NSAI

Irish National Mirror Committee
NSAI/TC 49/SC 02
Additive Manufacturing

Introduction to NSAI/TC 49/SC 2 & standardization for Additive Manufacturing

Version 2

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FOREWORD

This document is informative in nature and provides an overview of Additive Manufacturing (AM) from a standards perspective, following the structure of the International Organization for Standardization Technical Committee ISO/TC 261 and the joint standardization between ISO and ASTM in Joint Groups (JGs).

It starts by summarizing what Additive Manufacturing is, followed by an overview on how it can support the Green Economy in manufacturing sector in Ireland as well as highlighting the potential benefits for both Climate Action and for the industry.

Knowing about standards and standardization is essential for any manufacturers in Ireland as it enables them to adopt emerging technologies and keep their competitive advantage. Key information, insights into standards and the standardization process is then provided, focusing on the standards development process for ISO.

Linking findings from the Organization for Economic Co-operation and Development (OECD) on the importance of engaging in standards development for SMEs, the report stresses on the importance of standards by emphasizing on the connections and benefits achievable through standards, that can positively affect innovation.

The structure of our National Mirror committee is then detailed, linking the standardization work at an International level to the National level, before exploring the current International standardization framework and current activities within each working group (WG) and Joint group (JG) of ISO/TC 261 & ASTM F42.

In order to showcase the importance of standards for innovation a case study is employed, whereby the use of standards in the collaboration between the Irish Manufacturing Research and the Atlantic Prosthetic and Orthotic Services is outlined. Standards enabled the development of a digital workflow for Computer Aided Design (CAD) and Additive Manufacture (AM) for the identification of transtibial (through the shin) prosthetic sockets from scanned patient data. The output of the project was a state-of-the-art ceramic reinforced polymer or thermoplastic formed over a modified casting taken from the patient's limb, which was aided in its development by the utilization of existing and emerging standards by an expert from NSAI's National Mirror Committee.

EXECUTIVE SUMMMARY

The consensus-achieving standardization process is a powerful force for good in the world. This is being achieved through expert involvement in the International Organization for Standardization ISO, who are producing standards to aid in the adoption of Additive Manufacturing, an emerging technology set to revolutionize the Manufacturing Industry.

The benefits of Additive Manufacturing were recognised by the European Commission in its new Industrial Strategy (launched on the 10th March 2020 (COM (2020) 102 Final)) which is aimed at achieving a globally competitive, green and digital Europe. The Strategy makes reference to disruptive technologies such as Additive Manufacturing and the need for Europe to make the most of localisation, bringing more manufacturing back to the EU in a variety of sectors.

At a National Level, Ireland's industry 4.0 Strategy 2020-2025 was launched in December 2019 by the Department of Enterprise, Trade and Employment as an output from Future Jobs Ireland 2019. This was published in response to the new digital technologies that have already begun to transform global manufacturing value chains, supply chains and business models, redefining sources of competitive advantage for both firms and national economies. Additive Manufacturing was recognised as a technology underpinning digitalisation in Ireland's manufacturing sector. The National Strategy emphasises the importance of standards in its goal to establish a world class business environment for Industry 4.0 which is supported by an appropriate regulatory, legal, standards and internationally connected ecosystem.

This document is aimed at assisting companies to embrace Additive Manufacturing as part of their Industry 4.0 transformation. Standards and standardization are powerful tools that can enable the adoption of this technology. Other key information on Additive Manufacturing is provided, insights into standards and the standardization process are showcased, along with a demonstration of the importance of standards for innovation through a case study.

Enda McDonnell
Director of Standards & Metrology

INTRODUCTION

What is Additive Manufacturing & 3D Printing

The process of joining materials to make objects from 3D model data, usually layer-by-layer, as opposed to subtractive manufacturing, which is a process by which 3D objects are constructed by successively cutting material away from a solid block of material used in current manufacturing process such as milling, turning, laser cutting, wire EDM, and carving. Some of the key benefits of additive manufacturing are: [1]

- **Design complexity:** design changes that would often take months using conventional manufacturing methods can be implemented much faster. 3D printing is a cost-effective technology for producing parts with complex geometries. Designs that would otherwise be impossible to produce with conventional manufacturing can now be produced with 3D printing;
- **Shorter lead times:** as 3D printing requires no tooling, manufactures can reduce the time needed to produce parts, bypassing the time consuming and costly tooling production step;
- **On-demand production:** since 3D printing can produce physical parts from digital files in a matter of hours, companies can leverage a new model of manufacturing parts on demand;
- **Mass customization:** no tooling constraints means that products can be built to an individual's specification e.g. Invisalign take scan of consumers mouths and produce braces tailored for individuals using 3D Systems SLA printers; and
- **Light weight:** the ability to print internal strengthening structures allows the maximum strength to weight ratio e.g. the arm for monitors on virgin planes.

