[13]) (European Commission, 2002[14]):

- **Direct** reference, when the international standard is directly quoted in a legal text using its identification number and title;
- **Indirect** reference, when a list of standards deemed suitable by the regulator is compiled and published as an official information source outside of the regulatory instrument itself;
- **Dated** reference, when a specific edition of a standard is indicated; and
- **Undated** reference, when reference to the latest edition of a standard is intended or when the legislative text calls for “state of the art” or “acknowledged rules of technology” without targeting a specific standard.

Landscape of international and domestic regulatory actors in the international standardisation system

International, regional and domestic standardisation bodies

International standardisation takes place in an institutionally crowded space that encompasses international private standard-setting organisations, regional standardisation bodies, and domestic standardisation organisations. In addition, a number of other actors representing different interests participate in the international standardisation process, including business groups, non-governmental organisations (NGOs), and civil society.

International private standard-setting organisations are international bodies whose main activity is to produce international standards (OECD, 2016[1]). These bodies differ from traditional intergovernmental organisations (IGOs) in that they are established under domestic law rather than through a treaty. International private standard-setting organisations vary in their governance models and institutional structures. Their members may be public, private or a mix of public and private entities. Finally, they may restrict participation to only country representatives (IEC, ISO), allow for the direct participation of technical experts from private and public stakeholders (ASTM International), or only allow private actors to gain membership (IATA).

There are also a number of traditional IGOs that produce standards in specific policy fields, some of which at times overlap with ASTM International in certain sectors. These include, among others: the Codex Alimentarius Commission (food safety standards); the International Telecommunications Union (ITU) (telecommunications); the North Atlantic Treaty Organization (NATO) (military equipment and procedures); the OECD (chemicals and fruit and vegetables); the International Organisation for Legal Metrology (OIML) (legal metrology); the United Nations Economic Commission for Europe (UNECE) (trade standards); the Universal Postal Union (UPU) (postal service standards); the World Customs Organization (WCO) (harmonised system for custom tariffs and trade statistics); the World Health Organization (WHO) (health-related standards); and the World Meteorological Organization (WMO) (standards on meteorological and related observations).

In addition, there are several regional standards bodies tasked with co-ordinating regulatory positions in other international *fora* and, at times, engaging directly in the development of regional standards. A number of these bodies are partners of ASTM via an International Memorandum of Understanding Program, discussed below. The first of such bodies was the Pan American Standards Commission (COPANT),

created in 1949 to promote and strengthen standardisation in Argentina, Brazil, Chile, Colombia, Mexico, the United States, Uruguay and Venezuela. European Standardisation Organisations comprise the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI). Other regional bodies include the African Regional Organisation for Standardisation (ARSO); the Andean Standardization, Accreditation, Testing, Certification, Technical Regulations and Metrology System of the Andean Community (CAN); the APEC Sub-Committee on Standards and Conformance (SCSC); the Arab Industrial Development and Mining Organisation (AIDMO); the ASEAN Consultative Committee for Standards and Quality (ACCSQ); the Caribbean Common Market's (CARICOM) Regional Organization for Standards and Quality (CROSQ); the Euro-Asian Council for Standardization, Metrology and Certification (EASC); the Gulf Cooperation Council (GCC) Standardization Organization (GSO); the Interstate Council for Standardization, Metrology and Certification for the Commonwealth of Independent States (CIS); the Pacific Area Standards Congress (PASC); the South Asian Regional Standards Organization (SARSO); and the Southern African Development Community Cooperation in Standards (SADC).

Moreover, consortia-developed standards, which are standards created by groups of companies, are increasingly growing in number and scope with growing impact in the international arena, particularly in the fields of telecommunications and information.

Finally, domestic standard development organisations (SDOs) operate in different countries and, at time, with global impact. ASTM International is a lead developer of voluntary standards in the private-led United States system for standard setting, where over a hundred other private actors develop standards, act as accreditation bodies and/or engage in conformity assessment. These include, among others: the American Oil Chemists Society (AOCS); the American Petroleum Institute (API); the Institute of Electrical and Electronics Engineers (IEEE); the National Fire Protection Association and Underwriters Laboratories (UL) (NIST, 2009[15]).

Acknowledging the close mandates and fields of expertise that ASTM International shares with other national, regional and international bodies, the organisation undertakes a number of efforts to co-ordinate with some of these actors, particularly with the objective to join efforts toward common standards when relevant, or avoid duplication. Notably, at times this increased co-operation has been member-driven and promoted by participants in technical committees who are simultaneously members or familiar with the work of committees under different standard-setting organisations. This was the case of the joint work of ASTM International and ISO on additive manufacturing.

Note

[1] Article 2.4 of the Agreement on Technical Barriers to Trade reads: “Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems”.

2 Main characteristics of regulatory co-operation in the context of ASTM International

Governance arrangements and operational modalities

The unique membership structure of ASTM International aims to ensure an inclusive and representative decision-making process, with the goal of encompassing as many of the interested/affected actors in the regulated field or industry sector as possible, notwithstanding their pre-existing political or economic power. At the same time, and in line with other standard-setting organisations, its secretariat is relatively small, relying on the members to carry out the technical work of the organisation and technology infrastructure to support their work and minimise administrative burden.

Membership and participation

Open participation is one of the key features of ASTM International's standard-development process. Membership is open to individuals or organisations regardless of number or country, each representing their own interests. This model, common among US-based standard development organisations, distinguishes ASTM International from IGOs where membership is most commonly limited to States, as well as from other private standard-setting organisations where members may be public, private or mixed entities (for instance, IEC and ISO), but typically follow a member/country, one vote principle (OECD/ISO, 2016[16]).

Membership

ASTM International follows a direct membership model with participation open to individuals and organisations, which may be producers, users, consumers, governments, universities and other stakeholders. The organisation has over 30 000 members, 72% of which are based in the United States and 28% representing 157 other countries. ASTM International continues to work to diversify its membership and increase its global reach. A Memorandum of Understanding (MoU) programme was created in 2001 to promote the participation by stakeholders from MoU partner countries and allow technical experts to participate at no charge as full voting members in the ASTM standards development process. Furthermore, the programme gives participating national and regional standards bodies free access to the full library of ASTM standards.

According to ASTM International Regulations, applications for membership are submitted to specific technical committees for approval. This is granted if the individual or organisation represents voting interests that produce, use, regulate, or procure a material, product, system, or service covered by the scope of the committee or subcommittee; and documents their expertise in, or relevance to, activities under the scope of the body. Applicants have recourse to appeal the denial of membership or the assignment of classification and voting interest to the committee's executive subcommittee and then, if necessary, to the Committee on Technical Committee Operations (COTCO).

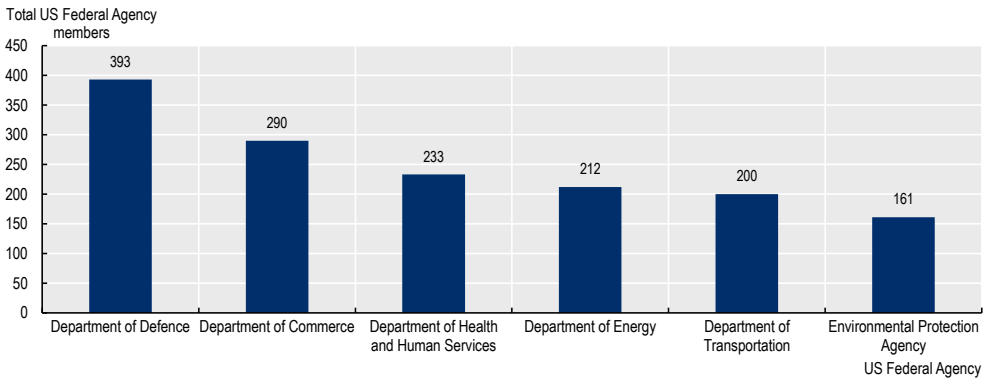
ASTM members can participate in one or more committees and are classified according to their voting interest as producer, user/consumer, and general interest. Membership is fee-based and organised around the calendar year. The organisation recognises four types of membership with different levels of access to ASTM's activities:

- *Participating Members* are individuals that can participate and vote in committees.
- *Organisational Members* are organisations that engage in the standard development process, designating one representative to join technical committees with the same rights as Participating Members.
- *Informational Members* have an interest in ASTM standards and related technical information but choose not to participate in technical committees.
- *Student Members* are full-time undergraduate or graduate students who receive information for free from ASTM, but who cannot participate in the standards development process.

Members of ASTM International have a set of responsibilities depending on the level of participation that they have in the standard-development process. Overall, members are expected to uphold ASTM's consensus process, through openness, transparency, balance and respect, and provide the organisation with timely, accurate, and complete information concerning their voting interest.[1]

In line with the direct membership model, the membership in ASTM International is also open to individuals representing governments. The organisation allows multiple agencies or ministries from the same country to participate within a committee. In these cases, each body is deemed to represent a different interest and permitted to express dissenting views. In the US, Circular A-119 encourages agency officials to participate in the standards development process (United States. Office of Management and Budget., 2016[17]). To date, ASTM International has 2 640 members representing central government ministries or agencies worldwide; of these, 1 489 represent United States Federal Agencies (Figure 2.1).

Figure 2.1. ASTM International United States federal government members



Note: The Department of Commerce includes the National Institute of Standards and Technology.
Source: ASTM International, September 2019.

Participation by non-members

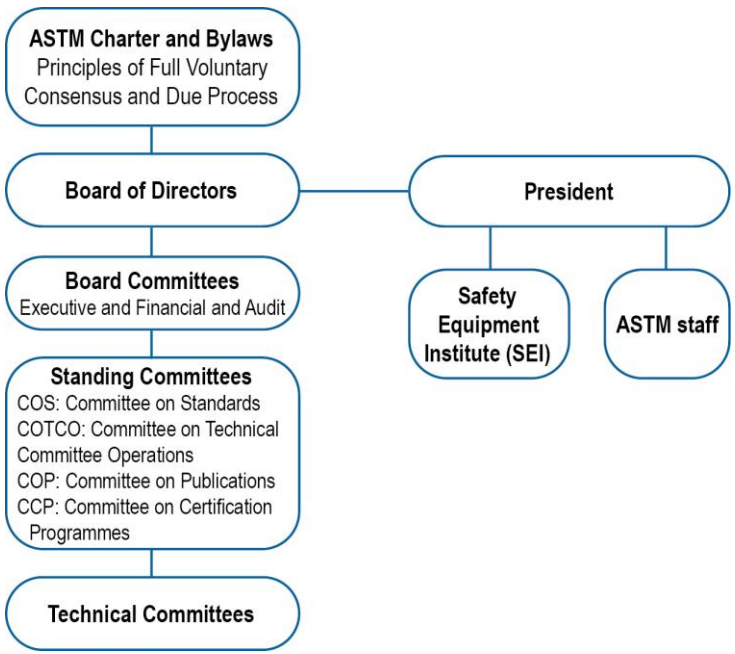
Additional actors are allowed to participate in ASTM activities. Participation in ASTM International meetings is open to all, but only Participating and Organisational Members have the right to vote officially on standards development. Non-members can be added to collaboration areas where members and non-members develop draft standards and submit revisions. ASTM International also offers a range of tools to assist members as well as non-members in the implementation of standards, including resources for professors and students, training sessions for engineers,

proficiency testing programmes for laboratories and more. The organisational structure of ASTM International also plays a pivotal role in supporting its standard-setting activities.

Structure of ASTM International

The ASTM International Charter and Bylaws provide the backbone of the organisation's structure. This sets out a framework comprising a range of bodies led by a 25-member Board of Directors, including an Executive Committee, a Finance and Audit Committee, four standing committees and technical committees; and Officers responsible for the day-to-day management of standard-setting activities – namely, a President, Secretary and Treasurer. ASTM International is headquartered in Pennsylvania, United States, with additional offices in Brussels (Belgium), Ottawa (Canada), Beijing (China), Lima (Peru), and Washington DC (United States). This underlines the decentralised nature of the organisation and facilitates contact with local authorities and businesses worldwide. While dedicated staff are assigned to support the activities of its technical committees, the meetings of the technical committees most often do not take place in the ASTM International headquarters.

Figure 2.2. ASTM International governance structure



Source: (ASTM International, 2015[18]).

Board of Directors and Board Committees

ASTM International bylaws grant responsibility for the direction of the organisation to a Board of Directors comprised of 25 persons: a Chair elected for a one-year term, two Vice Chairs elected for a two-year period, 18 Directors elected for a three-year term, the last two living Past Chairs, the Chair of the Finance and Audit Committee, and the President (*ex-officio* without vote). The Chair, Vice Chairs and Directors are elected by members through a process overseen by a Nominating Committee, while the Chair of the Finance and Audit Committee is appointed by the Board. The Board of Directors holds regular meetings at least twice a year.

When the Board is not in session, the Executive Committee is permitted to act on behalf of the Board if needed except for filling vacancies and amending the ASTM Board Procedures. The Finance and Audit Committee is responsible for the supervision of ASTM financial operations, monitoring employee benefits and salary administration programmes, and for issuing recommendations to the Board on these and other financial policy issues.

Standing Committees

The governance structure of ASTM International also includes four standing committees, which play key roles in the functioning of the organisation and report back to the Board of Directors. Two of these standing committees are critical for the development of ASTM standards and the operation of technical committees: the Committee on Technical Committee Operations (COTCO) and the Committee on Standards (COS) (ASTM International, 2015[18])]. Both bodies are formed by eight members and a chair; all elected for three-year periods.

The COTCO oversees the operation of technical committees, including their scope, structure, operation, formation, merger, planning, and discharge, and is responsible for resolving disputes that may arise between technical committees with respect to their areas of activity. The COTCO is also in charge of the Regulations Governing ASTM Technical Committees, including their development, implementation and enforcement, except for items related to actions on standards (ASTM International, 2019[12]).

Oversight over standards development falls to the COS. This committee reviews and approves technical committee recommendations for actions on standards. The COS verifies that the designated procedure for standard development and the criteria for due process are followed. The committee resolves jurisdictional disputes on

standards, including appeals from members on procedural violations. The COS is responsible for developing, maintaining, and interpreting the Form and Style for ASTM Standards manual and reviewing requests from technical committees for exceptions to the manual.

The Committee on Publications (COP) administers the publications programme and advises the Board of Directors on the formulation of publication policy, save for the acceptance for publication of ASTM standards. Separately, the Committee on Certification Programs advises the Board of Directors on the formulation of certification programme policy and decides on the approval or dissolution of these programmes.

