BUSINESS PLAN

ISO/TC 261
Additive manufacturing

EXECUTIVE SUMMARY

The main field and the overall size of the markets addressed by the committee

Additive Manufacturing (AM) technologies are an inherent part of the product development process. They are used to manufacture prototypes, tools and production parts. In comparison to conventional methods, where parts are molded into specified forms or cut from a massive block, AM bases on the principle that liquids, powders, stands and films are layered to build 3D-structures without the use of a mold.

The size of the market in 2021 was estimated at a value of 15.24 billion US $ (revenues generated in the primary AM market) according to Wohler's Report 2022.

The benefits already realized and/or expected through the availability of the standards

Benefits through standardization:

- systematic development, modification and use of processes of joining materials from 3D model data (AM) resulting in innovative products;
- assistance to users within the assessment of different additive processes resulting in using the appropriate technology for the specified product demands;
- specification of quality parameters of different processes needed for standardized test procedures;
- specification of appropriate test procedures, thereby ensuring uniform interpretation and evaluation of quality parameters;
- standardization of process chains of AM techlogies securing functionality and compatibility;
- standardization of data formats, data structures and metrics for AM models;
- standardization of vocabulary required to define the product and to find a common speech.

The main objectives and the priorities in the work of the committee

The main objectives of ISO/TC 261 are to standardize the processes of Additive Manufacturing, their process chains (Data, Materials, Processes, Hard- and Software, Applications), test procedures, quality parameters, supply agreements, fundamentals and vocabularies. It is agreed by all member bodies that those objectives always have to follow the market needs and enable flexible reaction on changes.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF THE ISO/TC 261

2.1 Description of the Business Environment

2.1.1 Introduction

The following political, economic, technical, regulatory, legal and social dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this ISO/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

2.1.2 State of the art of Additive Manufacturing

Additive Manufacturing is now being viewed as a serious method of manufacturing. It is having a significant impact on the way companies manufacture products. Tens of thousands of parts have been manufactured and installed on several different types of aircrafts (Source: Wohlers Associates, Inc.). The Boeing 787 for example already carries about 30 laser sintered components (Source: Scott Martin, Boeing, IAG member). GE Aviation has started to use metal AM to manufacture more than 30.000 fuel nozzles annually for its new LEAP engine (Source: Wohler Report 2015). More than 250.000 acetabular hip cups have been manufactured additively and about half of them implanted into patients already (Source: Lima Corporate 2022 , .). Meanwhile, according to EOS, more than five million metal dental copings (used to produce crowns and bridges) are being produced on EOS AM equipment every year.

As companies qualify and certify Additive Manufacturing processes and materials, many more types of parts will be produced in the future. The development of industry standards is a prerequisite to adopt AM for the production.

Still, AM is considered to be expensive , whereas part properties coming from several technologies fulfill expectations already now. Standards will help to support new users when deciding whether AM is suitable and where it has advantages over conventional manufacturing.

2.1.3 Marketing trends

AM will grow appreciably over the next ten years. The advantages are: developers can produce functional hollow structures in small batches, and the structures can be precisely modified to changing stress requirements. The components can be customized with specific porosities or surfaces, and ultra-lightweight components are also duable. Here, the aviation industry is one of the pioneers.

2.1.4 Relevant stakeholder

In the short history of Additive Manufacturing, certain stakeholders have recognized the advantages and always pushed the development of new technology, processes and materials. Also in the future, these stakeholders will lead and influence the growth of AM.

Users:

- supplier of medical devices and implants
- OEMs in Aerospace and Automotive
- OEMs in High-Tech equipment
- Universities and R&D organisations
- AM equipment and material supplier

Experts from those groups are essential to be included in the work of ISO/TC 261. Although the main committee already comprises representatives from the relevant groups, it will be a continuous effort to include more experts here and in the national mirror committees.

2.1.5 Environmental issues

Resources and energy efficiency combined with economical production are the central challenges in the future. Additive Manufacturing technologies are one of the key factors to tackle those challenges. Additive Manufacturing technologies will become in addition a key player in placing advanced industrial production on a cost- and resource-efficient footing.

