Chapter 3
Standardisation in AM

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3.1 Introduction to Standards

A standard is a published document that describes a technical specification or a list of guidelines in the form of rules, definitions, methods, vocabularies, or codes of practices. Standards provide a unified source of reference for specifying or representing products. Before the industrial revolution, manufacturers from different places used to compare and copy the dimensions and specifications of components to match those of a prototype. As mass-production led to parts being made at different factories, national standards became vital to provide unified information on materials, dimensions, and processes.

3.1.1 Significance of Standards

Standards formalise procedures, best practices and guidelines for every sector including several industries, academic institutions and the general society. It reflects good practice, builds trust with customers or users, improves productivity and efficiency, reduces cost and increases sustainability. Standards adoption and certification have a great impact on the quality of products and services. For example:

- Products that comply with established international standards will be more easily exportable and stay ahead of the game.
- Standards indirectly improve productivity, enhance the reliability of goods and services, and strengthen international competitiveness and enables access to overseas trade and markets.

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- Compliance with Standards enhances consumer confidence and trust in products, enabling shorter time to market and reduced cost from re-testing and re-certification.

The benefit of standards includes:

- Being precise with no room for misinterpretation
- Streamlining the process of a smooth transfer from design concept to manufacture
- Shortening the development time, increasing speed to market
- Improving the fit and function of parts
- Reducing production costs
- Achieving better quality and better product reliability
- Producing less waste and scrap
- Receiving fewer disputes over compliance.

3.1.2 Standardisation Bodies

Figure 3.1 presents the main actors at three levels of the system and their trajectories in Standards development. Standardisation bodies are the officially recognised organisations for the development and implementation of standards and certifications. These organisations principally act from three different levels in the form of national, regional, and international standardisation bodies as a joint system. National Standardisation Bodies (NSBs) and National Electrotechnical Committees (NCs) are the national points of access for standards development, usually one member per country, within the regional and international systems. They distribute and sell the implemented regional and international standards where applicable and withdraw conflicting national standards [1].

The regional level of the standardisation bodies works within a territory consisting of several member countries (e.g. European Union). These countries trade and run business sharing a single market. For example, European Standardisation Organisations (ESOs) develop and implement a common standardisation system within the European single market and free trade area. The ESOs consist of three officially recognised organisations named The European Committee for Standardisation

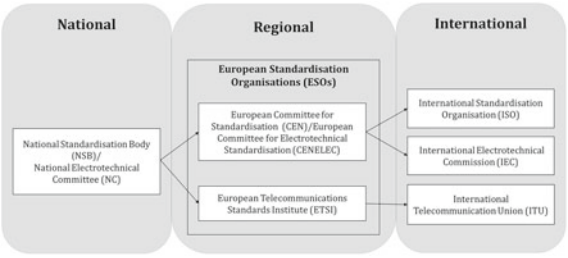

Fig. 3.1 The national, regional, and international standardisation bodies and their connections. (*Source* UBRUN)

Business Sectors of European Standardisation Organisations (ESOs)

CEN	CENELEC	ETSI
1. Chemicals	1. Accumulators, Primary Cells and Primary Batteries	1. Home and Office
2. Construction	2. Electric Motors and Transformers	2. Better Living with ICT
3. Consumer	3. Electric Equipment and Apparatus	3. Content Delivery
4. Defence and Security	4. Electronic, Electromechanical and Electrotechnical Supplies	4. Networks
5. Digital Society	5. Electrotechnology General	5. Wireless Systems
6. Energy and Utilities	6. Insulated Wire and Cable	6. Transportation
7. Food and Agriculture	7. Lighting Equipment and Electric Lamps	7. Connecting Things
8. Occupational Health and Safety	8. Low Voltage Electrical Equipment and Installations	8. Interoperability
9. Household Appliances and Heating, Ventilation and Air Conditioning (HVAC)		9. Public Safety
10. Mechanical and Machines		10. Security
11. Mining and Metals		
12. Services		
13. Transport and Packaging		
14. European Labels		

Fig. 3.2 Principal business sectors of ESOs (CEN, CENELEC and ETSI) (*Source* UBRUN)

(CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).