Technical committees

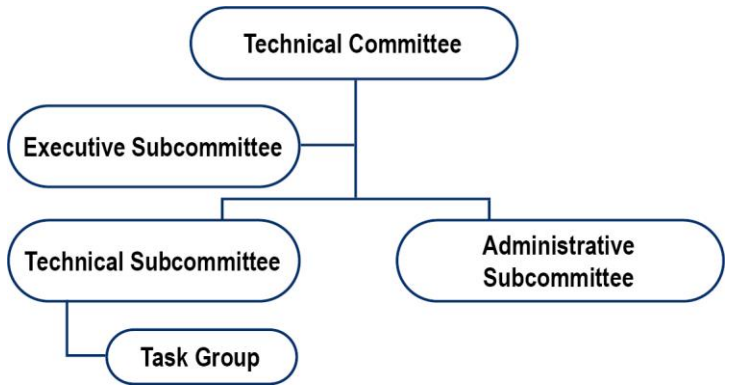
ASTM standards are developed through a bottom-up market driven approach led by 148 technical committees (TCs). These bodies are semi-autonomous from ASTM International, although the organisation assigns a staff manager in each committee to oversee management functions and the co-ordination of administrative services. Membership in Technical Committees is open to all interested individuals and organisations, and there is no limitation to the number of members in a committee. In each committee, members are classified by voting interest as producers, users, consumers or general interest participants. Technical committees typically meet twice a year, during a committee week or independently, both in the United States and abroad.

When new standardisation activity justifies the creation of a new technical committee, a meeting is organised with possible interested stakeholders identified through an initial internal stakeholder mapping activity and with the help of existing members. At this meeting participants decide on the possible approval of the new committee, its title, designation, scope, breakdown into and subcommittees. The COTCO and subsequently the Board of Directors are responsible for approving the creation of committees and agreeing on their titles and scopes. The Board may merge or discharge technical committees if their purpose can be fulfilled by another existing committee body, if the committee is deemed inactive, or once it has completed its purpose. Once a new committee has been set up, member training is provided, including new member orientation, virtual classes on participation and on balloting process. New activities may also fall within the scope of an existing technical committee, but a new subcommittee must be formed to accommodate it following a similar process. A recent example is formation in 2020 of a new subcommittee to focus on alternative sources of natural rubber and natural rubber latex within the D11 Committee on Rubber (ASTM International, 2020[19]).

Each committee adopts bylaws governing its operations, which need be consistent with the rules and requirements set forth in ASTM Regulations and approved by the COTCO (ASTM International, 2019[12]). They also establish liaisons and partnerships with other committees and with external organisations. Committees elect their main officers, including typically a chair, vice-chair and a membership secretary, following the rules on nomination and election procedures outlined in the ASTM Regulations. A dedicated Handbook guides committee officers in discharging their duties and responsibilities and applying the Regulations in the operation of committees.

Technical committees are required to establish executive subcommittees formed by committee officers and other members to provide overall direction to the main body. They can also create technical subcommittees to address specific issues within the committee scope, and administrative subcommittees to address the editorial review of standards or issues around terminology, government interface, international activities, strategic planning, symposia, awards, and liaison with other technical committees and external organisations. In turn, subcommittees may form sections and task groups (ASTM International, 2015[18]). To date, ASTM International has 2 102 Technical Subcommittees.

Figure 2.3. ASTM International technical committee structure



Source: Author's own elaboration.

ASTM Officers and Staff

ASTM International bylaws provide that the day-to-day management of the organisation falls to a President, who is in effect the chief operating officer. The President serves at the discretion of the Board of Directors and appoints other senior staff including a Secretary, Treasurer, and 9 Vice-Presidents. Overall, ASTM

International has a light organisational structure where a small-sized secretariat of approximately 300 individuals serve the committees-led activities of over 30 000 members. This contrast between large constituency and small secretariat can be compared to other committee-led standard-setting organisations where technical committees are responsible for central areas of work.[2]

Decision-making process

Consensus

Consensus has become by far the most applied rule for adopting substantive issues within IOs (OECD, 2016[1]).[3] This is also true for private international standard-setting bodies, and yet there is no uniform definition of consensus across these organisations (Barrios Villarreal, 2016[20]). "Consensus standards" typically expresses not unanimity but the observance of certain procedures that strive for the broadest possible agreement by hearing and addressing negative votes (Mcallister, 2014[21]).

At the technical level, ASTM International decision-making takes place on the foundation of three key principles: open participation, consensus, and balance of interest. ASTM International defines consensus as "the judgment arrived at through the balloting and review procedures of these regulations" (ASTM International, 2019[12]). In practice, there are several individual voting procedures for reaching consensus on each type of ballot or motion, and there is no requirement to reach unanimous agreement on all aspects of a standard to achieve consensus. In all cases, negative votes need to be addressed (See section below). Within an ASTM technical committee, consensus is not easily reached,[4] this staggered process aims to contribute to the technical quality of the deliverable.

Balance of interests

As a consequence of its distinctive membership structure, ASTM International's decision-making process is carried out with a view to ensuring balanced participation from diverse interests and participants and aiming to prevent over representation of certain types of members, namely producers, versus consumers or general interest participants. To this end, in a committee that develops standards for materials, products, systems, or services offered for sale, all members are classified by voting interest in accordance with ASTM Regulations and committee bylaws. The four classes of members are as follows:[5]

- *Producers*: members who represent an organisation that produces or sells materials, products, systems, or services covered in the committee or subcommittee scope;
- *Users*: members who represent an organisation that purchases or uses materials, products, systems, or services, other than household, that are covered in the committee or subcommittee scope, provided that the member is not also classified as a producer;
- *Consumers*: members who primarily purchase or represent those who purchase products and services for household use within the committee or subcommittee scope; and
- *General Interests*: members who cannot be categorised as a producer, user, or consumer. Representatives of government agencies and regulators are always classified in this category.

A balance of interests is secured by ensuring that voting producers cannot outweigh the combined voting user, consumer and general interest participants. This also creates an incentive for technical committees to represent a variety of interests. In order to provide for the necessary balance of interest, members have an obligation to provide ASTM with timely, accurate, and complete information concerning their voting interest.

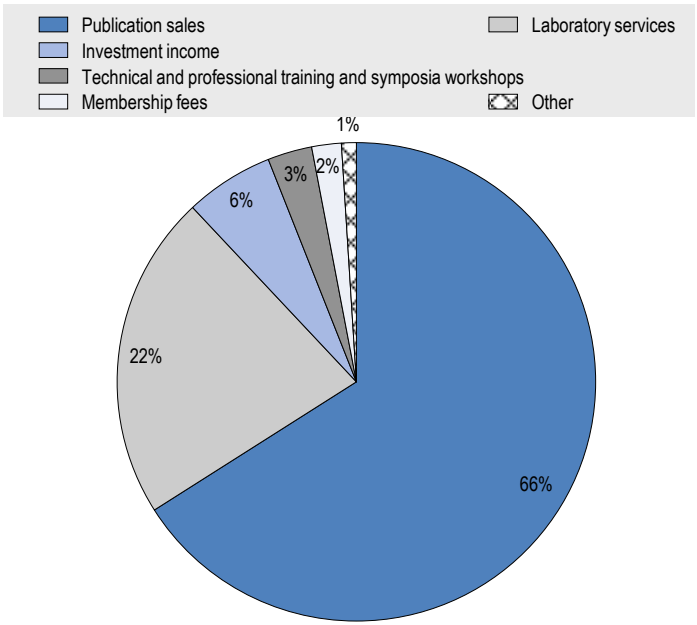
Budget and dedicated staff

International private standard setting organisations typically rely on a combination of membership contributions and revenues from the sales of their services to the public for founding (plus possibly but less consistently other sources) (OECD, 2016[1]). ASTM International's business model designates the sale of technical documents as the main source of its revenue, including earnings from standards and related documents (Figure 2.4).

The primary pathway to ASTM technical documents and an array of integrated services involves purchase of a subscription to ASTM Compass, an online, customizable and comprehensive library of technical information.[6] Entities worldwide purchase subscriptions to ASTM's products directly from ASTM International or from licensed aggregators such as IHS Markit, SAI Global, Techstreet and national standards bodies that act as re-sellers such as BSI (UK), DIN (Germany) and AFNOR (France). Laboratory Services also represent a significant source of revenue, encompassing Certification, Training and the Proficiency Testing Programs (see Box 3.1. and Box 3.2.).

Only a small fraction of earnings come from membership fees. Aiming to eliminate financial barriers and promote open participation in the standard development process, ASTM International's membership fees are nominal, varying depending on the type of membership from USD 75 for Participating Members and Informational Members to USD 400 for Organisational Members for a calendar year. In addition, the organisation waives membership fees for representatives from consumer groups as well as experts from developing countries, and considers all fee waiver requests from individuals with demonstrated needs. The budget of ASTM International is made available to the public every year in an Annual Report.

Figure 2.4. 2019 revenue breakdown by source



Source: (ASTM International, 2020[22]).

Technical committee activities are financed by the organisation. The executive subcommittee of any technical committee may solicit voluntary contributions from members to cover the costs of special events, costs associated with committee meetings held apart from ASTM Committee Weeks, and awards.

As the central source of revenue, ownership and use of ASTM documents is governed by the Intellectual Property Policy of ASTM International (ASTM International, 1999[23]). This policy is observed by individuals and organisations involved in the development, adoption, publication, use and/or distribution of ASTM standards, draft standards, adjuncts, certification programmes and related materials, technical papers, research reports, manuals, software, training course materials and logos.

As of 2020, ASTM International employs approximately 300 people across its headquarters located in the United States and international offices in Belgium, Canada, China and Latin America. Still, due to its decentralised operations, discharge of the work relies heavily on semi-autonomous technical committees.

The business model of private international standard-setting organisations has been challenged by some commentators on the basis that copyright restrictions and paid access to voluntary consensus standards may hinder access to the law when standards are referenced in domestic legislation or regulation (see for instance (Bremer, 2013[24])). In the United States, standards incorporated into regulation by reference are required to be made reasonably available to regulated and other parties (United States. Office of Management and Budget., 2016[17]). A set of factors are provided for agencies, to inform considerations on whether the availability of standards meets the criteria. ASTM International seeks to grant access for interested parties to view standards that are the part of the regulatory infrastructure. Since 2013, ASTM International provides free read-only access to ASTM safety, public health and environment standards that are incorporated in United States and other countries' regulations.[7] In response to the COVID-19 outbreak, ASTM International, among a number of standard-setting organisations, provided no-cost public access to certain standards relevant to critical COVID-19 products (Box 2.1).

Box 2.1. The international standardisation response to COVID-19

In reaction to the COVID-19 pandemic, a number of standard setting organisations provided free and open access to a range of standards in an effort to support countries increase availability of critical products that relied on international standards and faced limited prior production or import supply.

Overall, ASTM International, ISO, IEC, CEN and CENELEC made available nearly 70 standards. ASTM International allowed access to 28 standards used for personal protective equipment including facemasks, medical gowns, gloves, and hand sanitiser and critical products such as thermometers and respirators.

Facing the crisis, ASTM International took steps to make manufacturers, regulators and public health organisations worldwide aware of the collection of ASTM standards available to assist them. This included working with manufacturing and trade associations, reaching out to inter-governmental task groups, and delivering information to over 100 national and regional standards bodies through the ASTM MoU network. To date, ASTM standards posted on the COVID-19 site have been downloaded at no-cost by users in over 100 countries.

The WHO disease commodity package for COVID-19, a datasheet that list the critical commodities and the technical specifications for each commodity for the disease, includes reference to a number of international standards including ASTM standards for medical gloves, masks, aprons, gowns, bio-hazard bags and alcohol-based hand rub.

Sources: (ASTM, 2020[25]), (OECD, 2020[26]), and (WHO, 2020[27]).

Notes

[1] ASTM International Regulations Annex B. Responsibilities of Membership.

[2] Staff numbers for other bodies are IEC, 110; IFAC, 79; ISO, 156; OIE, 163. See (OECD, 2020[40]).

[3] Decision-making through consensus allows IOs to adopt a proposal only in the absence of any objection expressed, and without a formal vote. Consensus differs from unanimity which normally requires a formal vote of all the participants in favour of the proposal. The agreement obtained by consensus is less general, complete than that obtained by unanimity. Nevertheless, consensus is now being applied in priority by IOs because the adoption of a legal instrument (legally binding or not) through consensus is easier: all must compromise and none has a right of veto. In addition, consensus is preferred to a majority vote that, in the context of decision-making in IOs, tends to crystallise opposition by advantaging the interests of the majority, against those of minorities (OECD, 2016[1]).

[4] On a subcommittee ballot, a 60% ballot return rate is required; two-thirds of the total votes cast by voting members must be in the affirmative; all negative votes must be considered and resolved. On a main committee ballot, a 60% ballot return rate is required; 90% of the total votes cast by voting members must be in the affirmative; all negative votes must be considered and resolved. See https://www.astm.org/member_training/balloting-sequence-and-requirements.pdf.

[5] ASTM Regulations section 7. Classification of Committee Members.

[6] https://www.astm.org/Standard/enterprise-compass.html.

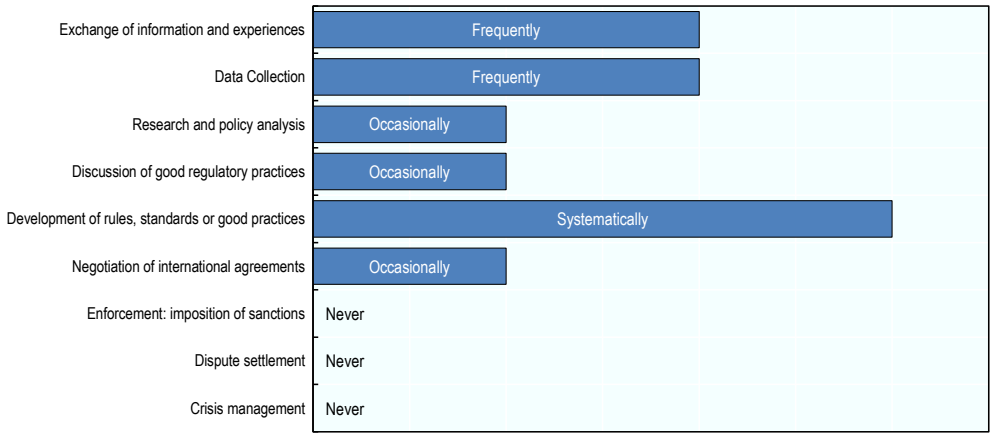
[7] See https://www.astm.org/readinglibrary/index.html.