The generation of parts layer-by-layer allows for a geometric design that is not possible using other methods. Moreover, it enables a design driven manufacturing. Branches like e.g. automotive and aerospace are forced to reduce fuel consumption in the coming years as resources are decreasing as well in many areas. Additive Manufacturing can support these industries to achieve

their goals, e.g. by enabling lightweight structures that help to reduce fuel consumption yet making sure that the part properties remain the same or are even better.

In AM usually only those raw materials are consumed that represent the part. There is a minimal amount of waste compared to conventional technology such as milling or turning.
AM uses 3D CAD data representing the geometry to control the manufacturing process. Such data can easily be transferred electronically and do not require sending drawings around the world. It also allows for distributed manufacturing, i.e. no need for central production facilities but on-site manufacturing units which has a positive effect on transportation costs and carbon emission.
AM in the spare part business enables an on-demand and on-site production, avoiding transportation and the use of storage facilities, which both have an effect on efficiency and emission.

2.1.6 Relevant international, regional, national standards and voluntary initiatives

Several initiatives have been established already years ago, mainly on a national base. Among those are the German VDI working groups, French,Spanish and US standardization activities and in particular the ASTM F42 committee on Additive Manufacturing, to name only a few.

As of April 2014, several industry standards have been published by ASTM, focused on terminology, testing, Ti6Al4V alloy and AMF file format, and with many others in development.
Due to the PSDO agreement between ISO and ASTM the joint development of common standards has started with ASTM F 42. Also the national initiatives shall be considered in ISO/TC 261 and therefore avoid the development of multiple competing standards.

Experts of ISO/TC 261 are also the key players in initiatives of the European Commission on the standardization of AM (CEN/TC 438 "Additive Manufacturing", thereby trying to direct this work such to avoid the development of multiple competing standards as well. Also in ISO, some other committees have started NWIPs in the field of Additive Manufacturing. ISO/TC 261 will decide in each case how to proceed (liasions, collaboration, change of jurisdiction).

Additionally, several national and international organizations and federations are becoming aware of the rising importance of AM and are therefore starting standardization initiatives themselves, which creates challenges for the implementation of the work programme of this business plan (see also clause 6).

2.1.7 Technical barriers and other regulatory issues

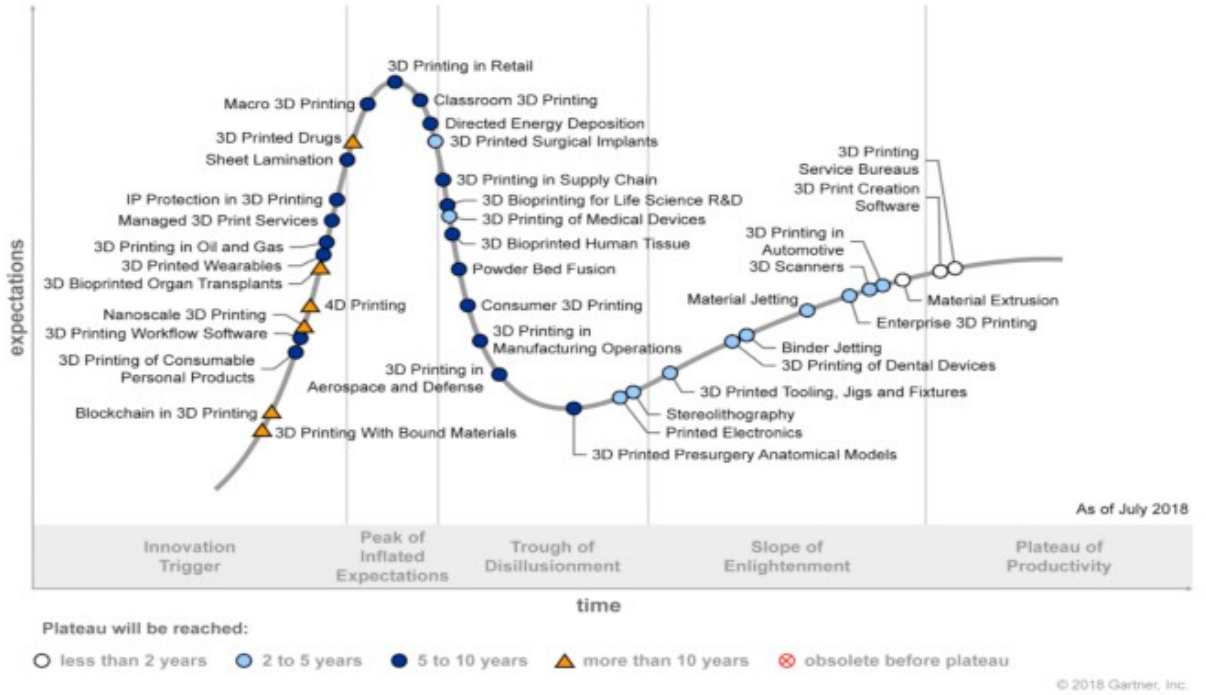
Not known so far.