To ensure the protection of consumers and interoperability of products, they facilitate cross-border trade and encourage innovation, technological development, environmental protection and business growth. ESOs work closely with the European Commission to ensure that the standards correspond with any relevant EU legislation. ESOs work within the following business sectors, shown in Fig. 3.2.

The international level of the standardisation bodies comprises three independent organisations, made up of the International Standardisation Organisation (ISO), International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU), who develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges. In 2001, ISO, IEC and ITU formed the World Standards Cooperation (WSC) to strengthen the standards systems of the three organisations. The WSC brings together experts from several NSBs worldwide to share knowledge and implement the international standards, wherever necessary.

Vienna Agreements

In 1991, ISO and ESOs signed the Vienna Agreement to avoid confusion, conflict and overlap across the organisations supporting the international trade. The agreement underlines the fact that international standardisation takes precedence over national standardisation as stipulated in the World Trade Organisation (WTO) Code

of Conduct. This is because International Standards are designed to help harmonise national standards and technical regulations that reduce technical barriers to trade. The Vienna Agreement provides three main modes of cooperation between ISO and CEN, namely cooperation by (1) correspondence/exchange of information, (2) mutual representation at meetings and (3) parallel approval of standards at the international and European levels. Where an International Standard is simultaneously approved as a European Standard, it automatically becomes a National Standard for all CEN members. CEN members must recognise the status of all European Standards at a national level and withdraw any pre-existent and conflicting National Standards.

3.2 AM Standards

3.2.1 Structure of AM Standards

ASTM International and the International Organization for Standardization (ISO) signed a Partner Standards Developing Organization (PSDO) cooperative agreement to govern the ongoing collaborative efforts between ASTM International Committee F42 for Additive Manufacturing Technologies and ISO Technical Committee 261 for Additive Manufacturing. The agreement aims to fast-track the adoption process of an ASTM International standard as an ISO international standard; formally adopt a published ISO standard by ASTM International; maintain published standards, publications, copyright and other commercial arrangements.

This has resulted in a three-tier structure of AM standards presented in Fig. 3.3. The general AM standards are divided into ten categories including Test methods, Design guides, Data formats, Terminology, Test artefacts, Qualification guidance, Safety, System performance and reliability, Round robin test protocols and Inspection methods. This level is broken down into three classes specifying raw materials, process/equipment and finished parts. The other category of AM standards also focuses on the material, process qualifications and applications for AM.

The three key organisations at national, regional, and international levels working on standardisation and certification in AM are ASTM international, CEN and ISO. A brief account of the history and scope of the corresponding AM technical committees are further described.

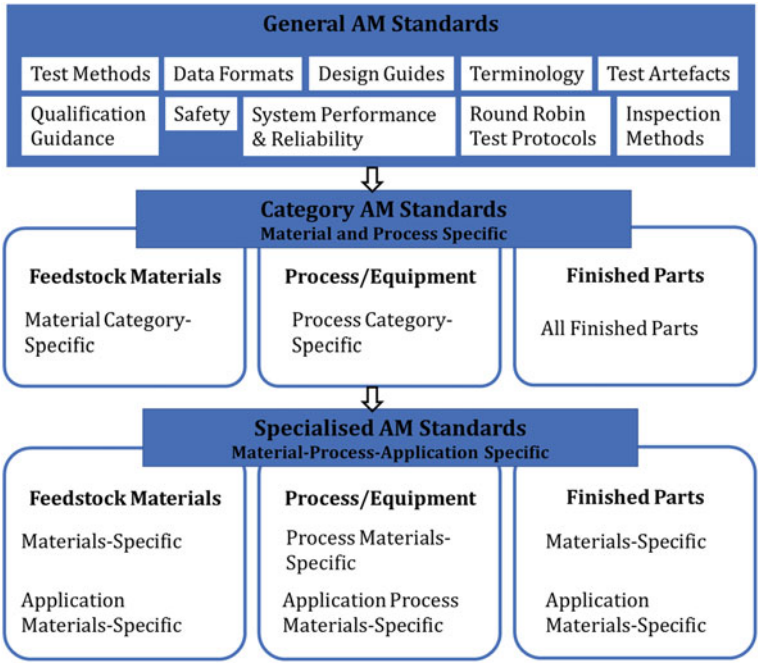

Fig. 3.3 Structure of AM standards. (*Source* UBRUN)