3 Forms of regulatory co-operation provided by ASTM International to its members

(OECD, 2016[1]) identifies a number of IRC processes and activities that IOs partake in. They involve exchange of information and experience, data collection, research and policy analysis, discussion of good regulatory practices, development of rules, standards and guidance, negotiation of international agreements, enforcement activities including imposition of sanctions, dispute settlement and crisis management.

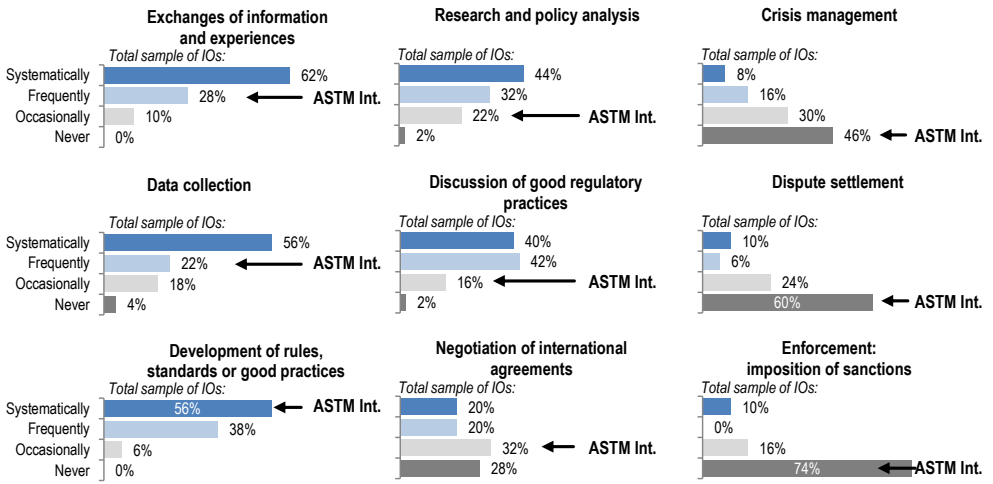
Like other IOs, ASTM International is active in the upstream part of the international rule-making cycle, on exchanging information, dialogue and evidence leading up to rule-making. While the majority of ASTM International activities centre on the development of standards, the organisation frequently engages in other IRC processes that support and precede the development of standards, such as exchanging information and experiences as well as conducting data collection (Figure 3.1). Occasionally, ASTM International develops research and policy analysis (for instance, through Technical Reports), discusses good regulatory practices or negotiates international agreements. Unlike some IOs, but similar to private international standard-setting organisations, ASTM International is less active in down-stream activities including imposition of sanctions, dispute settlement or crisis management. This composition of rule-making activities is also partly due to the voluntary nature of standards. Figure 3.2 shows how ASTM International IRC processes compare to those of other IOs.

Figure 3.1. IRC processes performed by ASTM International



Source: ASTM International profile available at http://www.oecd.org/gov/regulatory-policy/ASTM%20profile.pdf

Figure 3.2. IRC processes that take place within ASTM International



Note: The arrow situates ASTM International in the overall sample of IOs.
Source: OECD (2016), *International Regulatory Co-operation: The Role of International Organisations in Fostering Better Rules of Globalisation*, OECD Publishing, Paris, https://doi.org/10.1787/9789264244047-en.

Nevertheless, ASTM International does perform a range of functions that span the rule-making process. In particular, the organisation is involved in downstream activities to the extent of providing a number of services in the area of conformity assessment, that is, the demonstration that specified requirements are fulfilled (ISO/IEC, 2020[28]). While private international standard-setting organisations typically have expertise in the field of conformity assessment, for instance ISO/IEC publishing joint conformity assessment standards and guides known collectively as the CASCO Toolbox (ISO, 2010[29]), less often they take an active role in conformity assessment activities. ASTM International's conformity assessment services include 58 Proficiency Testing Programs (Box 3.1) and a set of Certification Programs delivered by the Safety Equipment Institute (SEI), which provides over 6 100 different product certifications (Box 3.2).

Box 3.1. ASTM International Proficiency Testing Programs

ASTM International Proficiency Testing Program (PTP) includes a suite of statistical quality assurance programs that allow laboratories to assess and compare their performance in conducting test methods within their own laboratories against other laboratories participating in the same programme worldwide. PTP results enable laboratories to improve their performance and to maintain and fulfil mandatory accreditation requirements. Laboratories from over 90 countries have participated, ranging from the United States and Canada to Brazil, Colombia, China, India, Saudi Arabia and Singapore, among others. Participation in PTPs is voluntary and fee based.

PTPs were created in 1993. ASTM International currently conducts over 50 programmes covering additive manufacturing and powder metallurgy, electrical insulating liquids, engine coolants and related fluids, petroleum products, plastics testing, metals testing, textiles, cement and concrete.

The creation of programmes takes place inside the technical committee responsible for the relevant ASTM standard. Once the Executive Subcommittee approves the initial concept for a program, ASTM staff conducts a market study to assess the level of interest. The programme proposal is then reviewed by the associated Executive Subcommittee that liaises with the ASTM PTP administration, providing detailed information regarding all aspects of the new programme. ASTM technical committees use the data generated by PTPs for the review and update of standards.

Source: (ASTM International, 2015[18]).

Box 3.2. Certification and Declaration Programs

The Safety Equipment Institute (SEI), an affiliate of ASTM International, provides third-party certification of safety and protective products used in the United States and Canada (including materials, processes, and services) through a range of Certification Programs. Under supervision of a separate Board of Directors, SEI administers voluntary conformity assessment programs for standards developed by ASTM International as well as other organisations, including the American Society of Safety Professionals (ASSP), American National Standards Institute (ANSI), Canadian Standards Association (CSA), Consumer Product Safety Commission (CPSC), International Safety Equipment Association (ISEA), National Fire Protection Association (NFPA), National Institute of Justice (NIJ), and National Operating Committee on Standards for Athletic Equipment (NOCSAE).

The SEI currently runs over 75 certification programs covering more than 6 100 products worldwide. The entity is accredited by the ANSI and the Standards Council of Canada (SCC) in accordance with ISO/IEC 17065, Conformity assessment – Requirements for bodies certifying products, processes, and services.

Source: (Safety Equipment Institute, 2020[30]).

Typology of ASTM International's deliverables

Technical standards are the main policy instrument used by ASTM International in support of IRC (Table 3.1). These standards are legally non-binding instruments developed in response to a need in a specific area expressed by stakeholders through a bottom-up process (OECD, 2016[1]). Technical standards may become legally-binding if harnessed by a state, for instance through their incorporation into law (Mcallister, 2014[21]). In addition, ASTM International produces guidelines and best practice documents to support the use and implementation of its standards. Recently, ASTM International began developing Technical Reports, which provide input and recommendations stemming from research conducted by technical committees in specific fields.

Table 3.1. Categories of legal and policy instruments

Type	Delivery by ASTM International	Number
Treaties for ratification by States (excluding the funding one)		
Legally binding decisions		
Recommendations		
Political declarations		
Model treaties or law		
Production of technical standards	√	Over 12 800
Non-binding guidance/best practices document	√	1 500

Source: Updated from ASTM International profile available at http://www.oecd.org/gov/regulatory-policy/ASTM%20profile.pdf.

Technical standards

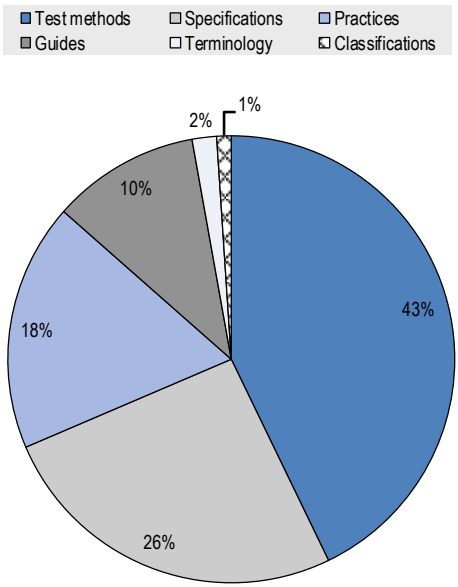
ASTM International's core deliverables are voluntary technical consensus standards. ASTM standards are typically performance standards that express requirements in terms of outcomes rather than specifying the means to those ends. This differentiates them from design standards that define characteristics or how a product is to be built (NIST, 2009[15]). This is influenced by Annex 3.I of the WTO TBT Agreement, which states "Wherever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics", and Principle 4 of the TBT Six Principles on "Effectiveness and Relevance", which states "Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics." Further, performance-based technical requirements are highlighted by the UNECE Working Party on Regulatory Cooperation and Standardization Policies (WP.6) in its "International Model for Technical Harmonization" according to which the technical content of regulations should be drafted in terms of broad objectives and refer to international standards for more detailed performance-based technical requirements (UNECE, 2001[31]). Performance standards are also favoured in the United States as they give regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way (OMB, 2003[32]).

All ASTM standards types are developed following the *Regulations Governing ASTM Technical Committees* (ASTM Regulations) that define six types of standards, and need to comply with the *ASTM Form and Style Manual* that provides requirements for their technical structure and content. Still, the distribution of standards across the various types is uneven, with most standards addressing test methods, specifications,

guides and practices, and only a minor fraction focusing on terminology and classifications (Figure 3.3). The different types and forms of standards are as follows:[1]

- **Classifications**, when a standard sets a systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use. This is the case of *ASTM D2000-18, Standard Classification System for Rubber Products in Automotive Applications*.
- **Guides**, which are standards containing information or a series of options without recommending a specific course of action. *ASTM F3335-20, Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion* is an example of this type of standard.
- **Practices**, when a standard provides a definitive set of instructions for performing one or more specific operations that do not produce a test result. For example, *F3356-19a, Standard Practice for Conformity Assessment of Metal Detectors Used in Safety and Security*.
- **Specifications**, which are standards containing an explicit set of requirements to be satisfied by a material, product, system, or service. This is the case of *ASTM F3411-19, Standard Specification for Remote ID and Tracking (for Unmanned Aircraft Systems).*
- **Terminology**, which refers to documents comprising definitions of terms; explanations of symbols, abbreviations, or acronyms. For example, *ASTM D883-20a, Standard Terminology Relating to Plastics*.
- **Test methods**, or standards that provide a definitive procedure that produces a test result. ASTM *C39/C39M–20, Standard Test Method for Compressive Strength of Cylindrical Concrete Specimens* falls within this type.

Figure 3.3. ASTM standards by type



Source: Provided by ASTM International (2020).

All ASTM standards are developed according to the principles outlined in ASTM Bylaws that, in turn, empower the Board of Directors to oversee the more detailed procedures set in ASTM Regulations. Standards are approved by the corresponding subcommittee and committee, subject to public review (referred to as "Society Review"), followed by final procedural review and approval by the COS. Box 3.3 provides a detailed description of the stages for the development of ASTM standards. After publication, all standards are subject to review and balloted for re-approval, withdrawal, or revision within 5 years of their publication date.

A set of basic principles apply to ASTM voting processes and encompass various levels. First, all voting is conducted via the ASTM website and available for a minimum of 30 days, which enables all members to participate in the process and grants sufficient time to review the balloted standard. Voting can be conducted online at any time on any day from anywhere in the world. At any level of balloting, the responsible subcommittee considers all negative votes on standards that contain a written explanation of the objections. Finally, to guarantee a consensus process, whenever a

negative vote leads to substantive changes in a standard the revised version is re-balloted at all levels. While there are no maximum timeframes, the development process for a full consensus standard takes on average 14 to 17 months. Still, depending on a committee's commitment to timely development and approval, the entire process may take place in less than a year.

Due process is afforded to all negative votes cast during the standards-development process following the rules set out in the ASTM International Regulations for in-person and online resolution of negatives. Negative votes may originate at subcommittee or main committee ballots, or during the Society Review. Negative votes originating on a subcommittee ballot are handled by the subcommittee while negative votes originating on a Main Committee/or Society Review are first handled by the subcommittee and then main committee as needed. Table 3.2 describes the six different mechanisms available to resolve negative votes.

Table 3.2. Handling of negative votes

Six resolutions for negative votes

Withdrawn	A negative vote may be withdrawn at any time unless the ballot item has already failed.
Withdrawn with editorial changes	A member can withdraw a negative vote agreeing to editorial changes that introduce no change in the technical content of the standard, but correct typos or promote clarity.
Not related	A negative vote is ruled as “not related” by a vote of 2/3 of those voting on the motion at a meeting or by a ballot. The subject of the negative is required to be brought forward as new business at the next meeting.
Not persuasive	A negative vote is ruled as “not persuasive” when 2/3 of the votes cast disagree with the content of the negative. The not persuasive motion must provide the rationale for why the subcommittee disagrees with the content of the negative vote.
Persuasive	A negative vote is ruled as “persuasive” when the 2/3 to find a vote not persuasive is not achieved. The item is removed from ballot for further work and deliberation.
Previously considered	A negative vote is marked as “previously considered” when the content of the negative was already found not persuasive by the subcommittee and main committee.

Source: (ASTM International, 2015[18]).

A member who has their negative vote found not persuasive by the subcommittee and main committee at a meeting, may request a confirming ballot of the full subcommittee within 30 days of being notified of their not persuasive resolution. A two-thirds affirmative vote by the subcommittee is required to confirm the action. Furthermore, negative voters may appeal to the Committee on Standards, if it is believed that due

process was not afforded. Still, the COS only adjudicates issues of a procedural nature while issues of a technical nature are addressed within the appropriate technical committee.

The standard-development process can be accelerated when a standard is needed in response to a safety situation, regulatory requirement, or to promote international commerce. In such events, a rapid ballot can be issued under certain requirements including an agreement of at least two-thirds of all official voters on the subcommittee, either by ballot or at a meeting, and approval of the main committee chair.[2] For instance, the accelerated process was used for the development of a new standard specification for barrier face coverings for use in combatting the spread of COVID-19 (see Box 6.2).