2.2 Quantitative Indicators of the Business Environment

3D Printing (3DP) is a synonym often used for Additive Manufacturing (AM) and summarizes various technologies and ways of using them. The following chart provides the expectations for these in the very popular Gartner Hype cycle.

As can be seen, the enterprise 3DP, which mainly comprises AM equipment at OEMs or 1st tier, is seen as close to being productive. The examples mentioned earlier proof that it is, in certain cases, possible already today.

Figure 1. Gartner's Hype Cycle 2018



Source: Gartner 2018

In 2017, the additive manufacturing industry, consisting of all AM products and services worldwide, grew significantly to $ 7.3 billion (Source: Wohlers Report 2018).

Following Seidel and Schaetz (2019), forecasts from various organizations, such as McKinsey or Wohlers, are expecting further double digit CAGR for the years to come (Sources: Seidel, C., Schaetz, R.: *Continuing education and part-time training on Additive Manufacturing for people in employment – An approach focused on content-related and didactical excellence*. Pei, E., Verona,

M. M., Bernard, A.: *Additive Manufacturing – Developments in Training and Education*. Springer, 2019)

3 BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC

Standardization is essential for the use of AM in various applications such as in energy saving applications in aircraft engines or for medical applications healing injured people with medical implants manufactured by AM.

Standards will support the possibilities for certification and approval for medical applications (e.g. FDA) and aviation applications (e.g. AIA). Without standards, such certifications and approvals are very complicated if not impossible. The business case for all stakeholders is evident as standardization will continue to boost the application of this technology in various sectors.

Generally speaking, the aims of standardization are:

a) to promote the quality of products, processes and services by defining those features and characteristics that govern their ability to satisfy given needs i.e. their fitness for purpose;
b) to promote improvements in the quality of life, safety, health and protection of the environment;
c) to promote the economic use of materials, energy, and human resources in the production and exchange of goods;
d) to promote clear and unambiguous communication between all interested parties, in a form suitable for reference or quotation in legally binding documents;
e) to promote international trade by the removal of barriers caused by differences in national practices;
f) to promote industrial efficiency through variety control.

(Source: SASAM)

Benefits through standardization:

- systematic development, modification and use of of processes of joining materials from 3D model data (AM) resulting in innovative products;
- assistance to users within the assessment of different additive processes resulting in using the appropriate technology for the specified product demands;
- specification of quality parameters of different processes needed for standardized test procedures;
- specification of appropriate test procedures, thereby ensuring uniform interpretation and evaluation of quality parameters;
- standardization of process chains of AM techlogies securing functionality and compatibility;
- standardization of data formats, data structures and metrics for AM models;
- standardization of vocabulary required to define the product and to find a common speech.

4 REPRESENTATION AND PARTICIPATION IN THE ISO/TC

4.1 Countries/ISO member bodies that are P and O members of the ISO committee
4.2 Analysis of the participation

In the ISO/TC 261 committee there are currently 27 P-members and 8 O-members. Liaison committees to and from ISO/TC 261 are updated regularly and are available on ISO's website, see here.

5 OBJECTIVES OF THE ISO/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

Standardization in the field of Additive Manufacturing (AM) concerning their processes, terms and definitions, process chains (Hard- and Software), test procedures, quality parameters, supply agreements and all kind of fundamentals.