3.2.2 ASTM International/ASTM F42

History

ASTM International

ASTM International is a standardising and testing organisation with its headquarters in West Conshohocken, PA, USA. It was founded in 1898 in Pennsylvania by a group of railroad engineers and scientists, led by the chemist Charles Benjamin Dudley to address the frequent rail breaks in the fast-growing railroad industry. Originally called the "American Society for Testing and Materials", it changed its name to "ASTM International" in 2001. The association has more than 30,000 members, classified as users, producers, consumers, academics, and consultants. It has several offices in Belgium, Canada, China, Mexico and Washington, D.C.

ASTM F42

The first AM standard technical committee ASTM F42 was formed within ASTM international in 2009. The committee has over 725 members (154 outside the USA) and nine technical subcommittees. The subcommittees developed over 40 documents independently and collaborated with the International Standardisation Organisation

(ISO). The committee has strategic relationships with NASA, NIST, FAA, FDA, DOD, CMH-17, etc.

Scope of ASTM F42

The AM technical committee ASTM F42 focuses on the promotion of knowledge, stimulation of research and implementation of technology through the development of standards for Additive Manufacturing technologies. The work of this committee is to coordinate with other ASTM technical committees and other national and international organisations having mutual or related interests. It has nine subcommittees on different topics related to AM process chain and applications. Each main subcommittee in ASTM F42 is composed of several working groups that address specific segments within the general subject area covered by the technical committee, as shown in Table 3.1.

Table 3.1 List of nine technical subcommittees and their working groups of ASTM F42

F42.01 Test methods
F42.04 Design
F42.05 Materials and processes
F42.05.01 Metals F42.05.02 Polymers F42.05.05 Ceramics
F42.06 Environment, health, and safety
F42.07 Applications
F42.07.01 Aviation F42.07.02 Spaceflight F42.07.03 Medical/Biological F42.07.04 Transportation/Heavy machinery F42.07.05 Maritime F42.07.06 Electronics F42.07.07 Construction F42.07.08 Oil/Gas F42.07.09 Consumer F42.07.10 Energy
F42.08 Data
F42.90 Executive
F42.90.01 Strategic planning F42.90.02 Awards F42.90.05 Research and innovation
F42.91 Terminology
F42.95 US TAG to ISO TC 261

3.2.3 CEN/TC 438

History

CEN is a major provider of European Standards and technical specifications. It is the only recognised European organisation according to Directive 98/34/EC for the planning, drafting and adoption of European Standards in all areas of economic activity apart from electro-technology (**CENELEC**) and telecommunication (ETSI). There are 34 national members work together to develop voluntary European Standards (ENs). The member countries include 27 countries from the European Union (EU), 3 (Iceland, Norway, and Switzerland) from the European Free Trade Association (EFTA), former Yugoslav Republic of Macedonia (FYROM), Turkey and the United Kingdom. The Croatian standards institute (HZN) is also part of the CEN/CENELEC network.

CEN TC 438

CEN/TC 438 'Additive Manufacturing' committee was established in 2015 to standardise the process of AM, their process chains (hard and software), test procedures, environmental issues, quality parameters, supply agreements, fundamentals, and vocabularies. CEN/TC 438 cooperates with ISO/TC 261 and ASTM F42 to develop and implement AM standards in Europe. The committee also recommends new projects that relate to aeronautic, medical, 3D manufacturing and data protection. It has published 12 documents and developed 29 working programmes in AM sectors.

Scope of CEN TC 438

The main objective of CEN/TC 438 is to provide a complete set of European standards on processes, test procedures, quality parameters, supply agreements, fundamentals and vocabulary based, as far as possible on international standardisation work. The aim is to apply the Vienna Agreement with ISO/TC 261 Additive Manufacturing to ensure consistency and harmonisation. In addition, the committee aims to strengthen the link between European Research programs and standardisation in AM, and to ensure the visibility of European standardisation for AM.