Additive Manufacturing is one of the important pillars of Industry 4.0 which automates production process with smart direct digital manufacturing technique. AM has reduced prototyping time or batch production time up to 90% than conventional manufacturing technique. Because of various benefits of additive manufacturing, it has found its applications in all fields ranging from jewelry, automotive, medical, aerospace, manufacturing, tooling, oil & gas, spare parts, chemical and food processing, pharmaceutical, creative part production, and so on the possibilities are endless.[2]

[1] https://amfg.ai/industrial-applications-of-3d-printing-the-ultimate-guide/

[2] https://3dincredible.com/how-is-additive-manufacturing-transforming-markets-2/

ADDITIVE MANUFACTURING SUPPORTING THE GREEN ECONOMY

Launched in 2013 and completed June 2017, AMAZE – short for Additive Manufacturing Aiming Towards Zero Waste and Efficient Production of High-Tech Metal Products – was the largest R&D programme for 3D printing ever run. The European Space Agency helped to initiate the programme, which was funded by the European Commission's Seventh Framework Programme and coordinated by the UK's Manufacturing Technology Centre (MTC).[3]

It was a collaborative project between 26 partners in the field of Additive Manufacturing (AM), including some manufactures such as Airbus and Thales Alenia Space that are involved in assessing prototype products for space use, while comparable end-users did the same for the automotive, aeronautics and nuclear fusion sectors. The project had the ambition to make the best quality metallurgical products ever made by using layer-upon-layer melt deposition of advanced alloys for the Aerospace, Space, Energy and Automotive sectors.

Using traditional manufacturing processes to machine complex parts, for example from forging, can result in as little as 10 % of the original material being used in the final part. Additive Manufacturing (AM) processing, whereby parts are 'grown' to the final shape required, is much more efficient.

Additive manufacturing (often referred to as 3D printing) was first introduced for the production of rapid prototypes almost 30 years ago. Unlike subtractive processes such as machining, where material is removed from a block to produce the required shape, or forming, where material is shaped in a mould, in additive manufacture parts are formed by the precise sequential deposition of layers of material.

The EU-funded AMAZE project was set up precisely to exploit this approach. The project was able to save manufacturing costs by as much as 50 %, reduce material waste to negligible amounts and half the floor space required, by combining two processes into one machine (combined additive and machining for a gas turbine part repair). Additionally, improved AM materials have been developed which, through their higher performance, cater for more demanding applications, for instance high 1 of 5 temperature refractory materials which had never been processed by AM before and are very difficult to process using conventional manufacturing methods.

The AMAZE project was able to dramatically increase the productivity of the AM processes, in some cases by as much as ten-fold in build rate. It did so by employing a range of techniques, such as using higher power/multiple processing lasers and novel build strategies whereby only the surface of a part is formed in the AM machine, with the remaining material fused in a (Hot Isostatic Pressing) HIP furnace.

Although Additive manufacturing is still seen as a promising manufacturing method for some application and is not yet accepted as a mainstream manufacturing process by the Space, Aerospace, Automotive or Energy sectors. A key objective of the project has been to tackle current issues to drive it from Technology Readiness Level (TRL) 4-5 to 7-8 by giving confidence through demonstrator components to key players in the European Space, Aerospace and Automotive sectors.

[3] https://www.esa.int/

The AMAZE project has successfully achieved its key aim of "Building Confidence in Additive Manufacturing" as clearly demonstrated by the top 4 key highlights:

1. Norsk Titanium through development of their Rapid Plasma Deposition (RPD) technology have increased process robustness, consistency and machine throughput. Leading to delivery of the world's first FAA-Approved, 3D-Printed Structural Titanium component for Boeing.
2. Over the course of the project Thales Alenia Space have gained knowledge and confidence in the metal AM processes to enable them to successfully deploy metal AM components (sun sensor brackets) on satellites which are now in orbit.
3. Generation of the World's most comprehensive metal AM database covering every aspect of metal AM from design, feed-stock quality, AM process parameters, post processing and inspection to provide an unparalleled resource for both research and exploitation of AM.
4. Four European AM factories at Irepa laser (France), Norsk Titanium (Norway), Avio Aero (Italy) and the MTC (UK) provide a unique network of industry credible pilot-lines covering all of the major direct fusion metal AM processes.[4]

Additive Manufacturing shows great potential in reducing the need for energy- and resource-intensive manufacturing processes, which in turn reduces the amount of material required in the supply chain, and enables more environmentally benign practices, they are also further benefits for the environment and the manufacturing as outlined below:[5]

- ✓ Industrial quality printers are now somewhat affordable for SME's and so are the common materials.
- ✓ You'll save on material waste and energy
- ✓ Prototyping costs much less
- ✓ Small production runs often prove faster and less expensive
- ✓ You don't need as much on hand inventory
- ✓ Its easier to recreate and optimize legacy parts
- ✓ You can improve part reliability
- ✓ You can consolidate as assembly into a single part
- ✓ It Uniquely supports new AI driven design methods

Additive manufacturing is inherently a means of production that could improve the sustainability of industries around the world. The very idea of producing by adding only the material needed, instead of removing material in excess, without the need of producing tools could be a game-changer for the global environment. If fewer materials are needed, less are wasted. Producing parts when they are needed, and where they are needed can go a long way reducing overall emissions from industrial production[6].