5.2 Identified strategies to achieve the ISO/TC's defined objectives

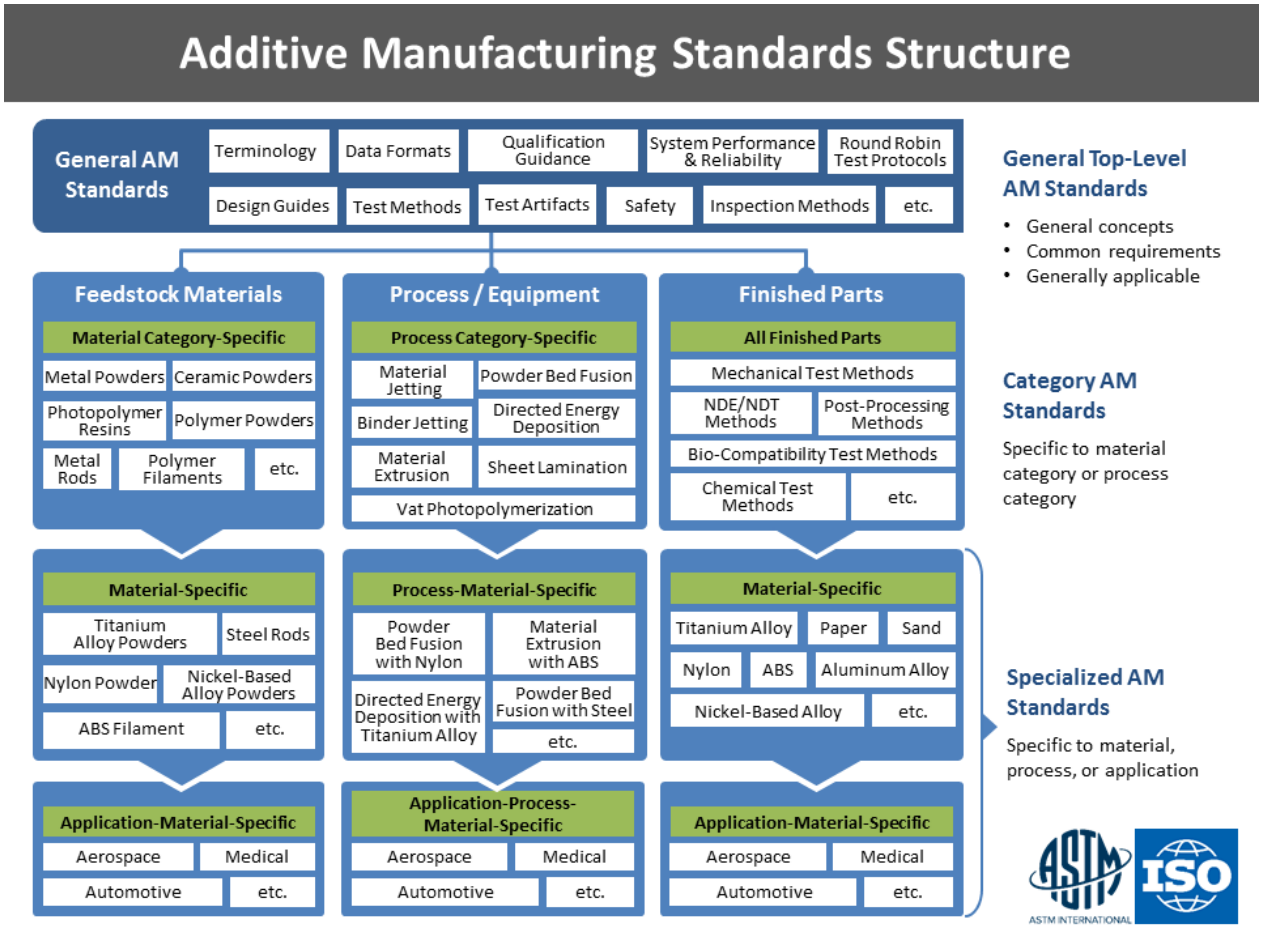
The following key strategies have been identified to achieve the defined objectives in 5.1:

- Use of national, regional or other standards as source documents on which to base International Standards
- Frequent physical and web meetings, use of correspondence and ISO's balloting portal in order to shorten the time of developing International Standards

A main part of the strategy is the close cooperation with ASTM F 42 according to the PSDO agreement with joint development resulting in of one set of AM standards In order to develop the common roadmap and organizational structure for AM standards, ISO/TC 261 and ASTM F42 agreed upon a common structure which defines multiple levels and a hierarchy of AM standards, with the following three levels:

- General standards: standards that specify general concepts, common requirements, or are generally applicable to most types of AM materials, processes, and applications
- Category standards: standards that specify requirements that are specific to a material category or process category
- Specialized standards: standards that specify requirements that are specific to a material, process, or application

The figure below illustrates the agreed-upon common structure of AM standards.