3.2.4 ISO/TC 261

History

ISO

The International Organization for Standardization (ISO) consists of a network, representing NSBs from 164 countries and working in partnership with international organisations such as the United Nations and the World Trade Organisation. It was founded in 1946 by delegates from 25 countries and began operating in 1947.

ISO/TC 261

The ISO technical committee ISO/TC261 is dedicated to activities regarding Additive Manufacturing standardisation. The committee was established in 2011, after an initiative from the German Institute for Standardization (DIN) based on VDI Guidelines (Verein Deutscher Ingenieure/ Association of German Engineers). The committee consists of 26 participating and 9 observing NSBs (see Table 3.2) involved in developing AM standards.

Scope ISO/TC261

The scope of ISO/TC261 committee is to develop standards in the field of AM concerning their processes, terms and definitions, process chains (Hardware and Software), test procedures, quality parameters, supply agreements and all kind of fundamentals. Table 3.3 shows the figures of published and in-progress standard documents and the number of members involved in the process.

Table 3.2 The national standardization bodies (NSBs) of ISO TC 261

NSBs of ISO TC 261	Countries	NSBs of ISO TC 261	Countries
Participating members (26)			
SA	Australia	IPQ	Portugal
NBN	Belgium	GOST R	Russian Federation
ABNT	Brazil	SSC	Singapore
SCC	Canada	UNE	Spain
SAC	China	SIS	Sweden
DS	Denmark	SNV	Switzerland
SFS	Finland	BSI	United Kingdom
AFNOR	France	ANSI	United States
DIN	Germany	**Observing members (9)**	
NSAI	Ireland	ASI	Austria
SII	Israel	UNMZ	Czech Republic
UNI	Italy	ISIRI	Iran, Islamic Republic of
JISC	Japan	JSMO	Jordan
KATS	Korea, Republic of	ILNAS	Luxembourg
NEN	Netherlands	NZSO	New Zealand
SN	Norway	ASRO	Romania
BPS	Philippines	SABS	South Africa
PKN	Poland	TSE	Turkey

Table 3.3 Metric of ISO AM standards from TC261

Published ISO standards* under the direct responsibility of ISO/TC 261	14
ISO standards under development* under the direct responsibility of ISO/TC 261	30
Participating members	26
Observing members	7

Structure of TC261

The ISO/TC261 technical committee consists of eight working groups (WG). Among the working groups, five groups work independently, and three groups work jointly with another Technical Committee. Table 3.4 presents the working groups and their field of activities involved in the standards development.

WG 1 works on the terms and definition of each entity used in the AM process chain. WG 2 deals with process, systems and materials specifications. The standardisation of testing and quality control in AM is conducted by WG 3. WG 4 develops aspects of data and design standards for AM. WG 6 works on issues related to the environment, health and safety. There are two joint working groups JWG 10 and 11 working together with other with other ISO technical committees and subcommittees for AM in aerospace applications and plastics, respectively. There is another joint working group (Joint ISO/TC 150 - ISO/TC 261 WG) for AM in surgical implant applications, which is now merged in the technical committee TC 150. To date, ISO/TC 261 has published 19 AM standards and is developing 35 more projects as listed in Appendix A.

Table 3.4 Working groups of ISO 261

Working group	Name of WG
ISO/TC 261/WG 1	Terminology
ISO/TC 261/WG 2	Processes, systems and materials
ISO/TC 261/WG 3	Test methods and quality specifications
ISO/TC 261/WG 4	Data and design
ISO/TC 261/WG 6	Environment, health and safety
ISO/TC 261/JWG 10	Joint ISO/TC 261—ISO/TC 44/SC 14 WG: Additive manufacturing in aerospace applications
ISO/TC 261/JWG 11	Joint ISO/TC 261—ISO/TC 61/SC 9 WG: Additive manufacturing for plastics
ISO/TC 261/JWG 12	Joint ISO/TC 261—ISO/TC 150 WG: Additive manufacturing in surgical implant applications

3.3 Reading, Writing and Retrieving Standards

3.3.1 Reading Standards

The rules for developing Standards are documented in the ISO/IEC Directives. These documents are publicly available on the ISO website. The ISO/IEC directives provide the necessary procedures for developing international standards and other publications. Part 1 of the Directives contains the required rules to follow in standard development, and Part 2 explains the structure and writing of the draft standard documents.