ASTM International has developed, adopted and applied digital technology to enable broad and inclusive development of, access to, and application of its standards and related services. All processes that used to be done manually using physical documents are now done digitally, increasing efficiency and resilience of the standard-development process. These digital tools enable constant engagement by members and stakeholders in technical committee activities. Furthermore, ASTM International shares this technology through an integrated technology platform, providing access to these digital tools for use by other SDOs to develop and manage their own standards.[3]

Box 3.3. The development of ASTM standards

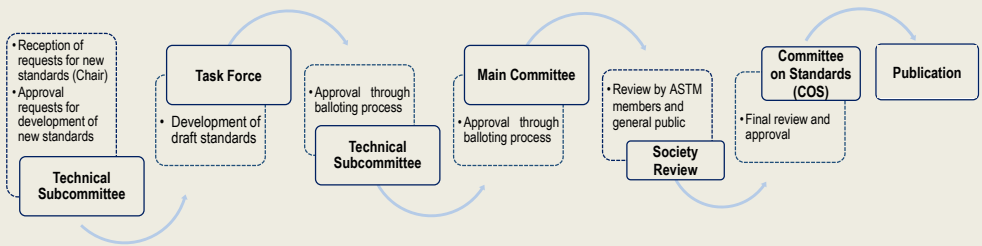
- **Request for the development of a new standard** – the request may come from any source and needs to be either approved by the subcommittee chair or presented at a subcommittee meeting and approved by a majority of the subcommittee.
- **Task Group** – if the subcommittee determines the need for a new standard, a task group is set up to produce a draft standard for subcommittee ballot. Task forces are led by a chair, often the individual presenting the request to the subcommittee, and members of task groups are not required to be members of ASTM International.
- **Subcommittee ballot** – approval of a new standard takes place through a balloting process that begins at subcommittee level. A rationale for why the new standard is being developed is required. Voting remains open for 30 days and until 60% the official voting members return ballots, including abstaining votes. Approval of a ballot item requires the affirmative vote of at least two-

thirds of the combined affirmative and negative votes cast by the official voting members. Abstentions are not included in this calculation.

- **Main Committee Ballot** – approval by a main committee requires the affirmative vote of at least 90% of the combined affirmative and negative votes cast by official voting members, excluding abstentions. Main committee ballots must also include an explanation of its rationale, the tally of the subcommittee ballot results, and detailed documentation of any subcommittee negative votes.
- **Concurrent ballot** – approval by the subcommittee and main committee simultaneously following the numerical requirements of the two bullets above.
- **Society review** – during the main committee ballot, ASTM International members and any member of the public has an opportunity to participate in the balloting process by reviewing the relevant documents and submitting comments.
- **Final review and approval by the Committee on Standards (COS)** – All "not persuasive" and "not related" actions on main committee negative votes are reviewed by COS. If COS determines the procedural requirements have been satisfied, the standard is approved for publication. If a standard fails to obtain COS approval, it returns to the sponsoring technical subcommittee for further work.
- **Approval and publication** – copy of the standard is sent by the ASTM Editor to the technical contact for final review and approval prior to publication.

At any time after publication, suggestions for revision may be submitted and editorial changes be made. Substantive technical changes must proceed through the entire balloting process.

Figure 3.4. Schematic of the stages of ASTM standards development



Source: (ASTM International, 2015[18]) and (ASTM International, 2019[12]).

Other normative deliverables

In addition to technical standards, ASTM International develops guidance and best practice documents aiming to support standard-development and implementation such as journal papers, special technical publications, manuals, monographs data series and technical reports. Technical Reports provide data, recommendations and conclusions stemming from the research conducted by technical committees in specific fields. To date, ASTM International has produced two Technical Reports to support discussions regarding the development of standards related to autonomous aviation systems. These reports contain harmonised terminology and fundamental principles applicable to the design and architectural development of increased automation for aviation systems (ASTM International, 2020[33]) (ASTM International, 2019[34]). Both Technical Reports include the expertise of ASTM International committees and members responsible for the development of a number of standards around aviation. Selected Technical Papers (STPs), a collection of over 29 000 peer-reviewed ASTM symposia papers are published and available on the ASTM website. Similarly, over 150 practical, "hands-on" application manuals, technical monographs, and data series are available under conditions of a standard cost-free license of the copyrighted material.

Notes

[1] ASTM International Regulations section 2.2.

[2] ASTM International Regulations section 11.7.

[3] See https://www.astm.org/Standard/specbuilder.html.

4 Use of tools and mechanisms to ensure the quality of ASTM standards

Over the years, international organisations have developed practices to support the quality of their rule-making activities following a similar path of that of countries through the range of tools developed to ensure the quality of their regulatory processes (OECD, 2016[1]) (OECD, 2019[5]). This can be observed, for instance, in the use of impact evaluation, stakeholder engagement and *ex post* review.

ASTM International operates in a special context that enables it to harness the quality of its standards through a range of tools and mechanisms. As discussed in the previous section, ASTM standards are underpinned by the framework of ASTM Bylaws and Regulations, which include rules for governance practices and a set of principles and a detailed standard-development process, containing thorough procedural and format rules. In addition, the activities of ASTM international are subject to certain legal instruments, including the regulations applicable to non-profit corporations incorporated in the State of Pennsylvania and US federal laws.

Moreover, the development of ASTM standards is also guided by certain international instruments. ASTM International applies the WTO TBT Committee's Six Principles for the Development of International Standards, Guides and Recommendations which seek to “to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries”, including for standardisation activities undertaken by international standardising bodies (WTO, 2000[10]). Standards developed in accordance with these principles are more likely to be considered as relevant international standards for the purposes of the TBT Agreement, which requires that WTO members use “relevant international standards” as a basis for their national regulations and standards (OECD/WTO,

2019[8]). These principles have also been used to inform the understanding of certain terms and concepts in the Agreement in the context of WTO dispute settlement. ASTM's standard-development process endeavours to ensure an open and transparent process, providing an impartial and consensus-based model of engagement to produce effective and relevant standards driven by research, data and science-based decision making. It collaborates with other standard-development bodies to avoid duplications and connects globally so all stakeholders contribute and benefit.

Further, ASTM International is a signatory of the UNECE's Declaration for Gender Responsive Standards and Standards Development. As a signatory, ASTM International commits to work towards gender balance at all levels within its infrastructure (including in governing bodies), and to a gender inclusive process resulting in gender responsive standards. ASTM International is tracking progress, collecting and sharing data, and publishing success stories and good practices on gender-responsive standards (UNECE, 2019[35]).

ASTM International is accredited by the American National Standards Institute (ANSI) and the Standards Council of Canada (SCC) as a standard developing organisation. ANSI and SCC accreditation warrant observance of requirements aligned with WTO principles that serve to ensure the organisation applies due process and grants all interested and affected parties the opportunity to participate in standard-development and to have their views considered on an equal footing (Box 4.1). Although ASTM procedures for all standards align with ANSI and SCC essential requirements, each individual ASTM technical committees decides, in alignment with its strategy and understanding of international market needs, whether or not to submit its standards to ANSI or SCC for recognition as "national standards" in either country.

Box 4.1. ANSI Essential Due Process Requirements for American National Standards

ANSI establishes minimum acceptable due process requirements for activities around the development of American National Standards, including their approval, revision, reaffirmation, and withdrawal. Due process establishes that any person, be it an individual, organisation, company, or government agency, or other entity, with a direct and material interest has a right to participate by: a) expressing a position and outlining its basis, b) having that position considered, and c) having the right to appeal.

In 1997, the American National Standards Institute (ANSI) signed the WTO TBT Code of Good Practice (CGP) acceptance letter on behalf of ASTM International and other ANSI-Accredited Standards Developers affirming that the WTO TBT principles as reflected in the Code of Good Practice (CGP) are met both in terms of the standards developer's accredited procedures and the ANSI Essential Requirements.

The minimum acceptable due process requirements for the development of American National Standards are the following:

1. **Openness** – participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.
2. **Lack of dominance** – the standards development process shall not be dominated by any single interest category, individual or organisation. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.
3. **Balance** – the standards development process should be marked by a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving this balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.
4. **Co-ordination and harmonisation** – good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.
5. **Notification of standards development** – notification of standards activity shall be announced through suitable media to offer an opportunity for participation by all directly and materially affected persons.
6. **Consideration of views and objections** – prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in Standards Action.

7. **Consensus vote** – evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.
8. **Appeals** – written procedures of an ANSI-Accredited Standards Developer (ASD) shall contain an identifiable, realistic, and readily-available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process.

Source: (ANSI, 2020[36]).

Ex ante assessment of ASTM standards

ASTM International receives a variety of requests for new standard-setting action, from the development of single standards to the creation of new main technical committees. Although work on new standards may begin at the request of any interested party, not all requests ultimately result in the development of a standard. Once a request is submitted, an assessment of need is conducted as to whether the proposal would result in a better test, new specification, safer product, etc. When a formal work item is created, ASTM International maps the scope and subject area to assign the potential work to an existing committee or decide on the creation of a new committee. As the work advances through the organisational process, a technical committee may determine that there is insufficient interest from participants, that a standard that satisfies the particular need has already been developed by a different standard-setting organisation, or that there are not sufficient conditions from the industry for the development of a consensus standards programme.

Engagement of stakeholders

Open and inclusive rule-making has become widely accepted as a fundamental pillar of the quality of rules and standards at the domestic and international level thus advancing the recognition of the importance of stakeholder engagement (OECD, 2019[5]). Open participation is one of ASTM International's main features. The organisation has harnessed stakeholder engagement into its membership and standard-setting activities allowing any individual with an interest in standard development to participate in the process. To ensure this, consumer and some general interest participants may have their fees waived by the technical committee.

ASTM International's membership currently comprises over 30 000 individuals representing producers, users, consumers, governments, universities and other stakeholders. This differentiates ASTM International from other IOs where there is a narrower concept of stakeholder, for instance IGOs where this refers to the engagement with those parties that are not involved in the formal governance and decision-making processes of the IO (OECD, 2019[5])

Moreover, stakeholder engagement is key to create and maintain the balance of interest needed for the operation of ASTM technical committees. This requires technical committees to actively encourage the representation of a variety of interests in the balloting process to ensure that voting producers do not outnumber the combined voting user and general interest participants. To these effects, technical committees and subcommittees continually review their list of participants to ensure balanced participation and avoid stakeholder gaps (Olshefsky and Hugo, 2003[37]). Participation is also promoted to increase technical expertise in specific areas or to initiate new committee activity, including new standards. For instance, in 2010 a new standard for throat protective equipment for ice hockey goalkeepers was developed by ASTM Committee F08 on Sports Equipment, Playing Surfaces following the standardisations needs flagged by civil society to the committee.[1] Representation of consumer interest through consumer advocacy organisations or non-profit public-interest organisations is particularly important in several ASTM technical committees that develop and revise standards in the consumer product industry, for example toys and children's products, household items, cleaning products, sports equipment and leisure activities such as amusement rides.

Stakeholder consultation and transparency are also promoted during the development of ASTM standards through a consultation stage, referred to as Society (public) review, during which all items undergoing main committee ballot are available for public comment (see Box 4.3.). A website lists all items open for balloting and allows the public to request to receive any draft standard that they have an interest in and provide comments which are forwarded to the appropriate subcommittee for consideration.[2]

Similar to other IOs, ASTM International has no whole-of-organisation policy or strategy for stakeholder engagement or formal guidance to attract the participation of key stakeholders (OECD, 2019[5]). Still, ASTM International conducts approximately 30-35 member promotion events each year to attract new stakeholders in the development of new standards. These promotions typically result in over 1 000 new members and a few hundred international stakeholders, that then participate in the development of new standards. The Manual for Development and Implementation of Strategic Plans includes considerations on stakeholder engagement and outreach. ASTM International also assists committees in monitoring engagement by

stakeholders in each subcommittee and supports outreach efforts connecting with potential participants, for instance, through the MoU Programme. Finally, the strong reliance on virtual methods for the development of standards facilitates the participation from stakeholder in different locations.

ASTM International develops an Annual Report that includes information on key activities and finances and holds an Annual Business Meeting to report to members on the organisation activities (ASTM International, 2009[38]). Technical committees are encouraged to develop individual strategic planning activities to ensure that they remain proactive in the development of standards, establish technical subcommittees and promote the participation of new individuals. A Manual to assist technical committees in this process includes guidance to self-evaluate their activities when preparing their strategic plans (ASTM International, 2014[39]).

As an ANSI-Accredited Standards Developer, ASTM International needs to comply with a set of activities and requirements to maintain its accreditation status active. These include submitting an annual form attesting to procedural compliance with ANSI's essential requirements and meeting potential audit process. Failure to comply results in suspension or withdrawal of the accreditation (ANSI, 2020[36]).

Review of standards

Technical standards are consistently at risk of falling into obsolescence due to technological changes and innovation. At ASTM International each technical subcommittee responsible for a standard follows a procedure for their review to ensure that their deliverables remain up to date and fit for purpose. Where a Proficiency Testing Programme is in place, technical committees use the data generated by the Interlaboratory Study Programme for the review and update of test method standards.

The ASTM International Review of Standards Procedure calls on each standard to be reviewed in its entirety and balloted for re-approval, revision, or withdrawal within five years of its last approval date. Still, often standards require more frequent revision and are updated before the 5-year mark. Standards are automatically withdrawn if they fail to receive a new approval date by 31 December of the eighth year since the last approval date. On average, 1 750 standards are revised each year following the review process, confirming a regular process to maintain the standards up to date. An average of 90 standards are withdrawn each year. Although this figure is marginal compared to the number of standards developed, revised and re-approved each year, it still suggests that ASTM International process provides opportunity to update its overall stock of standards and remove those that are no longer relevant or current.

Table 4.1 provides detailed information of ASTM International action with regard to standards between 1985 and 2019.

Regular update of dual standards developed under PSDOs typically proves more challenging to co-ordinate and follows different rules for review. For instance, the joint IEC/ASTM standards are reviewed and balloted at least every 8 years and may be proposed for withdrawal if they have not received a new approval date by 1 July of the 8th year since their last approval.

Table 4.1. ASTM International action around standards 1985-2019

Year	New standards	Revised Standards	Subtotal	Re-approved	Withdraw	Total
1985	285	1 277	1 562	394	65	2 021
1986	266	1 179	1 445	289	65	1 799
1987	310	1 156	1 466	439	79	1 984
1988	308	1 422	1 730	436	87	2 253
1989	295	1 484	1 779	421	75	2 275
1990	302	1 695	1 997	561	9	2 650
1991	320	1 480	1 800	501	61	2 362
1992	322	1 593	1 915	337	93	2 345
1993	339	1 962	2 301	644	75	3 020
1994	371	1 797	2 168	546	107	2 821
1995	529	2 570	3 099	625	113	3 837
1996	455	1 814	2 269	609	96	2 974
1997	350	1 698	2 048	540	93	2 681
1998	344	1 726	2 070	746	114	2 930
1999	286	1 624	1 910	758	79	2 747
2000	315	1 689	2 004	686	186	2 876
2001	302	1 590	1 892	794	115	2 801
2002	272	1 838	2 110	882	124	3 116
2003	268	1 682	1 950	986	198	3 134
2004	293	1 846	2 139	997	90	3 226
2005	317	1 897	2 214	944	91	3 249
2006	246	1 641	1 887	922	101	2 910
2007	244	1 756	2 000	943	75	3 018
2008	230	1 984	2 214	1 058	81	3 353
2009	250	1 850	2 100	986	93	3 179
2010	232	1 938	2 170	1 010	113	3 293
2011	264	1 870	2 134	999	71	3 204
2012	181	1 877	2 058	1 069	42	3 169
2013	197	1 997	2 194	1 019	90	3 303

Year	New standards	Revised Standards	Subtotal	Re-approved	Withdraw	Total
2014	195	1 819	2 014	905	72	2 991
2015	177	1 956	2 133	908	81	3 122
2016	180	1 922	2 102	818	75	2 995
2017	208	1 897	2 105	909	88	3 102
2018	196	1 994	2 190	957	48	3 195
2019	159	1 934	2 093	1 007	66	3 166

Source: Information provided by ASTM International.