Several specific procedures are determined for how ISO/TC 261 and ASTM F42 will cooperate and work together in a practical sense, in accordance with the agreement between ISO and ASTM.

ISO/ASTM Joint Groups: A joint group (JG) of committed experts will be formed from both ISO/TC 261 and ASTM F42 for each joint standards development. The committed experts will be removed from the joint group if not contributing. For each joint standards development, there is an open option for both ISO/TC 261 and ASTM F42 to contribute. The joint group will ensure the visibility of its work to the corresponding internal working group (WG) structure of ISO/TC 261 and the corresponding internal subcommittee (SC) structure of ASTM F42 at least twice a year and upon request. The experts that form the joint groups will be identified and confirmed by the respective ISO and ASTM organizations. The convener of the joint group will be jointly agreed upon by ISO/TC 261 and ASTM F42. A key contact from the organization other than the convener will be nominated to improve communications among the joint group and between the organizations.

Meetings of ISO/ASTM Joint Groups: The guiding principle is that joint groups will have limited face-to-face meetings and will have increased and substantial use of web-based and/or tele-conference meetings and online collaboration tools to complete their work. The first (kick-off) meeting of a joint group is recommended to be held as a face-to-face meeting to introduce the participants. All joint groups have the opportunity to meet (optionally and as needed) during the annual fixed plenary meetings of ISO/TC 261 and ASTM F42.

Online Collaboration Tools: The ISO Livelink and ASTM Collaboration Area online collaboration tools are available for use by the joint groups. Joint groups are strongly encouraged to use these online collaboration tools, at the discretion of the convener of the joint group. Access to the collaboration area for each joint group will be limited to the committed experts of the joint group and others as necessary from the internal working groups of ISO/TC 261 or subcommittees of ASTM F42.

Standards Development: The leadership of ISO/TC 261 and ASTM F42 will review the progress of each joint group periodically, especially via its Working Group Convenors or Subcommittee Chairs. During the development period, the joint group experts are encouraged to interact with their respective organizations to communicate the status of the development and to ensure that requirements are incorporated.

Standards Review and Balloting: Following the release of a document by a joint group, the draft standard will be distributed for review by both organizations. A three-month review period for feedback and comment is required, with all comments provided back to the joint group for resolution. The revised standard will then be balloted concurrently (in parallel) by ISO and ASTM. ISO/TC 261 will conduct a Draft International Standard (DIS) ballot with a three-month balloting cycle. ASTM F42 will conduct a final balloting with a 30-days balloting cycle. During this balloting period, true editorial changes are allowed and any comments resulting from the ASTM balloting can be submitted into the ISO balloting process. Key contacts from each organization, likely technical experts from the joint group, must be identified to address any issues resulting from the balloting.

Formatting of Documents: The formatting of the joint standards documents should be the same and should adhere to the requirements specified in the formal agreement already established between ISO/TC 261 and ASTM F42. Both ISO/TC 261 and ASTM F42 agree to distribute their existing language usage and style guidance. For example, the word “shall” means required and the word “should” means optional, based on existing agreements.

Standards Projects: Both ISO/TC 261 and ASTM F42 shall have the option to continue and to finish their current standards activities that are already in process as of the start of this joint Additive Manufacturing Standards Development Plan. As such, both organizations will share their

lists of existing standards activities. All new ideas or new standards projects by either ISO/TC 261 or ASTM F42 shall be communicated to the other organization, with an invitation to participate through the joint development process. The invitation to participate shall include the title, abstract, and any other available information for the new standards project in a common new item proposal format. Any revision of a published standard shall be done by the joint development process.

A Joint Steering Group was established to review progress reports on the joint group activities provided by Working Group convenors or Subcommittee chairs, manage joint groups, resolve any problems, present proposals for joint activities to the respective plenary groups, and maintain a three-year plan for joint standards development, see Table 1.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC WORK PROGRAMME

As already mentioned in clause 2.1.6, more and more national and international organizations and federations are becoming aware of the rising importance of AM and are trying to start standardization initiatives themselves. Such competing initiatives would endanger the benefits of the standardization efforts described above. In order to avoid these competing initiatives their representatives are being contacted as soon as they have made themselves aware in the hope to channel these initiatives into the combined work of ISO and ASTM).