Reading the Title

A maximum of three elements is used to form a *Title* in a standard document, which includes (a) Introductory, (b) Main, and (c) Complementary elements. The *Introductory* element gives a general subject area. The *Main* element mentions the main subject matter of the document relative to the subject area. The *Complementary* element indicates the specific category of the general subject area which distinguishes the document. The *Introductory* and *Complementary* elements can be optional for some document *Titles*. For example, the following *Title* belongs to an AM published standard showing the different fields or elements.

Additive manufacturing (General field or Introductory element)—General principles (Specific field or Main element)—Part 2: Overview of process categories and feedstock (Detail field or Complementary element).

Reading the Foreword

The *Foreword* is an informative and mandatory element of the standard document. The *Forward* provides the information on the organisation responsible for publishing the document, the committee that developed the document, procedures and rules under which the document was developed, the voting process, legal disclaimers, as well as other relationships between the present document and other documents. A typical *Foreword* of an ISO standard document is a single section with a few paragraphs. The content of the *Foreword* has two parts, general and specific. The general part is a fixed text which provides information relating to the organisation responsible, general and legal texts about the documents as well as the procedures and rules under which the content was developed. The specific part of *Foreword* supplied by the committee secretariat provides the designation of the technical committee and other internal organisation, relationship of the document with other documents, statements of amendments and indication using of additional language.

Reading the Structure

All documents must start with the following fixed structure, comprising of the *Scope*, *Normative References*, and *Terms and Definitions*. The *Scope* clearly defines the subject of the document and the aspects covered, thereby indicating the limits of

Table 3.5 The common terms and definitions of an ISO standard document

Terms	Definitions
2.1.2	Term number
additive manufacturing	Preferred term
AM	Abbreviated term
process of joining materials to make parts (2.6.1)* from 3D model data, usually layer (2.3.10)* upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies	Definition *Cross-reference
Note 1 to entry: Historical terms: additive fabrication, additive processes, additive techniques, additive layer manufacturing, layer manufacturing, solid freeform fabrication and freeform fabrication	Notes or examples
Note 2 to entry: The meaning of "additive-", "subtractive-" and "formative-" manufacturing methodologies are further discussed in Annex A	
[ISO/ASTM 52,900:2015(en) Additive manufacturing—General principles—Terminology]	Source

applicability of the document or parts of it. The *Scope* is succinct so that it can be used as a summary for bibliographic purposes, for example, as an abstract. The *Normative References* clause lists, for information, those documents which are cited in the text in such a way that some or all of their content constitutes requirements of the document. How a referenced document is cited in text determines whether it is listed in the *Normative References*, such as documents that are required uses the word *Shall*. For example, "The test shall be in accordance with ISO 12345". The use of *Shall* indicates that the requirement of the document is strictly followed and no deviation is permitted. *Terms and Definitions* provide information about certain terms used in the document. Table 3.5 shows how *Terms and Definitions* are included in the standard document.

Normative References, *Terms and Definitions* are mandatory elements. This section shall be introduced in each ISO standard document. If there is no requirement of these clauses, then it shall be left empty.

3.3.2 Writing Standards

The development of standards is based on achieving consensus. National standards are usually developed to meet purely national interests or to start a new work area. But this often leads to elevating them as International or European standards at some stage. Given the global nature of most industries and supply chains these days, multinational companies often prefer to refer to international standards so that they can use just one standard across all their subsidiaries and areas. In terms of European work, some of them are linked to European Directives, which is the

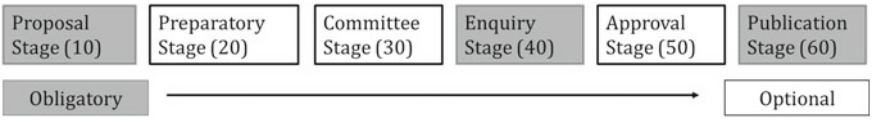

Fig. 3.4 Different stages of a standard development (*Source* UBRUN)

legislative framework developed in the EU. In some areas, European Standards might be more appropriate, depending on the nature of the industry, sector, or supply chain.