Monitoring the implementation of ASTM standards

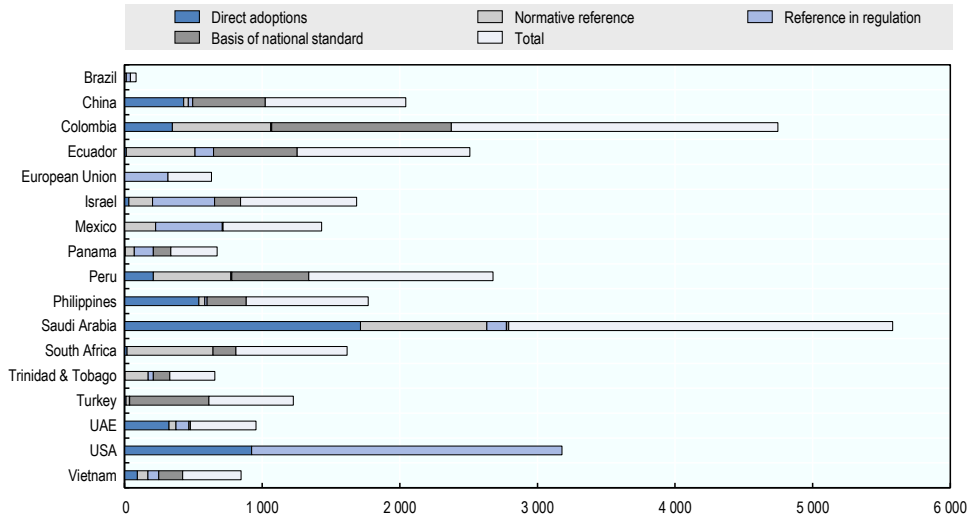
The discussion around implementation of international instruments is difficult and particularly so when it comes to voluntary international standards. Broadly speaking, normative instruments developed by international organisations need to be adopted or used domestically to have a legal and practical effect. The ways in which this is done depends on each country's legal system, and often occurs without any involvement of the IO responsible for an instrument (OECD, 2020[40]). Nevertheless, IOs may track the use of their instruments, and provide related support and guidance to their Members to implement them (OECD, 2019[5]). Monitoring the implementation of their instruments allows IOs to gather evidence to support the assessment of their impact and obtain relevant input for the review of their deliverables.

Overall, a broad notion of "implementation" of voluntary international standards has two dimensions (OECD, 2020[40]): i) the *de jure* application of an international standard in domestic legislation; and ii) the *de facto* use made of the international standard in practice, either in the inspection and enforcement processes or by private companies in their production, management, procurement, and service delivery processes, as needed (Combacau and Sur, 2016[41]). Although ASTM International is not responsible for monitoring the implementation of its standards, it has certain tools and programs that indirectly assist in tracking the uptake of the standards in the market.

The implementation of ASTM standards from a *de jure* perspective depends on each country's domestic procedures to adopt standards into laws and regulations and may take different forms (incorporation by reference, or by partial or complete transcription, among other). ASTM International collects information on the national uptake of standards from exchanges of information and dialogue with government representative and agencies in specific countries, particularly for countries or regions covered under the MoU Programme required to report annually to ASTM International on their standardisation activities.

As of June 2020, there are nearly 8 400 citations of ASTM standards worldwide (ASTM International, 2020[22]). In the US federal regulations there are about 1 350 ASTM standards referenced 2 255 times, with certain standards referenced in multiple regulations. There are 410 references to ASTM standards in the EU law and case law, including 304 in legal acts (Regulations, Directives, Decisions), 99 in international agreements and 7 in case-law.[3] In Colombia, where the national standard body, the Colombian National Institute of Technical Regulations and Certification (*Instituto Colombiano de Normas Técnicas y Certificación*, ICONTEC International) is an ASTM MoU partner since 2005, over 1 300 ASTM standards are used as the basis of Colombian national standards, and more than 1 700 have been adopted, consulted or referenced. Figure 4.1 shows the relevance of ASTM standards in selected countries as of October 2020 either as direct adoption as a national standard, use as a normative reference, reference in regulation and/or use as the basis for a national standard.

Figure 4.1. Relevance of ASTM standards for selected national standard development organisations and regulators



Note: Each instance is counted. Some ASTM standards are used by authorities in some countries in more than one way. The data for the United States includes only adoptions as American National Standards and references in federal laws and regulations. Normative references by other US-based SDOs are not included.
Source: ASTM International, October 2020.

ASTM International communicates regularly with national regulatory authorities about the use of ASTM standards in technical regulations. ASTM staff monitors notifications made by WTO members of proposed technical regulations that may pose barriers to trade to check for notifications that may reference one or more ASTM standards.

The *de facto* use made of international standards entails the actual application of the standard by its end-users. Evidence of such use is generally harder to monitor by international organisations. ASTM International has certain tools available to collect internal input on the relevance and use of its standards, mainly from indicators around the sales of standards and member enrolment. ASTM International conformity assessment activities, namely through its PTP Programs and Certification and Declaration Programs, may provide additional information on specific ASTM standards, particularly relevant for their review.

Co-operation between ASTM International and other standard-setting bodies and international organisations

In the face of increasingly interconnected and complex policy challenges, business models and technological changes, IOs need to co-ordinate their rule-making responses to capitalise on their combined strengths and avoid unnecessary overlaps (OECD, 2019[5]). ASTM International co-operates with a number of actors relevant in the field of international standardisation, including private international standard-setting bodies, traditional IGOs and regional standardisation bodies.

Under the UNECE's initiative on 'Standards for the SDGs', 189 ASTM standards have been identified as tools that can help accomplish and demonstrate achievement of the targets set by the United Nations Sustainable Development Goals (SDGs) in a range of areas, including 77 ASTM standards in support of SDG 6 on clean water and sanitation (UNECE, 2018[42]). Other UNECE instruments related to the World Forum for Harmonization of Vehicle Regulations (WP.29) reference ASTM standards on tire safety and performance (UNECE, 2016[43]).

The organisation has a co-operation agreement with the North Atlantic Treaty Organization (NATO) (Box 4.2) and has also established co-ordination arrangements with the Asia Pacific Economic Co-operation (APEC) forum, the International Atomic Energy Agency (IAEA), the International Air Transport Association (IATA), the International Civil Aviation Organization (ICAO), the OECD, the United Nations Industrial Development Organization (UNIDO), the WHO, and the World Bank. The United Nations Framework Convention on Climate Change (UNFCCC) Clean Development Mechanism, which enables emission-reduction projects in developing

countries to earn emission credits that can be sold to developed countries, adopted a methodology on solid waste management that recommends use of ASTM standards to estimate the fossil carbon percentage in emissions from waste-derived fuels such as municipal solid waste (UNFCCC, 2020[44]).[4] Table 4.2 provides an overview and illustrates examples of the types of interactions that take place between ASTM International and other IOs active in the field on international standard-setting.

Table 4.2. Interactions with other international organisations active in international standardisation

Mechanisms of interaction		Approximate number of IOs involved	Examples
Develop joint instruments	✓	2 (ISO, IEC)	United Nations, OECD, ISO, IEC, EASC (Euro Asian Council for Standardization, Metrology and Certification), NATO, SAE International, ASME (American Society of Mechanical Engineers)
MoU or other agreements	✓	3 (ISO, IEC, NATO)	
Participate in co-ordinating institution	✓	10	
Joint meetings that provide forum for co-ordination	✓	10-20	
Observe relevant actions of other bodies	✓	10-20	
Exchange information	✓	10-20	

Source: Updated from (OECD, 2016[1]), International Regulatory Co-operation: The Role of International Organisations in Fostering Better Rules of Globalisation, OECD Publishing, Paris, https://doi.org/10.1787/9789264244047-en.

Box 4.2. ASTM International technical co-operation with NATO

NATO's Policy for Standardization creates a framework for the adoption of and reference to international standards noting that the organisation shall base its practices on civil and national defence standards instead of developing dedicated standardisation documents as much as possible, and that NATO-specific standards will only be developed in the absence of a suitable equivalent. In 2004, ASTM International signed a technical co-operative agreement with NATO's Standardization Office to support the mutual value of co-operating in all fields of standardisation in support of NATO's mission.

The agreement expanded the list of civil standards organisations recognised by NATO to include ASTM International and made it possible to reference or adopt ASTM standards to enhance interoperability, lower costs, and improve efficiencies.

Over the last 15 years, 127 ASTM Standards have been referenced or adopted into Standardization Agreements (STANAGs), NATO's standardisation document that specifies the agreement of member nations to implement a standard, in whole or in part, with or without reservation, in order to meet an interoperability requirement. Sectors covered by these standards range from fuels, composite materials, textiles to high-grade steel and metals. According to a 2018 NATO report, ASTM International ranks as the 7th most frequently referenced civil standards organisation in STANAGs.

The ASTM technical co-operation agreement with NATO has enabled NATO members from the Canada Department of National Defence, French Armed Forces, United Kingdom Defence and the Norwegian Ministry of Defence to become participating members in ASTM technical committees. In 2017, technical members of ASTM Interventional were invited to share technical knowledge with the NATO Explosive Ordinance Disposal Standards Committee regarding ASTM Homeland Security Applications involving Response Robots standard test methods to quantitatively evaluate ground, aerial, and aquatic system capabilities and operator proficiency.

Source: ASTM International and https://www.dsp.dla.mil/Portals/26/Documents/Publications/conferences/2018/2018%20international%20standardization%20workshop/20181031-item4-uk_nato_useofcivilstandards-intlstdznworkshop_lapsely.pdf?ver=2018-11-06-151834-190,%20see%20slide%2012.

In an effort to maximise synergies and avoid duplicative efforts in specific areas of international standardisation, ASTM International co-operates with other international standard-setting bodies to facilitate development of joint international standards. The organisation has developed *Guidelines for Cooperation with Other Standards Organizations* and *Principles for the Use of ASTM Intellectual Property by Other Standards Organizations* that address the logistical aspects underpinning the development of joint standards ((ASTM International, 2010[45]) (ASTM International, 2008[46])) Between 1999 and 2004, ASTM International and ISO conducted a pilot project to develop and maintain a group of joint radiation processing dosimetry standards. The initiative resulted in the transformation of 25 ASTM dosimetry standards into joint ISO/ASTM standards, dealing with the use of ionising radiation for

the treatment of commercial products – for instance, for sterilisation purposes (NIST, 2014[47]). In the past decade, ASTM International has entered into Partner Standards Development Organization (PSDO) co-operation agreements with ISO (Box 4.3) and IEC (Box 4.4). These agreements represent strongly formalised mechanisms of co-operation in the field of international standardisation and have resulted in the development on joint standards between the participating organisations.

A number of regional standardisation bodies (ARSO, the AIDMO, the CROSQ, the EASC, the GSO, and SADC) participate in the ASTM International MoU Programme, which was established to promote the engagement of international technical experts in its standards development process and broaden the global reach and use of ASTM standards. Furthermore, in 2019 ASTM and CEN signed a MoU on technical co-operation with the aim to increase technical compatibility and maximise co-ordination in areas related to circular economy and sustainability. Most recently, in October 2020, ASTM signed a MoU with ASD-STAN, an associated body to CEN, for co-ordination and collaboration on emerging aerospace standards.

ASTM International also engages with some trans-governmental networks of regulator (TGNs), an IRC mechanisms involving direct co-operation among individual units of government such as regulatory agencies (Abbott, Kauffmann and Lee, 2018[48]). For example, ASTM International is a member of the Stakeholder Consultation Body of the Joint Authorities for Rulemaking of Unmanned Systems (JARUS), a group of experts from the national aviation authorities in charge of designing a set of common technical and operational requirements for the integration of drones in the airspace and at aerodromes.[5]

Box 4.3. Collaboration between ASTM International and ISO on Additive Manufacturing (AM)

In 2011, ASTM International and ISO agreed to co-operate on international standards for additive manufacturing, also known as 3D printing. The collaboration takes the form of a Partner Standards Development Organization (PSDO) co-operation agreement, covering the work of ASTM International Committee F42 on Additive Manufacturing and ISO's Technical Committee 261 on Additive Manufacturing. The initiative reflects the shared objective of the involved international standard-setting organisations to minimise duplication in the work of their respective committees, while maximising efficient resource allocation in the

additive manufacturing industry. The agreement is undergoing steps for renewal in 2021.

The PSDO agreement covers:

- Development and fast-track adoption process of an ASTM International standard as an ISO final draft international standard;
- Formal adoption of a published ISO standard by ASTM International through ANSI;
- Maintenance of published standards; and
- Publication, copyright and commercial arrangements.

This collaboration initiative delivered an Additive Manufacturing Standards Development Structure, which is a framework designed to help meet the need for new technical standards in 3D printing. The structure is designed to:

- Guide the work of global experts and standards development organisations involved in AM standardisation;
- Identify standards-related gaps and needs in the AM industry;
- Prevent overlap and duplicative efforts in AM standards development;
- Ensure cohesion among AM standards;
- Prioritise AM standards areas; and
- Improve usability and acceptance among the AM community, including manufacturers, entrepreneurs, consumers, and others.

Based on this structure, standards can be developed at three levels:

- General standards (e.g. concepts, common requirements, guides, safety)
- Standards for broad categories of materials (e.g. metal powders) or processes (e.g. powder bed fusion); and
- Specialised standards for specific materials (e.g. aluminium alloy powders), processes (e.g. material extrusion with ABS), or applications (e.g. aerospace, medical, automotive).