[4] https://cordis.europa.eu/project/id/313781/reporting
[5] https://www.ptc.com/en/blogs/cad/10-additive-manufacturing-advantages
[6] www.3dprintingmedia.network

HOW STANDARDIZATION IN ADDITIVE MANUFACTURING IS TRANSFORMING INDUSTRY

At DePuy Synthes, we have a vision to Keep People Moving and a rich history consisting of innovation, working with industry leaders, and making a difference in the lives of many patients around the world. To continue this journey we are proud to be part of the team of technical experts whom develop and apply Additive Manufacturing standards that are being co-created by ISO/TC 261 & ASTM F42. ISO/TC 261 and ASTM F42 are collaborating closely in the development and maintenance of standards on Additive Manufacturing (AM). No matter where you are in your AM journey the applications of standards can be a great benefit, for example if you are starting out "ASTM WK73227 - New Guide for Additive Manufacturing -- Investigation for Additive Manufacturing (AM) Facility Safety Management" can help you to create a safe working facility and environment, and then as you move into qualifications then "ISO/ASTM DIS 52920 - Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing sites" will help you design and set-up quality -assured processes.

TRUMATCH CMF
Titanium 3D Printed Plates

KEY IMPACT: Utilizing standards helps advance patient care while delivering clinical and economic value to health care systems worldwide both today and tomorrow.

Eddie Kavanagh,
Senior Principal Engineer,
DePuy Synthes

WHAT IS A STANDARD?

A Standard is a document for voluntary application that has been established by consensus between all interested parties and approved by a recognized body. It is meant for common and repeatable use. It provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

Standards may include requirements and/or recommendations in relation to products, systems, processes or services. Standards can also be used to describe a measurement or test method or to establish a common terminology within a specific sector.

Are Standards Mandatory?

Standards, unlike legislation, are voluntary in application unless called up in legislation. Where a Standard is referenced in as part of a commercial contract it becomes mandatory under the contract agreement.

Legislation can refer to a Standard as means of compliance with regulatory requirements. This means that compliance with the Standard is recognized as a possible way of fulfilling regulatory obligations. Other ways to comply with these obligations may be chosen, but those using the Standard have the presumption of being in conformity with legal requirements (presumption of conformity).

TYPES OF STANDARDS DOCUMENTS

The documents produced by Technical Committees are International (ISO) and European Standards (EN),Technical Specifications (TS), Technical Reports (TR), CEN Workshop Agreements (CWA) and Publicly Available Specifications (PAS)

ISO Standards are not automatically adopted as national Standards. All published European Standards documents are required to be adopted by each National Standards Body (NSB) as National Standards. In Ireland all published European Standards documents are all Irish Standards. European Standards can only be purchased from National Standards Bodies or approved distributers.

Where there is a justified national need and where an International (ISO) or European Standard (EN)does not exist a national Standard can be produced. Irish Standards are produced in a similar process toa European Standard by NSAI Standards Consultative Committees.

Standards generally contain quality, safety and/or performance requirements.

International Standards (ISO) are published in English and French and at time in Russian. European Standards are required to be made available in the 3 official languages (English, French and German) but can be translated into other languages.

European Standards can, where required, support EU legislation. National measures can also be incorporated where required under special national conditions.

Technical Specifications

A Technical Specification is a document for which there is the future possibility of agreement on a Standard, but for which at present:

— the required support for approval as a Standard cannot be obtained;

— there is doubt on whether consensus has been achieved;

— the subject matter is still under technical development; or

— there is another reason precluding immediate publication as a Standard.

A Technical Specification is not allowed to conflict with an existing International Standard.

Technical Report

A Technical Report (TR) is a document containing informative material not suitable to be published as a Standard or a Technical Specification (TS). A TR can include, for example, data obtained from a survey carried out among the national members, data on work in other organizations or data on the state of the art in relation to national Standards on a particular subject.

CEN Workshop Agreements (CWA)

A CEN Workshop Agreement (CWA) is a document published by CEN in at least one of the CEN three official languages.

A CWA is an agreement developed and approved in a CEN Workshop; the latter is open to the direct participation of anyone with an interest in the development of the agreement. There is no geographical limit on participation; hence, participants may be from outside Europe. The development of a CWA is fast and flexible, on average between 10-12 months.

A CWA does not have the status of a European Standard. It involves no obligation at national level. A CWA may not conflict with a European Standard; if a conflicting EN is subsequently published, the CWA shall be withdrawn.

Publicly Available Specifications

A Publicly Available Specification (PAS) is published to respond to an urgent market need, representing either the consensus of the experts within a working group, or a consensus in an organization external to ISO. As with Technical Specifications, Publicly Available Specifications are published for immediate use and also serve as a means to obtain feedback for an eventual transformation into an International Standard. Publicly Available Specifications have a maximum life of six years, after which they can be transformed into an International Standard or withdrawn.

STANDARDS & THE STANDARDIZATION PROCESS

Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent. Standards are created by bringing together all interested parties such as manufacturers, consumers and regulators of a particular material, product, process or service. All parties benefit from standardization through increased product safety and quality as well as lower transaction costs and prices.

Standardization is the process through which requirements and recommendations for products, processes and services are developed by experts and agreed upon through a consensus-based mechanism.

Standards are developed at National, European and International level through designated bodies of which NSAI, as the national standards body for Ireland, is the Irish member body of CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) in Europe and internationally at ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

NSAI is also a member of the ETSI (European Telecommunications standards Institute), which employs a different membership participation model.