Standard Development Stages

The *Programme Management* for development of the standards comprises the *Proposal*, *Preparatory*, *Committee*, *Enquiry*, *Approval* and *Publication* stages shown in Fig. 3.4.

Proposal Stage (10) is the first step is to confirm that a new International Standard in the subject area is really needed. A new work item proposal (NWIP) is submitted to the committee for the vote using Form 4. The electronic balloting portal should be used for the vote. The person being nominated as project leader is named on the Form.

Preparatory Stage (20) commences when a working group is set up by the parent committee to prepare the working draft (WD). The working group is made up of experts and a Convenor (who is usually the project leader). During this stage, experts continue to look out for issues around copyright, patents and conformity assessment. The successive WD is circulated until the experts are satisfied that they have developed the best solution they can. The draft is then forwarded to the working group's parent committee who will decide which stage to go next.

Committee Stage (30) is an optional phase. During this stage, the draft from the working group is shared with the members of the parent committee. If the committee uses this stage, the committee draft (CD) is circulated to the members of the committee who then comment and vote using the electronic balloting portal. Successive CDs can be circulated until a consensus is reached on the technical content.

Enquiry Stage (40) is where the Draft International Standard (DIS) is submitted to the ISO Central Secretariat by the committee secretary. It is then circulated to all ISO members who get 3 months to vote and comment on it. The DIS is approved if two-thirds of the P-members of the committee are in favour and not more than one-quarter of the total number of votes cast are negative. If the DIS is approved, the project goes straight to publication. However, the committee leadership can decide to include the FDIS stage if needed.

Approval Stage (50) may be automatically skipped if the DIS has been approved. However, if the draft has been significantly revised following comments at the DIS stage (even if the DIS has been approved), committees can decide to carry out this stage. If this stage is used, the Final Draft International Standard (FDIS) is submitted to the ISO/Central Secretariat (ISO/CS) by the committee secretary. The FDIS is then circulated to all ISO members for a two-month vote. The standard is approved

if a two-thirds majority of the P-members of the committee is in favour and not more than one-quarter of the total number of votes cast are negative.

Publication Stage (60) is where the secretary submits the final document for publication. Only editorial corrections are made to the final text. It is published by the ISO Central Secretariat as an International Standard. Committee secretaries and project leaders get a two-week sign off period before the standard is published.

3.4 Conclusion

In a manufacturing context, Standards are documents that comprise principles, rules and guidelines for the specifications of built parts. They are developed by a group of experts from a relevant field based on consensus building. From the industrial revolution to mass production to the evolution of information technology, Standards play an important role to enhance efficiency, consumer confidence and trust in products, enabling shorter time to market and reduced cost from re-testing or re-certification. This is even more important, especially in Additive Manufacturing, where new technologies, materials, processes and applications are continually evolving.

3.5 External Resources

The following links provide further detail about ISO standards and other resources:

1. ISO online: www.iso.org
2. List of committees on ISO online: https://www.iso.org/technical-committees.html
3. ISO/IEC Directives (including Parts 1 & 2, the Consolidated ISO Supplement and the JTC- 1 Supplement): www.iso.org/directives
4. Description of the different ISO deliverables: https://www.iso.org/deliverables-all.html
5. List of ISO members: www.iso.org/isomembers
6. Stages of development for ISO deliverables: https://www.iso.org/stages-and-resources-for-standards-development.html
7. How to Write Standards: www.iso.org/iso/how-to-write-standards.pdf
8. The ISO Code of Conduct: https://www.iso.org/publication/PUB100397.html
9. Guidance and tools for stakeholder engagement: https://www.iso.org/resources.html

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