The agreement has paved the way to the development of fifteen joint standards in additive manufacturing, including:

- Guide for AM – General Principles – Requirements for Purchased AM Parts (ISO/ASTM 52901);
- Guidelines for Design for AM (ISO/ASTM 52910);
- Specification for AM File Format (AMF) Version 1.2 (originally published as F2915-11) (EN ISO/ASTM 52915);

- Terminology for AM – General Principles – Terminology (EN ISO/ASTM 52900); and
- Terminology for Additive Manufacturing — Co-ordinate Systems and Test Methodologies (originally published as F2921-11) (EN ISO/ASTM 52921).

Source: ISO/ASTM Partner Standards Development Organization (PSDO) Cooperation Agreement provided by ASTM staff, (ASTM International, 2017[49]), and https://www.astm.org/commit/subcommit/f42.htm.

Box 4.4. Co-operation Agreement between ASTM International and IEC

Since 2017, ASTM International and IEC have collaborated on the joint development of market-relevant standards related to vacuum cleaners. A PSDO Agreement covers the activities of the secretariat of IEC SC 59F on Surface Cleaning Appliances and ASTM committee F11 on Vacuum Cleaners.

The agreement sets out a joint procedure to develop IEC/ASTM dual-logo international standards, including rules for the adoption of new standards, merging existing ones, as well as their revision and withdrawal. The procedure for the development of new projects includes the creation of a Joint Working Group, tasked with preparing a draft using the IEC standards development template. Draft standards are reviewed by each organisation's committees, followed by voting, approval and publication processes.

Joint IEC/ASTM standards are reviewed and balloted at least every 8 years and may be proposed for withdrawal if they have not received a new approval date by July 1st of the eighth year since their last approval.

To date, the IEC/ASTM 62885-6:2018 and IEC/ASTM 62885-7:2020 standards on Surface cleaning appliance have been developed under this PSDO agreement.

Source: IEC/ASTM Partner Standards Development Organization Cooperation Agreement (2017).

Notes

[1] ASTM F3165 -16 Standard Specification for Throat Protective Equipment for Hockey Goaltenders.

[2] See: https://www.astm.org/society_review.

[3] See https://eur-lex.europa.eu/search.html?dtc=false&dom=legislation%2cinter_agree%2ctreaties%2ceu_case_law%2cefta&subdom_init=all_all&textscope0=te&lang=en&type=advanced&qid=1605713521166&andtext0=astm.

[4] These standards are ASTM D6866, Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis and ASTM D7459, Standard Practice for Collection of Integrated Samples for the Speciation of Biomass (Biogenic) and Fossil Carbon Dioxide Emitted from Stationary Emissions Sources.

[5] Membership in JARUS Stakeholder Consultation Body is organised through Communities of Interest (COI) comprised of stakeholder representative bodies from all sectors of the aviation industry. ASTM International is member of the COI No 11 – Standards Bodies: http://jarus-rpas.org/sites/jarus-rpas.org/files/jarus_scb_28aug2019.docx.pdf.

5 ASTM standards: experience from key sectors

New technology: additive manufacturing

Additive manufacturing (AM), also known as 3D printing, uses computer-aided design to build objects layer by layer. This contrasts with traditional manufacturing, which cuts, drills, and grinds away unwanted excess from a solid piece of material, often metal. A wide range of different substances can be used for layering materials, including metals, plastics, ceramics, concrete and glass. Overall, new equipment, technologies, and materials in AM drive down the costs of building parts, devices, and products in industries such as aerospace, medicine, automotive, consumer products, among other. Still, while in traditional manufacturing most hazards, risks, and considerations are well understood and documented, new fields such as AM where different forms of substances are used require further attention to ensure safety (Sprinkle, 2020[50]).

ASTM International's technical committee on additive manufacturing technologies (F42) is the main ASTM body developing standards in this field. The committee was established in 2009 and brings together over 900 participants from 34 countries (ASTM International, 2020[51]). To date, it has published 28 standards on additive manufacturing (see Box 5.1.). A further eight ASTM technical committees write standards related to this field:

- Aerospace and Aircraft/F07;
- Aircraft Systems/F38;
- Fatigue and Fracture/E08;
- General Aviation Aircraft/F44;

- Medical and Surgical Materials and Devices/F04;
- Metal Powders and Metal Powder Products/B09;
- Plastics/D20; and
- Unmanned Aircraft Systems/F38.

International standards for additive manufacturing promote the use of common terminologies and testing methods. This builds shared frameworks of understanding in this emerging field, promotes the diffusion of knowledge across and beyond the industry, and underpins research activities (OECD, 2013[2]). Common standards for constituent materials and production processes help to measure performance, specify procedures for the calibration of machines and ensure the quality of end products. Joint design and application standards aim to encourage a wider and more uniform implementation of additive manufacturing technologies.

Notably, as a new area of standardisation, the work around additive manufacturing has facilitated co-ordination between ASTM International and other standard-setting organisations working on this field promoting synergies and reducing duplication efforts. Under a PSDO agreement, ISO and ASTM International have developed fifteen standards with guidance, terminology and specifications for additive manufacturing (Box 5.1). The European Committee for Standardization (CEN) has published these joint ISO/ASTM standards as European Standards (EN) and plans to tighten the co-operation of its own Technical Committee 438 on Additive Manufacturing with the ongoing ISO and ASTM work on the topic, including by proposing new ideas for European standards to help ensure consistent international standards. Furthermore, building on the PSDO Agreement with ISO, in 2020 ASTM International and Underwriters Laboratories signed an MOU to publish standards documents as ASTM-UL standards. Under the terms of the MOU, ASTM International convened ASTM's additive manufacturing technical committee to review and advance an international standard on the basis of UL 3400 Outline of Investigation for Additive Manufacturing Facility Safety Management (ASTM International, 2020[52]).

The co-ordination of efforts to develop international standards in additive manufacturing results in a single set of rules, serving to broaden coverage, increase uptake among industrial actors, support smooth and predictable trade flows, and pool the limited expertise in this area. From the perspective of ASTM International and ISO, the use of a common roadmap and organisational structure for the creation of AM standards enhances their responsiveness to changes in this rapidly evolving sector. Through dynamic collaboration, these organisations are able to leverage their combined procedural and constitutional strengths to better serve end-users. A Joint Steering Group (JSG) monitors the progress of the shared technical groups, reports

on their status, resolves any emerging issues, presents proposals for further collective activities, and maintains a joint three-year plan for the development of AM standards.

Moreover, ASTM International has developed partnerships in additive manufacturing with other actors. The ASTM International Additive Manufacturing Center of Excellence (AM CoE) was created in 2018 to and R&D and standards development processes around additive manufacturing (Additive Manufacturing Center of Excellence, 2020[53]). The Center brings together industry government representatives and members of academia and was established in partnership with Auburn University, manufacturing technology innovator EWI, UK-based Manufacturing Technology Centre (MTC), the National Institute of Aviation Research at Wichita State University (NIAR), National Additive Manufacturing Innovation Cluster (NAMIC), a Singapore-based public-private collaboration) and National Aeronautics and Space Administration (NASA).

Box 5.1. ASTM International key standards for additive manufacturing

- Practice for Reporting Data for Test Specimens Prepared by AM (F2971)
- Guide for Evaluating Mechanical Properties of Metal Materials Made via AM Processes (F3122)
- Specification for AM File Format (AMF) Version 1.2 (EN ISO/ASTM 52915)
- Guidelines for Design for AM (ISO/ASTM 52910)
- Guide for AM – General Principles –Requirements for Purchased AM Parts (ISO/ASTM 52901)
- Terminology for AM – General Principles – Terminology (EN ISO/ASTM 52900)
- Terminology for Additive Manufacturing – Coordinate Systems and Test Methodologies (EN ISO/ASTM 52921)
- Guide for Characterizing Properties of Metal Powders Used for AM Processes (F3049)
- Specification for Powder Bed Fusion of Plastic Materials (F3091/F3091M)
- Guide for Directed Energy Deposition of Metals (F3187)

Source: (ASTM International, 2020[51]).

Standard setting activities around sustainable aviation fuels

Aviation is currently responsible for around 2-3% of man-made CO^2, NOx and aerosol emissions (ITF, 2019[54]). Since the beginning of powered flight, aviation has mainly relied of fuel derived from liquid hydrocarbons; jet fuel refined from oil (kerosene) is the most widely used by commercial aviation. Biofuels are key for sustainable aviation as they present a solution for decoupling the growth in air travel from the associated CO^2 emissions. Indeed, most CO^2 emission reductions from aircraft derive from biofuels and increased fuel efficiency of newer aircraft (ITF, 2019[54]). The International Air Transport Association (IATA) and others in the global aviation actors identify sustainable alternative fuels as key elements in helping achieve the industry's emission reduction goals. Still, a widespread uptake of SAF has been slow due to their high cost and limited availability, along with concerns about possible negative side effects of biofuel generation.

ASTM International Technical Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants, established in 1904, is responsible for standards for jet fuel used by airlines, that include qualifications on key operating parameters including composition, volatility, fluidity, combustion, corrosion, thermal stability, and contaminants (ASTM International, 2020[55]). A special subcommittee on Emerging Turbine Fuels leads the work on sustainable alternative fuels (SAF) used by civilian aircraft, including fuels produced from biological and non-biological alternative sources. ASTM International D1655 sets the Standard Specification for Aviation Turbine Fuels, fuels that comply with it are automatically recognised as meeting the specification for conventional jet fuel. ASTM D 1655 and the UK Ministry of Defence Standard 91-91 (DefStan) are the standards are used as the basis for the Aviation Fuel Quality Requirements for Jointly Operated Systems (AFQRJOS) also known as the ´Checklist´ published by the Joint Inspection Group, an organisation focused on the development of aviation fuel supply standards (Joint Inspection Group, 2019[56]).

ASTM International standards in sustainable aviation fuels encompass the entire life-cycle of the production process. Material standards and testing requirements verify the chemical composition of a given fuel, establish minimum blending levels for molecular compounds, analyse their comparability with conventional sources, and support their safe and sustainable use. Specification standards establish a technical pathway through which a new fuel source can be approved and brought to market. Through a detailed assessment of the performance (value-added), operability (safety), and drop-in (infrastructural compatibility), the quality of prospective fuels can be ensured. ASTM standards are referenced in IATA documents related to SAF, including the Sustainable Alternative Jet Fuels Roadmap designed to increase deployment of SAF in a manner that is cost-competitive with conventional jet fuel; and

the Guidance for SAF Management that orients airlines on existing requirements relating to SAF fuel purchase, handling, and regulations and proposes industry-standard best practices for managing SAF transactions (IATA, 2015[57]) (IATA, 2020[58]). In January 2020, a fast-track approval process for sustainable aviation fuels was introduced by ASTM.

The importance of developing international standards in sustainable fuels is underscored by the inherently transboundary nature of aviation. The globalisation of supply chains, industry actors, and travel routes means that instruments with international coverage are required to promote sustainability without compromising business models. Despite the current costliness of biofuels vis-à-vis conventional kerosene, the market for sustainable alternative fuels is projected to double over the next 20 years (EERE, 2020[59]). The international standards produced by ASTM International support the scalability of this market and, by extension, help to driving down the costs of SAFs.

Sustainable construction

Concrete is ubiquitous as a base building material for road and housing infrastructure. Significant attention is currently paid to the contribution of fossil fuels to climate change, and the consequent need to reorient energy grids to place a greater emphasis on renewable technologies. Although building materials and construction activities account for roughly a quarter of overall greenhouse gas emissions (GHGs), these often receive less scrutiny (UNEP, 2020[60]). While the role of fossil fuels in the economy is set to decline over the following decades, albeit unevenly and gradually, the use of building materials was recently projected to almost double by 2060 – in which concrete production is set to account for 12% of total GHGs (OECD, 2019[61]). Effective application of concrete as a sustainable building product can contribute to unlock efficiencies in the use of existing building materials.

The development and adoption of international standards in construction can facilitate international trade in building materials, reducing wastage and inefficient resource allocation. By pooling evidence and technical expertise in formulating the frameworks according to which building materials are produced and used, these standards can help promote up-to-date knowledge in sustainable techniques. Standards for sustainable construction can also work to forge common terminologies and effective communication among key stakeholders, increase product quality by identifying core principles and decision-making methodologies, and evaluate the environmental performance of building materials through certification programmes and ratings systems (ASTM International, 2015[62]).

ASTM International Committee C09 on Concrete and Concrete Aggregates works to develop and maintain standards for concrete and for the constituent materials of concrete (except cement), as well as for certain related materials, such as materials used in curing or repair of concrete. The committee currently has over 1 500 members representing 62 countries and is responsible for 175 standards, including key specifications for ready-mixed concrete and concrete aggregates together with conformity assessment procedures that support implementation of these standards.

More recently, attention to sustainability aspects has prompted the industry to develop better practices around concrete that support SDG 6 aimed at ensuring access to water and sanitation for all. In particular, ASTM International has developed guidance for adding water to concrete at a job site through two standards that support testing requirements and qualifications for the use of water — especially recycled water — in ready mixed concrete. These are standard C1602, covering mixing water for producing hydraulic cement concrete, and C1603, providing details for measuring solids in water. Storm water management has also been taken into account by Committee C09 with development of standards that support effective usage of pervious concrete, which captures storm water and allows it to seep into the ground, reducing the amount of runoff and thus helping to achieve compliance with certain environmental protection regulations and reduce potential for damage to transportation and utility infrastructure. In support of the implementation of these standards, and because of its nature pervious concrete cannot be tested using traditional methods, ASTM has also developed test methods to verify compliance with these requirements (ASTM C1688 and ASTM C1701). Aiming to support SDG 12 on responsible consumption and production, the Committee 09 has also advanced work on the reuse of other industrial materials in concrete through two standards: ASTM C1697, addressing ASTM-compliant blended supplementary cementitious materials for use in concrete or mortar, and ASTM C1798M, *Standard Specification for Returned Fresh Concrete for Use in a New Batch of Ready-Mixed Concrete*.

6 Assessment of the impact and success of regulatory co-operation through ASTM International

Benefits, costs and challenges of regulatory co-operation through ASTM standards

Benefits

There are numerous benefits derived from the adoption of international standards. In particular, they ensure safety and quality of products and services, facilitate international trade, create new markets and protect and improve the environment. At the same time, there are typically many bodies working in similar subject areas, and a large volume of standards, making it difficult for national regulators to navigate among.

The benefits from the use of standards can be discussed across four categories, paralleling the grouping provided by (OECD, 2013[2]) for the potential benefits from IRC: economic gains, progress in managing risks and externalities across borders, administrative efficiency, and promoting knowledge flow.

- From an *economic gains* perspective, standards typically reduce divergences leading to economies of scale, increase efficiency in productivity and innovation (Guasch et al., 2007[63]). The incorporation of international standards support the harmonisation of technical specification of products across export markets reducing specification costs (OECD, 2017[3]).