CEN, CENELEC and ETSI are the three European Standardization Organizations (ESO) that have been officially recognized by the European Union and by the European Free Trade Association (EFTA) as being responsible for developing and defining voluntary standards at European level.

CEN, CENELEC, ETSI are the regional mirror bodies to their international counterparts, i.e. ISO (the International Organization for Standardization), IEC (the International Electrotechnical Commission) and ITU-T (the International Telecommunication Union, telecommunication standardization sector) respectively.

In the European Union, only standards developed by CEN, CENELEC and ETSI are recognised as 'European Standards'.

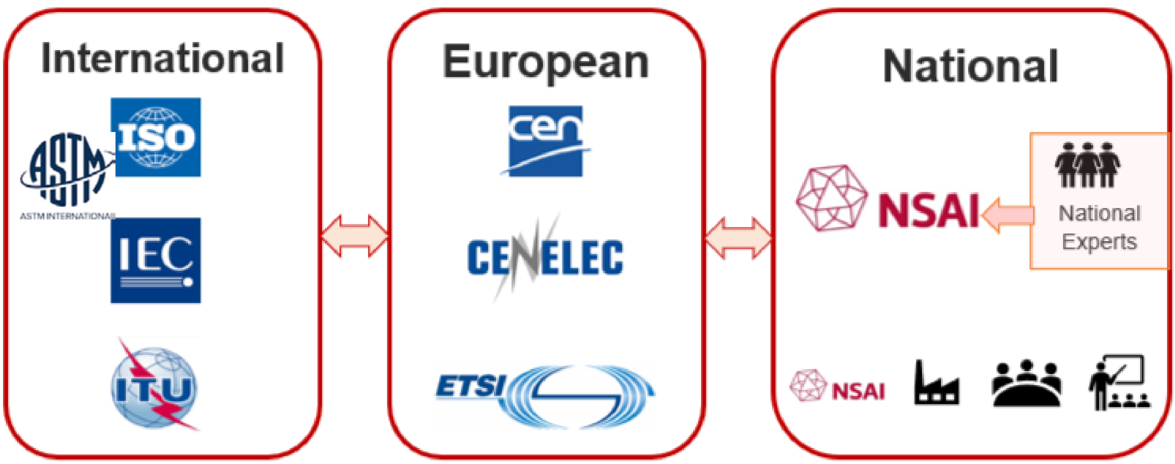

Figure 1: NSAI's Relationship to European and International Standards Organisations

Through its national committee structure NSAI facilitates Irish based experts and stakeholders to participate in standardization at all levels. Currently NSAI has experts engaged in standardization work at European and International level as contributing experts, as members of Irish delegations and in leadership roles as chairs of committees and working groups and as project leaders.

ISO - International Organization for Standardization

ISO, the International Organization for Standardization develops and publishes International Standards. ISO is an independent, non-governmental organization made up of members from the national standards bodies of 165 countries. There is only one member per country. Each member represents ISO in its country and counts for one vote in ISO standardization process. ISO is governed by its council and produces standards through Technical Board and committees.

ASTM - American Society for Testing and Materials

ASTM American Society for Testing and Materials, now known as ASTM International, is an American standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.

Membership in the organization is open to anyone with an interest in its activities. Standards are developed within committees, and new committees are formed as needed, upon request of interested members. Membership in most committees is voluntary and is initiated by the member's own request, not by appointment nor by invitation.

In order to meet the requirements of antitrust laws, producers must constitute less than 50% of every committee or subcommittee, and votes are limited to one per producer company. Because of these restrictions, there can be a substantial waiting-list of producers seeking organizational memberships on the more popular committees. Members can, however, participate without a formal vote and their input will be fully considered.

IEC - International Electrotechnical Commission

The IEC is a global, not-for-profit membership organization, which publishes standards in electrical and electronic (collectively as “electrotechnology”) goods. The IEC brings together more than 170 countries and provides a global, neutral and independent standardization platform to 20,000 experts globally. It administers 4 Conformity assessment systems whose members certify that devices, systems, installations, services and people work as required.

Upon admission, every IEC Member – one National Committee per country - promises to fully represent all private and public national interests in the field of electrotechnology at the global level in IEC standardization and conformity assessment activities. The IEC publishes around 10 000 IEC International Standards which together with conformity assessment provide the technical framework.

ITU - International Telecommunications Union

ITU facilitates international connectivity in communications networks, allocates global radio spectrum and satellite orbits, develops the technical standards that ensure networks and technologies seamlessly interconnect, and strive to improve access to ICT.ITU's global membership includes 193 Member States as well as some 900 companies, universities, and international and regional organizations. ITU has three main areas of activity organized in 'Sectors' namely Radiocommunication, Standardization and Development. The Study Groups of ITU's Telecommunication Standardization Sector (ITU-T) assemble experts from around the world to develop international standards known as ITU-T Recommendations.

CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) bring together the national standards agencies of 34 countries. Their network involves business federations, commercial and consumer organizations, environmental groups and other societal stakeholders. More than 60,000 technical experts from industry, research, academia and other backgrounds are directly involved in the work.