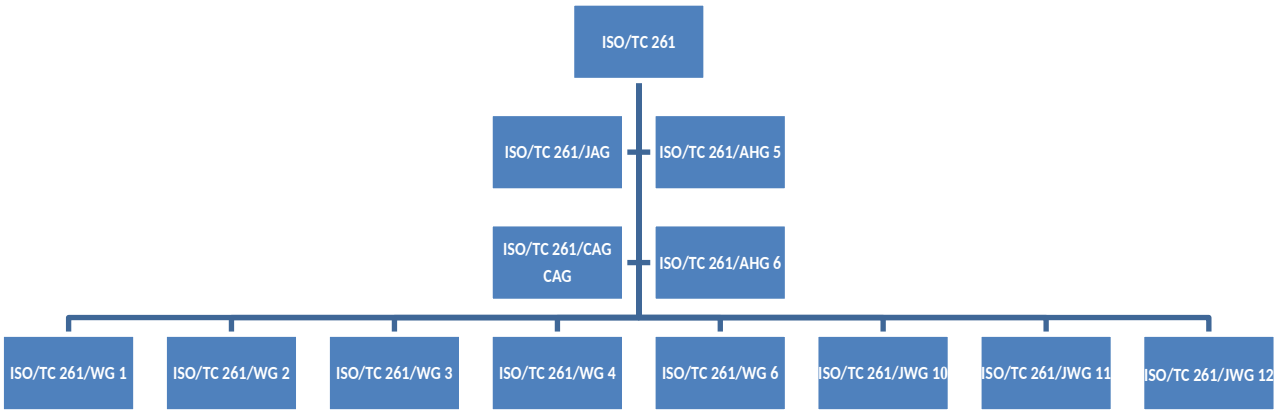
The more such initiatives insist on staying in existence, the greater are the demands on the resources to keep these initiatives in line and informed about the developments.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC 261

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 Structure of the ISO committee

The following Figure and Table show the working groups as established under the Technical Committee ISO/TC 261 "Additive manufacturing".



Key

ISO/TC 261/AHG 5	Content for ISO/TC 261 homepage
ISO/TC 261/AHG 6	Coordination of work between ISO/TC 261 and ISO/TC 184/SC 1 and ISO/TC 184/SC 4
ISO/TC 261/CAG	Chairman's advisory group
ISO/TC 261/JAG	ISO/TC 261 - ASTM F42 Steering group on JG activities
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 130 WG: Colour and translucency measurements

Figure 1 – Structure of ISO/TC 261 and its working groups

The tasks of the above groups are specified in Table 1.

Table 1 – Task of the working and steering groups

Working and Steering Groups	Task
ISO/TC 261 CAG	The CAG comprises a Chair and the WG/JWG/AHG convenors and appointed experts of ISO/TC 261.

	The Chairman's Advisory Committee (CAG) oversees the WG scopes,, reviewing the allocation ISO/ASTM JG to a given WG of ISO/TC 261, review the timelines of standards production; approval and maintenance of existing standards, if needed; reviewing the need for new standard projects; and maintenance of liaisons. The CAG • ensures objectives of ISO/TC 261 are correctly implemented and followed accordingly as mentioned in this strategic business plan. • suggests objectives for TC261 and reviews, if objectives are met, • advises, guides and coordinates joint ISO/ASTM work under the ISO/ASTM PSDO Agreement with the aim of ensuring consistency and efficient and timely development, • provides strategic guidance on specific areas of technical activity that require coordination both for new initiatives and ongoing work.
ISO/TC 261/ WG 1 to JWG 12	ISO/TC 261 has also installed working groups with the following tasks: a) Sufficient flow of information between ISO/TC 261 experts participating in the JG activities with ASTM F 42 on the work of the Joint Groups (JGs), b) Coordination of the work of the ISO/TC 261 experts in the JGs, c) Monitoring of progress, efficiency and effectiveness of the work of the JGs from ISO point of view, d) Developing proposals for further joint ISO/ASTM activities and possible JGs, e) ISO feedback to current questions/discussions in JGs, f) Continuous reporting of the JG activities, so that: • the main documents of the JGs (JG minutes, drafts etc.) will be distributed both in the respective JG and its corresponding working group, • necessary technical discussion while developing a draft in the JG will take place in the respective ISO WG, • appointed ISO experts for JGs are requested to to report on the JG activies, • the output of the JGs will be more familiar and acceptable to ISO/TC 261 when voting procedure starts according to PSDO agreement with ASTM. WG/JWG comprise a Convenor appointed by ISO/TC 261, technical experts appointed by the members of ISO/TC 261. The WG/JWG meet as deemed to be necessary.
ISO/TC 261/JAG	As explained in 5.2, in the cooperation with ASTM F 42 Joint Groups is used for the development of combined ISO/ASTM standards. The work of these Joint Groups is being monitored by a Joint Steering Group. The Joint Steering Group was established to review progress reports on the joint group activities provided by Working Group convenors or Subcommittee chairs, manage joint groups, resolve any problems, present proposals for joint activities to the respective plenary groups, and maintain a three-year plan for joint standards development. The ISO/ASTM Steering may also decide upon the provisional nomination of ISO experts to JGs (final nomination to be performed by ISO/TC 261). At a minimum, the Joint Steering Group will be composed of the ISO/TC 261 Chair and committee manager, ISO/CS Technical Program manager,