International standards may also help to harmonise conformity assessment procedures across countries. Furthermore, they support a multilateral approach fit for globalised production and markets.

- *Standards can also enable progress in managing cross-border risks and externalities*. The increased interconnectedness and complexity of policy issues has intensified IRC efforts around global non-economic challenges where an adequate reaction require co-ordination across countries to ensure an effective regulatory response. Examples of this include environmental problems such as cross-border air or water pollution and climate change, and health threats such as the COVID-19 crisis where international standards played a role supporting and international regulatory co-operation response to the pandemic (OECD, 2020[26]).
- International standards can *promote knowledge flow and peer learning*. Standards reduce imperfect information for actors in the marketplace and provide consumers with information about the quality and safety particularly for consumers. Standards also facilitate innovation, particular through the dissemination of technological information (Guasch et al., 2007[63]).
- As a key IRC tool, international standards are an *efficient administrative strategy* improving the capacities of domestic regulators through peer learning and sharing of resources. By relying on international standards regulators can achieve certain objectives for regulatory design, implementation and enforcement reallocating public resources to areas of higher priority (Mcallister, 2014[21]). International standards can also be leveraged to maximise public performance for instance, in public procurement processes.

Costs and challenges

The main costs of IRC through ASTM standards come from the need to purchase their standards for use and the membership fees that, while low, are required for certain participants.

Challenges to successful IRC through ASTM International technical committees may arise from difficulties in gathering a balanced diversity of participants and achieving consensus on specific standards. ASTM standards are developed under a process with which some countries and participants are often unfamiliar. Further, all activities and standards are developed and published in English with only non-official translations available into other languages. An additional challenge comes from the need to review certain standards to avoid obsolescence. The review process needs to ensure that participants in the process are acquainted with the rationale that informed the original or previous versions of the standard under assessment. The

review process for standards developed jointly with international standard-development organisations may represent additional challenges for co-ordination.

(OECD, 2017[3]) discusses some of the general challenges associated with the domestic use of international standards, which impact their effectiveness. Despite the policy commitment, the evidence suggests that actual use of standards in regulatory documents is highly diverse, complex and opaque – even when broad policy guidance may exist there is limited knowledge of how practically international standards are reflected into domestic technical regulations. Similar to other international organisations, absence of consistent evidence over the implementation of ASTM standards may also pose a challenge to the assessment of the organisation's impact.

Moreover, (NIST, 2009[15]) identifies a range of challenges facing the US voluntary standardisation system but frequently applicable to standards system outside the United States. These include: i) legal challenges arising from legal action taken against standards developers, particularly related to health or safety related issues; ii) copyright issues regarding the enforceability of copyright for standards referenced in law; iii) potential antitrust action against standards resulting from collaboration by competitors or that unfairly discriminate against certain products or manufacturers; iv) actors engaging in forum shopping for selecting the most convenient standard-development organisation; v) the open access debate over standards that report on the result of government-funded research; vi) the increasing growth of consortia standards; and vii) potential anti-competitive market place effects resulting from the incorporation of patented technology or copyrighted material into a standard without certain safeguards.

Assessment of ASTM International's success

The voluntary nature of ASTM standards together with the diversity of industry sectors covered make it difficult to fully assess the uptake and impact of its deliverables. Still, some indicators demonstrate the success of ASTM International in expanding the international use and adoption of its standards and the dynamism in stepping into standardising action in emerging areas.

Development of standards for emerging areas

Certain key features of ASTM International promote standardisation work in new areas. Members are encouraged to identify opportunities for the new standard-development and a streamlined process facilitates the creation of new committees

and standards. This is further enabled by the use of tools for remote participation in technical committees, including virtual meetings, collaboration areas and online balloting. Together with a large membership that includes technical experts, this has allowed the organisation to react to the standard-setting needs of a range of dynamic industries delivering standards in key emerging areas where technologies and markets are growing fast and regulation is either new or still under development (Box 6.1). Moreover, these activities contribute to attract new participants to ASTM standard-development work.

As a result, a number of ASTM International committees develop work around key new production technologies, including a variety of digital technologies (i.e. the Internet of Things and advanced robotics, and human exoskeleton technology), industrial biotechnology, additive manufacturing, new materials and nanotechnology. These are all technologies of great current economic and policy interest likely to have significant effect over production in the next 10 to 15 years (OECD, 2017[64]).

ASTM has also acted in other industries in need of standardisation action to address quality and safety needs. For example, in 2017, as some countries introduced partial or total legalisation of cannabis, Committee D37 on Cannabis was formed to develop standards for cannabis, its products and processes (ASTM International, 2020[65]). With around 900 members from 30 countries, the committee has delivered fourteen standards produced by technical subcommittees focused on the development of test methods, practices and guides for cultivation, quality assurance, laboratory considerations, packaging and security (ASTM International, 2020[65]).

Box 6.1. Advancing from innovation and research to standards

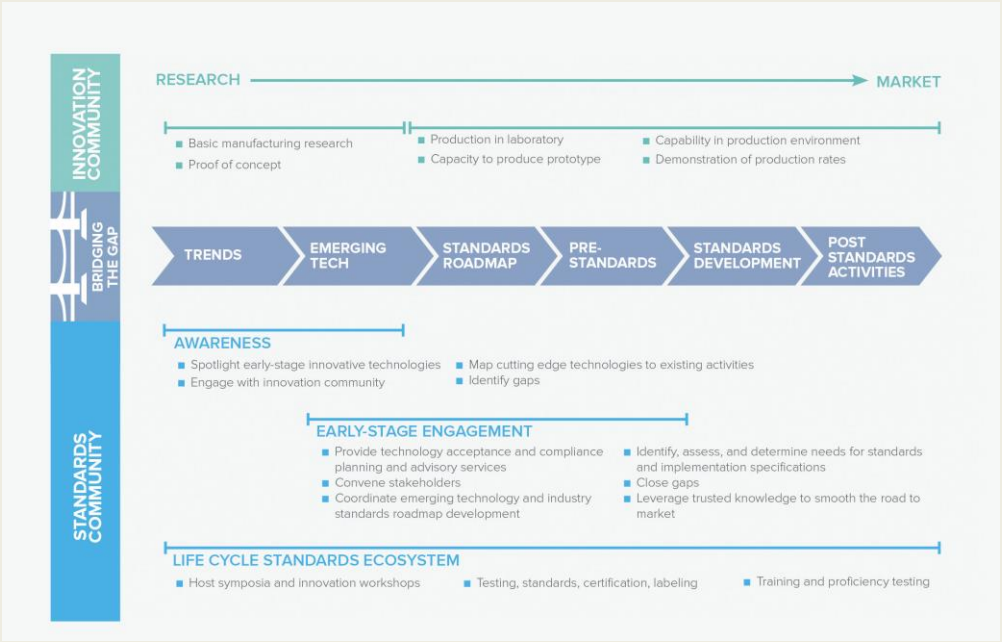
ASTM International has placed particular attention at how the innovation and standardisation communities can work together accelerate the widespread commercialisation of new technologies in the global manufacturing industry. Overall, proactivity can help standards-development activities keep pace with marketplace innovation. Still, a collaborative and integrated approach in three key areas around standards development can help bridge the gap between both communities:

- Early engagement in strategic planning to provide the interface between science and technology, research and market;
- Robust participation of all key stakeholders to ensure alignment of technology and process goals; and

- Leveraging the strength of standards development organizations, including speed, collaborative expertise, and agility.

Figure 6.1 depicts how the standards and innovation communities can move forward in parallel with ongoing interactions.

Figure 6.1. Opportunities for collaboration for standard-development



ASTM International has established two Centers of Excellence aimed at bridging standards development with R&D to better enable efficient development of standards, education and training, certification and proficiency testing programs. The ASTM International Additive Manufacturing Center of Excellence (AM CoE) to carry out work around 3D-priniting and the ASTM International's Exo Technology Center of Excellence (ET CoE), that brings together industry, healthcare, academia, and government to accelerate safety and reliability standards for exoskeletons and their systems to ensure greater confidence in their baseline performance and promote commercialisation and adoption of this technology.

Source: (ASTM International, 2018[66]).

Facing the COVID-19 crisis, ASTM International worked to identify needs and deliver standards for Personal Protective Equipment (PPE), a set of products that play a critical role in controlling infections and minimising exposure to disease and that experienced a surge in demand with the pandemic. This work served to identify high priority standardisation needs around PPE and launched the fast-track update and development of a series standards (Box 6.2). As an output of this work, in February 2021 ASTM approved a new standard (F3502) for barrier face coverings that sets minimum design, performance, labelling, and care requirements for reusable barrier face coverings. Furthermore, ASTM International is working with APEC Economies and the International Medical Device Regulators Forum (IMDRF) on a project to that analyses the standardisation needs around AM-produced (i.e. 3D-printed) parts of PPE and medical devices, specifically face shields and nasopharyngeal swabs, that require testing for regulatory approval. Work with APEC Economies is also ongoing to explore the use unmanned aircraft systems (drones) to monitor and disinfect public spaces, support delivery of essential goods and information during the pandemic.

Box 6.2. Identifying needs and delivering standards for PPE

PPE plays a critical role in controlling infections and minimising exposure to disease. The COVID-19 pandemic increased the demand for PPE fit to ensure the safety and health of front line workers, particularly in the health sector.

Standards are key to ensure the safety and quality of a number of PPE and infection control items including masks, respirators, gloves, gowns, face shields, barriers to biological agents, infrared thermometers, thermometer caps, test swabs and testing materials, laboratory supplies, cleaning, sanitising, disinfecting, and sterilising supplies, among other. Still, there are a number of challenges around the standardisation of PPE including gaps in standardisation, qualification, and certification for certain high-demand products and lack of test and methods for washing and reusing PPE, an option to address shortages.

Since July 2020, ASTM Committee F23 on Personal Protective Clothing and Equipment and Committee F04 on Medical Devices worked together to fast-track the development of PPE standards. An international workshop bringing together a broad range of participants was held to identify needs and promote collaboration around PPE standards. The workshop served to identify standardisation needs across various categories of infection control PPE, including: respirators and facemasks, protective clothing and face shields, reprocessing and reuse of PPE, conformity assessment and modelling and additive manufacturing, i.e. the use of 3D printing technology around PPE.

ASTM Committee F23 published a new voluntary standard for barrier face coverings in February 2021. In March 2021, ASTM launched a global collaboration forum for PPE quality, innovation and standards and signed a Memorandum of Understanding with the International Finance Corporation, an arm of the World Bank Group, to promote awareness, compliance, and use of PPE in selected countries worldwide.

Source: (ASTM International, 2021[67]).

ASTM International growing membership and global reach

ASTM International's membership has grown considerably since its creation reaching over 30 000 members. In 2019, it surpassed 6 000 international members growing its non-US membership by 4%, included a 14% growth in the Middle East and 8.5% growth in Europe (ASTM International, 2020[22]).

ASTM International's membership growth is driven, in part, by an active outreach strategy through a Memorandum of Understanding (MOU) Programme launched in 2005 promote the participation of technical experts from around the world the standard-development process and broaden the global acceptance and use of ASTM standards (ASTM International, 2020[68]). The initiative rests on MoU agreements between ASTM International and national or regional standard-development organisations, to date the initiative has 114 partners (ASTM International, 2020[22]). The programme gives national or regional standards body free access and authorisation to sell ASTM standards and allows technical experts to participate free of charge as full voting members in the standard-development process.

Overall, the MoU Programme promotes communication between signatory member standards bodies increasing awareness of each other's standardisation systems. It supports the development of national standards and minimises duplications and overlaps supporting the development activities of members. In addition, the programme addresses the "development dimension" principle of the WTO TBT committee which calls for standards developers to include as many nations as possible in the creation of standards.

Conclusion

ASTM International's standard-setting activities provide a unique example of a committee-led and inclusive process to deliver voluntary technical standards responsive to global market and standardisation demands. Building on participation of a variety of individuals with different expertise and interests, over the years, the organisation has developed a significant volume of standards covering a range of industries, including on emerging areas. Its broad membership and global reach has led ASTM International to consistently use and rely on remote tools of participations for technical committees, including virtual meetings and voting mechanisms, well before the COVID-19 pandemic pushed all international bodies to embrace remote decision-making (OECD, 2020[69]). Still, its highly decentralised governance structure reliant on a user-funded business model may be difficult to replicate for other IOs focused on developing international normative instruments of different nature.

ASTM International is quick to react to emerging areas in need of standardisation action, notably around key new production technologies. This is facilitated by the participation of technical experts across committees that raise attention to new opportunities for standard-development and a streamlined process enables the creation of new committees and standards. More broadly, certain features shared by other similar international private standard-setting bodies, including the participation of public and private actors, a strong engagement of stakeholders, and a bottom-up approach to standard-development, create an adaptable environment for ASTM International to develop market-relevant standards.

Still, like all IOs, ASTM International faces a number of challenges to ensure the effectiveness, impact and relevance of its standards. Fostering an active engagement of members throughout the standard-setting process is central to ensure the quality and relevance of its standards but can prove challenging particularly when dealing with multiple standards that require constant review. Further, the focus on a diverse membership has left little space for an active stakeholder engagement strategy, with space for further reflection of viewpoints beyond the ASTM membership. In addition, while regular review is well embedded into the standardisation process, the large

volume of standards developed and the fast-paced evolution of the areas involved, call for priority efforts in this regard to ensure that standards remain relevant and fit for purpose.

The inclusive, flexible and constantly available decision-making process of ASTM International offers unique and innovative perspective on standard-development.

References

Abbott, K., C. Kauffmann and J. Lee (2018), "The contribution of trans-governmental networks of regulators to international regulatory co-operation"*, OECD Regulatory Policy Working Papers*, No. 10, OECD Publishing, Paris, https://dx.doi.org/10.1787/538ff99b-en. [48]

Additive Manufacturing Center of Excellence (2020), *2019-2020 Annual Report*, http://www.amcoe.org. [53]

ANSI (2020), *ANSI Essential Requirements: Due process requirements for American National Standards*, http://www.ansi.org/essentialrequirements (accessed on 8 October 2020). [36]

ASTM (2020), *ASTM Standards & COVID-19*, https://www.astm.org/COVID-19/. [25]

ASTM International (2021), *Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation*, https://www.astm.org/about/ppe-white-paper-R2.pdf (accessed on 22 February 2021). [67]

ASTM International (2020), *Additive Manufacturing Overview*, https://www.astm.org/industry/additive-manufacturing-overview.html (accessed on 14 October 2020). [51]

ASTM International (2020), *ASTM International 2019 Annual Report*, https://www.astm.org/about/images/astm-annualreport-2019.pdf (accessed on 30 September 2020). [22]

ASTM International (2020), *Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants*, https://www.astm.org/committee/d02.htm [55]

(accessed on 23 October 2020).