Their National Members work together to develop European Standards and other deliverables in a large number of sectors to help build the European internal market in goods and services, removing barriers to trade and strengthening Europe's position in the

global economy. They also work closely with the European Commission to ensure that standards correspond with any relevant EU legislation.

A European Standard (EN) automatically becomes a national standard and therefore is included in the standards catalogue of CEN and CENELEC's Members (the National Standardization Organizations in 34 countries).

European commission can ask one of its ESOs to develop a European standard to comply with a legal provision; such a standard is called harmonized standard and gives manufacturers and other operators with presumption of legislative conformity. Their use is optional.

ETSI European Telecommunications Standards Institute

European Telecommunications Standards Institute (ETSI) is an European Standards Organization (ESO). They are the recognised regional standards body dealing with telecommunications, broadcasting and other electronic communications networks and services. They have a special role in Europe which includes supporting European regulations and legislation through the creation of harmonised European standards. Only the standards developed by the three ESOs (CEN, CENELEC and ETSI) are recognized as European standards (ENs).

NSAI is also a member of the ETSI, which employs a different membership participation model to which NSAI does not facilitate memberships. ETSI has Industrial Specification groups (ISG) as well as Technical Committees carrying out standardization work.

STANDARDS DEVELOPEMENT PROCESS FOR ISO

The below describes the main stages involved in drafting an ISO standard, for a full list of ISO stage codes please see the Link.

Proposal of Work Item – Stage 00.60

Having been assigned a Work Item number, the TC requests the WG to commence work on the Standard. This work can include the drafting of a new Standard, Technical Specification or Technical Report, revision of an existing document or amendment of an existing document. There is no time limit set at this stage and the WI is considered to be waiting and inactive. The WG works on preparing an initial draft. This stage is usually the most labour-intensive stage for the WG. Once the draft is ready the WG Convenor submits it to the TC Secretary.

In the ISO system the draft document is circulated as an ISO/NP draft

Adoption of Work Item – Stage 10.99

Using the draft as a reference document the TC Secretary issues another Committee Internal Ballot (CIB) to the NSB's. Each of the National Standards Bodies is given the opportunity to vote. At a national level NSAI will request the National Mirror Committee to vote on the adoption of the Work Item. The TC Secretary then issues a Decision based on the result of the vote for the adoption of the Work Item. On adoption of the Work Item it is then activated and time milestones set out. The TC is responsible for meeting the milestone dates set out. The process takes approximately 3 years from this point.

Circulation of 1st WD – Stage 20.60

In CEN, the WG is given 4 months to issue a 1st Working Draft. Other Standards Organizations differ. The WG Convenor submits the 1st WD to the TC Secretary. The TC Secretary submits this document to CEN management and circulates it to the TC members. The National Mirror Committees often submit comments on the draft at this stage.

Submission of Enquiry draft – Stage 30.99

The WG has a further 4 months to submit the fully revised draft to the TC Secretary.

The TC secretary submits the draft document to ISO/CEN management. The document is then sent for translation into French and German. For new Standards, this is the point at which the document is given a Standard number. When the document is ready, it is then submitted for public comment.

Within ISO, the draft Committee Draft is often circulated as an ISO/CD for voting and upgraded to a Draft International Standard, ISO/DIS.

Enquiry opens – Stage 40.20

ISO/CEN makes the draft Standard publicly available, through the NSBs, for review and comment. The ISO enquiry document will be numbered with the prefix ISO/DIS 12345 and the CEN enquiry document will be numbered with the prefix prEN 12345. All members are alerted that the document is available. The draft can be accessed from the National Mirror Committee Livelink and through NSAI Your Standards, Your Say (YSYS). The public is invited to review the draft document and make technical, general and editorial comments. This stage lasts 3 months. Comments are submitted using the Commenting Template.

Enquiry closes – Stage 40.60

When the voting is closed a Report on Voting is issued by the TC. All the national comments are collated by CEN/ISO into a comments book. The comments book is then sent to the TC Secretary and the Working Group. Each of the comments is addressed and the draft is changed as is decided by the WG experts. For Standards of interest with active WG members, it is important for the WG experts to attend to ensure that their comments are addressed fully by the WG.

When the comments book has been completely addressed and the draft document is ready, the WG submits both documents to the TC secretary. Input by the WG finishes here. The document is then edited by the TC editing committee made up of the WG Convenor and English, French and German speaking experts from the TC.

The TC secretary then submits the draft document as a Formal Vote draft to the TC members. The national mirror committee members then vote to send the document to Formal Vote. As part of the new ISO and CEN rules the TC Chairman and Secretary can now make the decision without requiring a vote from the members. This stage takes up to 8 months.

A new process within ISO and CEN allows for Standards that have not received many technical comments and passed the enquiry stage, 4.6, with positive votes to skip the Formal Vote process and go directly to publication.

Submission of FV draft – Stage 45.99

Having been edited and agreed for Formal Vote the TC secretary submits the draft document to the
ISO/CEN management. The document is then edited and sent for translation.

Within CEN the document is generally translated into French and German.

Within ISO the document is generally translated into French and Russian.