	the convenors and secretaries of Working Groups and Joint Working Groups, along with the ASTM F42 Chair, ASTM F 42 Staff manager, ASTM F42 membership secretary and Subcommittee Chairs. If a Joint Steering Group member cannot attend a meeting, a replacement may be nominated. The Joint Steering Group will conduct virtual meetings on a monthly basis. The group may also take the opportunity to meet face-to-face at meetings of ISO/TC 261 or ASTM F42.

It should be noted that ISO/TC 261 has formalized collaboration with ASTM International. The technical committee ISO/TC 261 has the objective of creating a framework of technical standards for allowing AM technology to become “the” industrial manufacturing alternative.

In order to avoid competing global standards between ISO and ASTM, a PSDO agreement between ISO/TMB and the Executive board of ASTM International (Oct 14, 2011, see document ISO/TC 261 N 24) was formed to manage the AM activities between ISO and ASTM which has evolved into the present system of collaboration and joint AM standards development through ISO/ASTM Joint Groups.

ISO/TC 261 and ASTM F 42 are collaborating closely in the development and maintenance of ISO/ASTM standards on AM, a good example is ISO/ASTM 52900 *Additive manufacturing — General principles — Fundamentals and vocabulary*. These two stamp standards are elaborated in the so called ISO/ASTM Joint Groups that are designated as ISO/TC 261/JG 51 to JG 79, see here. The ISO/ASTM joint groups are intended to be small and effective (ideally consisting of similar amounts of ASTM experts and ISO experts) and to work mainly by web-conference, possibly with a high frequency. The result of their work is then being given to ISO and ASTM for commenting, and in the next step for voting (DIS in case of ISO). The ISO/ASTM JGs are mirrored by the existing ISO/TC 261/WG 1 to JWG 12 which are open to all ISO members, see below Table.

Usually working drafts of the ISO/ASTM joint groups are available in ISO/TC 261/WG 1 to JWG 12; they have the task of the technical discussion and commenting of the ISO/ASTM JG activities from the ISO side – the ISO experts in the ISO/ASTM JG are accountable in their work to ISO/TC 261/WG 1 to JWG 12.

Table 2 – Mirroring of ISO/ASTM Joint Groups within ISO/TC 261

	WG 1	**WG 2**	**WG 3**	**WG 4**	**WG 6**	**JWG 10**	**JWG 11**	**JWG 12**
Mirroring of ISO/ASTM Joint Groups (JG)	JG 51	JG 55[1] JG 56 JG 66[1] JG 71 JG 72[1] JG 75 JG 79 JG 80 JG 81	JG 52 JG 58 JG 59 JG 61 JG 62 JG 63 JG 76 JG 77	JG 54 JG 57 JG 64 JG 67[1] JG 70 JG 73	JG 68 JG 69 JG 78	JG 74		

1 dormant

		JG 82						

7.2 Current projects of the ISO technical committee and its subcommittees

This information is updated regularly and is available on ISO's website, ISO Online, see here.

7.3 Publications of the ISO technical committee and its subcommittees

This information is updated regularly and is available on ISO's website, ISO Online, see here.

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work