ASTM International (2020), *Factsheet Technical Committee D37 on Cannabis*, https://www.astm.org/COMMIT/D37_Fact_Sheet_2020.pdf (accessed on 1 October 2020). [65]

ASTM International (2020), *Global Cooperation and ASTM International*, ASTM International, https://www.astm.org/GLOBAL/mou.html (accessed on 13 October 2020). [68]

ASTM International (2020), *New ASTM International Activity to Focus on Alternative Natural Rubber Sources*, https://newsroom.astm.org/new-astm-international-activity-focus-alternative-natural-rubber-sources (accessed on 8 February 2021). [19]

ASTM International (2020), *TR2-EB - Developmental Pillars of Increased Autonomy for Aircraft Systems*, https://www.astm.org/digital_library/technical_reports/pages/fc2da6dc-733d-4d86-bb09-75a555b85330.htm (accessed on 8 October 2020). [33]

ASTM International (2020), *Underwriters Laboratories and ASTM International Sign First International Collaboration Agreement*, https://www.astm.org/newsroom/underwriters-laboratories-and-astm-international-sign-first-international-collaboration (accessed on 23 October 2020). [52]

ASTM International (2019), *Regulations Governing ASTM Technical Committees*, http://www.astm.org. [12]

ASTM International (2019), *TR1-EB - Autonomy Design and Operations in Aviation: Terminology and Requirements Framework*, https://www.astm.org/digital_library/technical_reports/pages/1fe1b67c-5ff0-488e-ab61-cb0d329bc63c.htm (accessed on 8 October 2020). [34]

ASTM International (2018), "Standards Development: Enabling Manufacturing Innovation and Accelerating Commercialization"*, ASTM White Papers*, ASTM International, https://www.astm.org/about/innovations-white-paper.pdf (accessed on 8 March 2021). [66]

ASTM International (2017), *Global Leader in Additive Manufacturing Standards*, https://www.astm.org/about/overviewsforweb2014/additive- [49]

manufacturing.pdf (accessed on 1 October 2020).

ASTM International (2015), *ASTM Technical Committee Officer Handbook*, https://www.astm.org/handbook_Handbook_sdrb.pdf (accessed on 30 September 2020). [18]

ASTM International (2015), *Helping our World Work Better: Standards for Sustainable Construction*, http://www.astm.org (accessed on 23 February 2021). [62]

ASTM International (2014), *ASTM International Manual for Development and Implementation of Strategic Plans*, ASTM International , West Conshohocken, PA, https://www.astm.org/commit/planmanual98.pdf (accessed on 9 October 2020). [39]

ASTM International (2010), *Guidelines for Cooperation with Other Standards Organizations*, https://www.astm.org/commit/cooperationGuidelines.pdf (accessed on 29 September 2020). [45]

ASTM International (2009), *ASTM Bylaws*, https://www.astm.org/commit/bylaws052009.pdf (accessed on 30 September 2020). [38]

ASTM International (2008), *Principles for the Use of ASTM Intellectual Property by Other Organizations*, ASTM International, https://www.astm.org/commit/ipprinciples.pdf (accessed on 29 September 2020). [46]

ASTM International (1999), *Intellectual Property Policy of ASTM International*, ASTM International, https://www.astm.org/ltpolicy.pdf (accessed on 6 October 2020). [23]

ASTM International (1998), *ASTM 1898-1998: A Century of Progress*, ASTM International, https://www1.astm.org/images03/century_of_progress.pdf. [9]

ASTM International (1902), *ASTM Charter*, https://www.astm.org/commit/charter.pdf (accessed on 28 September 2020). [11]

ASTM international (n.d.), *White paper - Standards Development: Enabling Manufacturing Innovation and Accelerating Commercialization*, [73]

https://www.astm.org/about/innovations-white-paper.pdf (accessed on 13 October 2020).

Barrios Villarreal, A. (2016), *International Standardization and the TBT Agreement: Demystifying International Standardizing Bodies and their Processes*, Graduate Institute of International and Development Studies, Geneva, https://repository.graduateinstitute.ch/record/294569?ln=en (accessed on 29 September 2020). [20]

Bremer, E. (2013), "Incorporation by Reference in an Open-Government Age", *Harvard Journal of Law & Public Policy*, Vol. 36, pp. 131-210, https://dx.doi.org/ (accessed on 6 October 2020). [24]

Combacau, J. and S. Sur (2016), *Droit international public*, LGDJ-Lextenso, https://www.lgdj.fr/droit-international-public-9782275045092.html (accessed on 12 September 2018). [41]

EERE (2020), *Sustainable Aviation Fuels: Review of Technical Pathways*, https://www.energy.gov/sites/prod/files/2020/09/f78/beto-sust-aviation-fuel-sep-2020.pdf (accessed on 23 February 2021). [59]

European Commission (2002), *Methods of referencing standards legislation with an emphasis on European legislation*, European Commission, Brussels, https://ec.europa.eu/growth/content/methods-referencing-standards-legislation-emphasis-european-legislation-0_en (accessed on 29 September 2020). [14]

Guasch, J. et al. (2007), *Quality Systems and Standards for a Competitive Edge*, The International Bank for Reconstruction and Development/The World Bank, http://dx.doi.org/10.1596/978-0-8213-6894-7. [63]

IATA (2020), *Developing Sustainable Aviation Fuel (SAF)*, https://www.iata.org/en/programs/environment/sustainable-aviation-fuels/#tab-2 (accessed on 23 October 2020). [58]

IATA (2015), *IATA Sustainable Aviation Fuel Roadmap*, https://www.iata.org/contentassets/d13875e9ed784f75bac90f000760e9988/safr-1-2015.pdf (accessed on 14 October 2020). [57]

IATA (n.d.), *IATA Sustainable Alternative Jet Fuels Strategy*. [71]

International Law Commission (2011), *Draft Articles on the Responsibility of* [6]

International Organizations, Article 2(a).

ISO (2010), "Using ISO/CASCO standards in regulation". [29]

ISO/IEC (2020), *ISO/IEC 17000:2020, Conformity assessment — Vocabulary and general principles*, ISO/IEC, https://www.iso.org/obp/ui/#iso:std:iso-iec:17000:ed-2:v1:en (accessed on 7 October 2020). [28]

ITF (2019), *ITF Transport Outlook 2019*, OECD Publishing, Paris, https://dx.doi.org/10.1787/transp_outlook-en-2019-en. [54]

Joint Inspection Group (2019), *Product Specifications Bulletin Aviation Fuel Quality Requirements for Jointly Operated Systems*, http://www.jigonline.com/wp-content/uploads/2019/11/Bulletin-125-AFQRJOS-Issue-31-Nov-2019-FINAL2.pdf (accessed on 23 October 2020). [56]

Mcallister, L. (2014), "Harnessing Private Regulation", *Michigan Journal of Environmental & Administrative Law*, Vol. 3/2, https://repository.law.umich.edu/mjealhttps://repository.law.umich.edu/mjeal/vol3/iss2/6 (accessed on 6 October 2020). [21]

Ming Du, M. (2020), *The Regulation of Product Standards in World Trade Law*, Hart Publishing, New York, https://books.google.fr/books?id=zlaeeaaaqbaj&pg=pa180&lpg=pa180&dq=1997+ansi+wto+tbt+cgp&source=bl&ots=yyv2fdmug0&sig=acfu3u1e5mooj_j2aamox3ai-lp_whr5zq&hl=en&sa=x&ved=2ahukewic1mmbvjxvahugo-wkhqlrbxoq6aewa3oecasqaw#v=onepage&q=1997%20ansi%20wto%20tbt%20cgp&f=false (accessed on 4 March 2021). [72]

NIST (2014), *A Review of U.S.A. Participation in the ISO and IEC*, National Institute of Standards and Technology, http://dx.doi.org/10.6028/nist.ir.8007. [47]

NIST (2009), *The ABC's of Standards Activities*, National Institute of Standards and Technology, https://www.nist.gov/system/files/nistir_7614.pdf (accessed on 29 September 2020). [15]

OECD (2020), *International organisations in the context of COVID-19:* [69]

adapting rulemaking for timely, evidence-based and effective international solutions in a global crisis, https://www.oecd.org/gov/regulatory-policy/summary-note-covid-19%20webinars.pdf.

OECD (2020), *No policy maker is an island: The international regulatory co-operation response to the COVID-19 crisis*, OECD, https://www.oecd.org/coronavirus/policy-responses/no-policy-maker-is-an-island-the-international-regulatory-co-operation-response-to-the-covid-19-crisis-3011ccd0/. [26]

OECD (2020), *OECD Study on the World Organisation for Animal Health (OIE) Observatory: Strengthening the Implementation of International Standards*, OECD Publishing, Paris, https://dx.doi.org/10.1787/c88edbcd-en. [40]

OECD (2019), *Global Material Resources Outlook to 2060: Economic Drivers and Environmental Consequences*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264307452-en. [61]

OECD (2019), *The Contribution of International Organisations to a Rule-Based International System*, OECD, Paris, https://www.oecd.org/gov/regulatory-policy/io-rule-based%20system.pdf. [5]

OECD (2017), *International Regulatory Co-operation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264275942-en. [3]

OECD (2017), *The Next Production Revolution: Implications for Governments and Business*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264271036-en. [64]

OECD (2016), *International Regulatory Co-operation: The Role of International Organisations in Fostering Better Rules of Globalisation*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264244047-en. [1]

OECD (2013), *International Regulatory Co-operation: Addressing Global Challenges*, OECD Publishing, Paris, https://dx.doi.org/10.1787/9789264200463-en. [2]

OECD (Forthcoming 2021), "Compendium of International Organisations' [70]

Practices for Effective International Rulemaking".

OECD (2021 forthcoming), *Compendium of International Organisations' Practices: Working Towards More Effective International Instruments*, https://community.oecd.org/servlet/jiveservlet/previewbody/182627-102-1-322737/gov%20rpc%202020%2012.pdf (accessed on 3 November 2020). [4]

OECD/ISO (2016), *International Regulatory Co-operation and International Organisations: The Case of the International Organization for Standardization (ISO)*, OECD/ISO, https://www.oecd.org/gov/regulatory-policy/iso_full-report.pdf. [13]

OECD/ISO (2016), *The Case of the International Organization for Standardization (ISO)*, http://www.oecd.org/gov/regulatory-policy/iso_full-report.pdf (accessed on 5 June 2019). [16]

OECD/WTO (2019), *Facilitating Trade through Regulatory Cooperation: The Case of the WTO's TBT/SPS Agreements and Committees*, OECD Publishing, Paris/World Trade Organization, Geneva, https://dx.doi.org/10.1787/ad3c655f-en. [8]

Olshefsky, J. and J. Hugo (2003), *Getting Key Stakeholder Participation*, ASTM International, https://www.astm.org/snews/june_2003/howto_jun03.html (accessed on 11 October 2020). [37]

OMB (2003), *Circular A-4, Regulatory Analysis*, United States Office of Management and Budget, Washington DC, http://www.whitehouse.gov/omb/memoranda/m00-08.pdf. [32]

Raustiala, K. (2002), "The Architecture of International Cooperation: Transgovernmental Networks and the Future of International Law", *Virginia Journal of International Law Association*, Vol. 43/1, p. 5. [7]

Safety Equipment Institute (2020), *Safety Equipment Institute*, https://www.seinet.org/index.html (accessed on 7 October 2020). [30]

Sprinkle, T. (2020), *Making Additive Manufacturing Safer*, ASTM International website, https://sn.astm.org/?q=features/making-additive-manufacturing-safer-.html (accessed on 8 March 2021). [50]

UNECE (2019), *Declaration for Gender Responsive Standards and* [35]

Standards Development, UNECE, Geneva, http://www.unece.org/fileadmin/dam/trade/wp6/areasofwork/genderinitiative/unecegenderdeclaration_english.pdf (accessed on 22 September 2020).

UNECE (2018), *Standards for the Global Goals*, https://standards4sdgs.unece.org/standards?field_standard_sdg_goals_target_id_verf=All&field_standard_sdg_targets_target_id_verf=All&field_standard_organizations_target_id_verf=144&items_per_page=4 (accessed on 29 September 2020). [42]

UNECE (2016), *Regulation No 117 of the Economic Commission for Europe of the United Nations (UNECE) — Uniform provisions concerning the approval of tyres with regard to rolling sound emissions and/or to adhesion on wet surfaces and/or to rolling resistance [2016/1350]*, UNECE, Geneva, https://op.europa.eu/en/publication-detail/-/publication/48d3ed27-604f-11e6-9b08-01aa75ed71a1 (accessed on 8 March 2021). [43]

UNECE (2001), *UNECE Recommendation L, An International Model for Technical Harmonisation Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards*, UN. ECE, Geneva, https://digitallibrary.un.org/record/467938?ln=en (accessed on 8 March 2021). [31]

UNEP (2020), *Resource Efficiency and Climate Change: Material Efficiency Strategies for a Low-Carbon Future*, UNEP Publishing, Nairobi, https://wedocs.unep.org/bitstream/handle/20.500.11822/34351/reccr.pdf?sequence=1&isallowed=y (accessed on 23 February 2021). [60]

UNFCCC (2020), *ACM0022: Alternative waste treatment processes - Version 2.0*, https://cdm.unfccc.int/methodologies/db/yinq0w7suyoo2s6gu8e5dyvp2zc2n3 (accessed on 8 March 2021). [44]

United States. Office of Management and Budget. (2016), *OMB Circular A-119, Revised: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/a11 [17]

9/revised_circular_a-119_as_of_1_22.pdf.

WHO (2020), *Disease Commodity Package COVID-19 v5*, https://www.who.int/emergencies/what-we-do/prevention-readiness/disease-commodity-packages/dcp-ncov.pdf?ua=1. [27]

WTO (2000), *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"*, https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm (accessed on 22 September 2020). [10]

International Regulatory Co-operation and International Organisations

The Case of ASTM International

ASTM International, formerly known as American Society for Testing and Materials, is an international standards organisation that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. Some 12 575 ASTM voluntary consensus standards operate globally. This case study provides an overview of ASTM's role in International Regulatory Co-operation (IRC) – its institutional context, its main characteristics, its impacts, successes and challenges.

Contents

www.oecd.org/gov/regulatory-policy/irc.htm