Formal Vote opens – Stage 50.20

The Formal Vote draft reflects the proposed version of the Standard that will be published. This is the final opportunity to review and vote on the Standard.

The draft Standard is issued only to the members of CEN and ISO for review. Only editorial comments are considered at this stage. Members are asked to vote to approve the Standard for publication. This stage lasts 2 months. The ISO Formal Vote document will be numbered with the prefix ISO/FDIS 12345 and the CEN Formal Vote document will be numbered with the prefix FprEN 12345. Comments are submitted using the Commenting Template.

Where a European Standard (EN) is harmonized to a European New Approach Directive, a New Approach Consultant will review the draft document and approve the document to go ahead. Specific information on harmonized Standards.

Formal Vote closes – Stage 50.60

All votes and comments are gathered, and the result of voting issued.

Document ratification – Stage 60.55

The ISO/CEN Management process the comments received during the Formal Vote and make the editorial changes as required. The TC Secretary is allowed to address the comments and review the final draft before the document is published.

Definitive text available – Stage 60.60

CEN management publish the new Standard in 3 languages, English, French and German.

European Standards (EN) are made available to the National Standards Bodies (NSB) to publish as national Standards.

ISO Standards are published by ISO and are not automatically adopted as Irish Standards (I.S. ISO 12345)

Systematic review – Stage 90

5 years after publication of the Standard an automatic Systematic Review eBallot is circulated through Livelink. The TC members are requested to review the Standard and vote whether to confirm the Standard for another 5 years or revise the Standard or withdraw the Standard. This is done through the Livelink eBalloting system.

STANDARDIZATION + INNOVATION FOR IMPACT

For countries, organizations and individuals involved in research, innovation and enterprise development across industry, academia and government, there are many benefits of engaging in international standards development for new and emerging technology areas, including Industry4.0. Standards help build customer trust and confidence in new technologies, thereby enabling the accelerated mass-market diffusion and adoption of related products and services. In effect, standards help bridge the innovation gap between research and global markets by enabling efficient and effective knowledge and technology transfer, resulting in maximum socio-economic and environmental benefits and impact. The EU Commission stated the following in relation to standardization[7]:

'The development and implementation of research and innovation agendas including through standardization is essential for EU competitiveness. Horizon 2020 will give strong support to the market uptake of innovation, in particular to supporting standardization through research and putting science into standards. Standardization activities are an essential channel for the market adoption of research results and for the diffusion of innovation'.

At a national policy level, Innovation 2020 and Enterprise 2025 emphasise the importance of standards as a source of competitive advantage to help Ireland fulfil its ambition to become a 'Global Innovation Leader', and state that 'Irish-based enterprises must embed standards in their research, development and testing processes'. In their recent extensive report on SME productivity and entrepreneurship in Ireland, the Organization for Economic Co-operation and Development (OECD)[8] emphasised the importance of engaging in standards development and use. OECD highlights that 'compliance with standards is underplayed as a lever to support SMEs to upgrade their management practices'. The report also recommends that Ireland "Increase policy attention to the role that adopting and developing international standards can play in enhancing SME productivity". It also states that Ireland should "Increase support for international standards adhesion by SMEs as an additional lever for encouraging upgrading to international best practice business management approaches".

[7] The annual Union work programme for European standardisation for 2017. COM/2016/0357 final

[8] OECD report, 'SME and Entrepreneurship Policy in Ireland', launched 31st Oct 2019

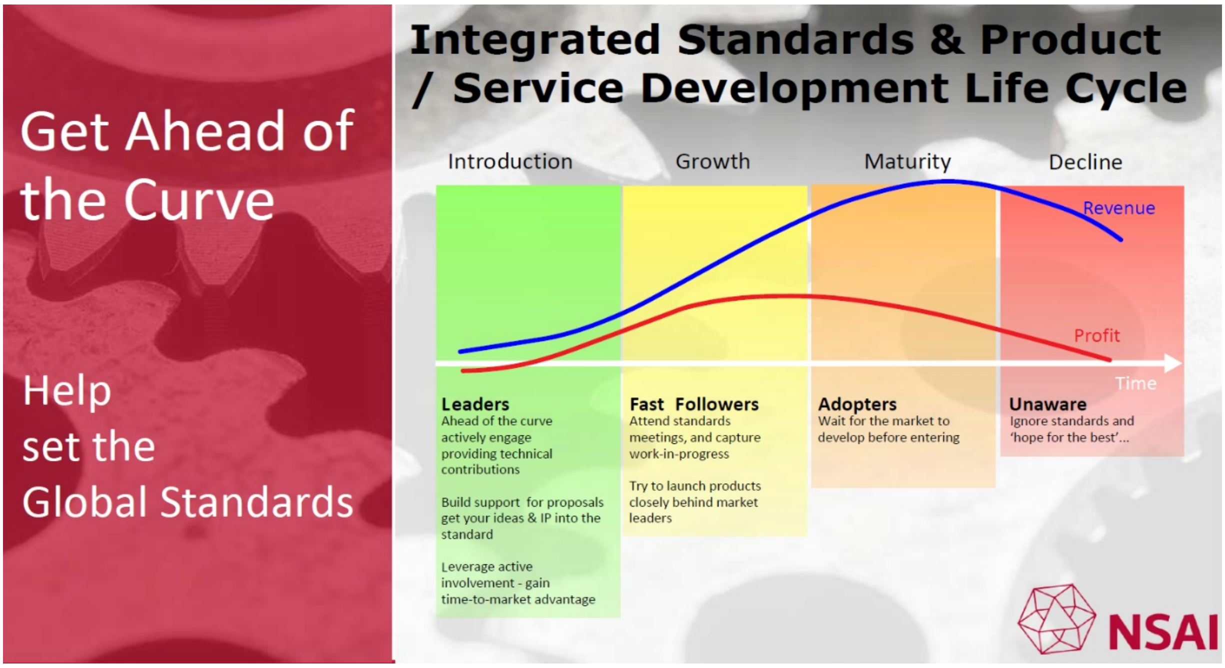

Figure 2: Getting ahead of the curve by early and active engagement in international standards development

Figure 3 above illustrates the Technology Adoption Life Cycle, including the different levels of potential engagement by stakeholders in standards development to either lead, follow, adopt (or ignore) new standards development in support of the latest technologies, innovations and trends. The earlier a company or RDI center engages in the standards development process – integrated within their overall innovation process as illustrated – the sooner they can bring their standards-informed innovation to competitive global markets, resulting in greater rewards. Hence the 'leaders' and 'fast-followers' get ahead of the curve by leveraging their early and active involvement in setting new standards. During the standards development process, they gain new technical insights and time-to-market advantage over their competitors and have the opportunity to add their own unique product or service innovations on top of the foundational standard that they helped set. Hence standardization leaders and fast-followers are fully prepared to successfully launch their standards-aligned products and services across international markets ahead of their competitors.

As illustrated in the Innovation process figure, the sooner the standards-informed innovation can be brought to competitive global markets, the greater the rewards. Hence the 'leaders' and 'fast-followers' get ahead of the curve by leveraging their early and active involvement in setting new standards. During the standards development process, new technical insights are gained and time-to-market advantage over competitors and have the opportunity to add their own unique product or service innovations on top of the foundational standard that were helped set. Hence standardization leaders and fast-followers are fully prepared to successfully launch their standards-aligned products and services across international markets ahead of their competitors.

Standards + Innovation awards 2020

In 2019, CEN and CENELEC launched the "Standards + Innovation Awards" to acknowledge the important contribution of research and innovation to standardization and celebrating the contributions of researchers, innovators and entrepreneurs to standardization.

In 2020 the founder and CEO at Origin Chain Networks (OCN) Fiona Delaney picked up a prestigious award at the European Committee for Standardization's (CEN and CENELEC) "Standards + Innovation Awards".

Ms. Delaney, who was nominated by the National Standards Authority of Ireland (NSAI), was awarded the accolade for her involvement in standardization in the field of interoperable blockchain infrastructure. Ms. Delaney and OCN submitted a unique agri-food application of blockchain called Universal Farm Compliance to the 'Blockchain and distributed ledger technologies' standards committee.

The use case describes a blockchain-enabled platform available to farmers and agri-compliance bodies, facilitating rapid and near real-time data-sharing. Universal Farm Compliance helps farmers and the entire agri-food ecosystem to implement a safer, more transparent food supply chain, and advances digital transformation in the agri-food industry.

Digital Innovation Hubs (DIHs) in Europe

The European Commission is investing in Digital Innovation Hubs as means to support businesses in their digital transformation and is promoting cooperation among them.

Digital Innovation Hubs (DIHs) can help ensure that every company, small or large, high-tech or not, can take advantage of digital opportunities. DIHs are one-stop shops that help companies become more competitive with regards to their business/production processes, products or services using digital technologies. DIHs provide access to technical expertise and experimentation, so that companies can "test before invest". They also provide innovation services, such as financing advice, training and skills development that are needed for a successful digital transformation. See Link for list of Ireland's DIHs.

Research Centres in Ireland

Research centres in Ireland help in fusing new technologies into the production process to improve manufacturing performance via automation, data analytics, 3D printing and Robotics. These partnerships between Fellows, Postdocs, PhDs, Masters, & PDRAs and industry can:

- Offer expertise and experience in Academic and Industrial settings;
- Help to address crucial research questions;
- Promote the development of new and existing companies to create innovative products; and
- Encourage early adoption of emerging technologies.

Research Centres work collaboratively with industry to drive business readiness for Industry 4.0. There have been many successful case studies showing how these research centres have identified new pathways using emerging technologies to save both time and cost while also expanding production.

For the full list of Ireland's Research Centres see the Knowledge Transfer Ireland website.

INTRODUCTION TO IRELAND'S NATIONAL MIRROR COMMITTEE

NSAI/TC 49/SC 02 is the Irish National Mirror Committee (NMC) following standardization in additive manufacturing. NSAI Technical Committee 49 is the parent standards committee for Advanced Manufacturing. Subcommittee 2 is the standards committee following standardization for Additive Manufacturing.

At an international level ISO/TC 261 was created to carry out Standardization activities in the area of Additive Manufacturing. This Technical Committee (TC) collaborates with ASTM International (formerly known as American Society for Testing and Materials), through Joint Groups to develop ISO international standards and adopt ASTM standards.

At a regional European level CEN/TC 438 was created to adopt and develop EN European standards. Normally, ISO standards will be adopted as European standards (EN ISO) and subsequently published by NSAI as Irish standards (I.S. EN ISO).

Committee Mapping

NSAI/TC 49/SC 02 is mapped to ISO/TC 261 and CEN/TC 438. Within SC 02 there are Working Groups (WG) which mirror the Working Groups of ISO/TC 261. These are treated as separate Committees. Figure 1 shows the mapping of the international committees to the NSAI NMC committees on Livelink.

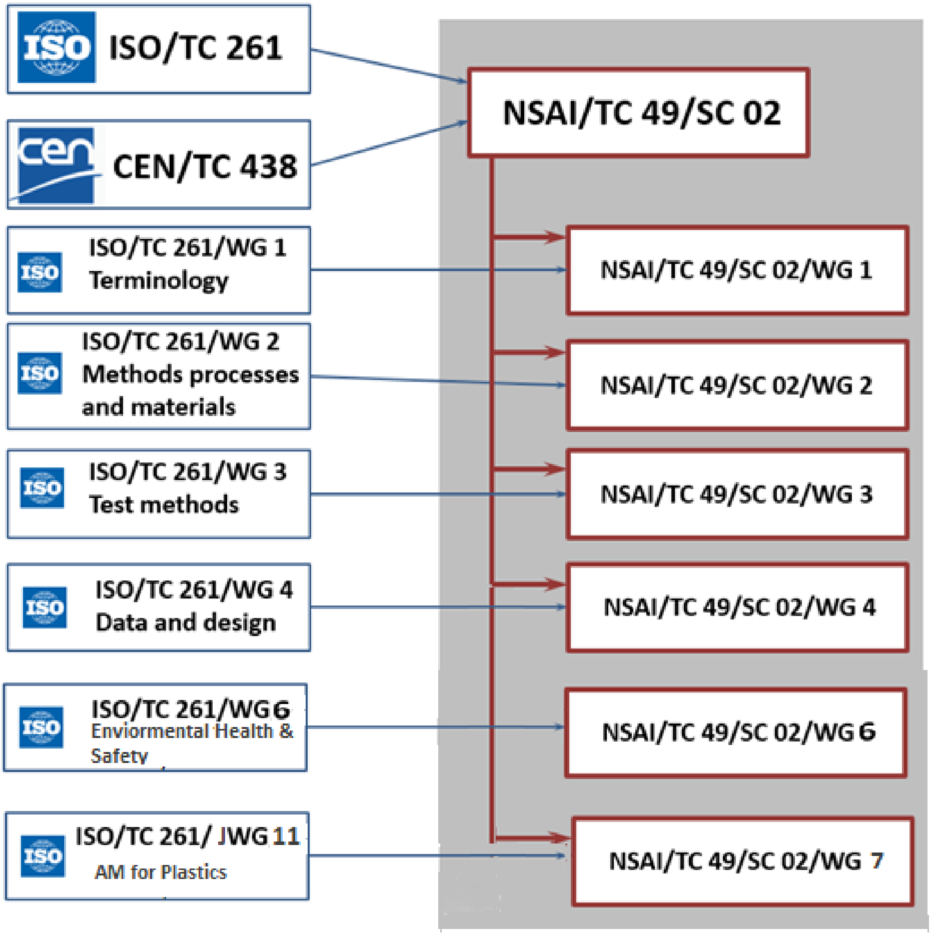

Figure 3 - Livelink mapping for international committees

STRUCTURE AND OPERATION OF ISO/TC 261

The main difference of ISO/TC 261 to the other, “normal” ISO Technical Committees is that shortly after the establishment of ISO/TC 261 in 2011 a Partner Standards Development Organization (PSDO) cooperation agreement has been agreed between ISO and ASTM International.

Therefore ISO/TC 261 and ASTM F42 are collaborating closely in the development and maintenance of standards on AM (which will be ISO/ASTM standards) and have also established procedures for the quick adoption of ASTM standards (also as ISO/ASTM standards). After some difficulties at the beginning (change of personnel, lack of established channels of information) this collaboration started in earnest in 2013, when in July the summer meeting of ASTM F42 in Europe was held in conjunction with the ISO/TC 261 plenary meeting in Nottingham. An *AM Standards Development Plan ASTM* was jointly developed in 2013 , which included a general structure/hierarchy of AM standards in order to achieve consistency of all projects started by one of the partners.

This agreement was immediately implemented during the Nottingham meetings 2013 by identifying high priorities and the establishment of four Joint Groups (which are defined in A2.2 of the PSDO agreement), in which ASTM and ISO will develop standards for the identified priorities:

- Terminology
- Standard test artifacts
- Requirements on purchased AM parts, and
- Design guidelines
- Aerospace
- Health, Safety and Environment

These JGs are intended to be small (~ 10 participants max., 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).

It was also agreed by ISO/TC 261 and ASTM F42, that in case one organization starts to work on a new work item, it will invite the other to form such a Joint Group. Only in case the other organization is not interested, the standard will be developed "alone". Projects already started in July 2013 will be finished by the two organizations without necessary cooperation with the other organization.

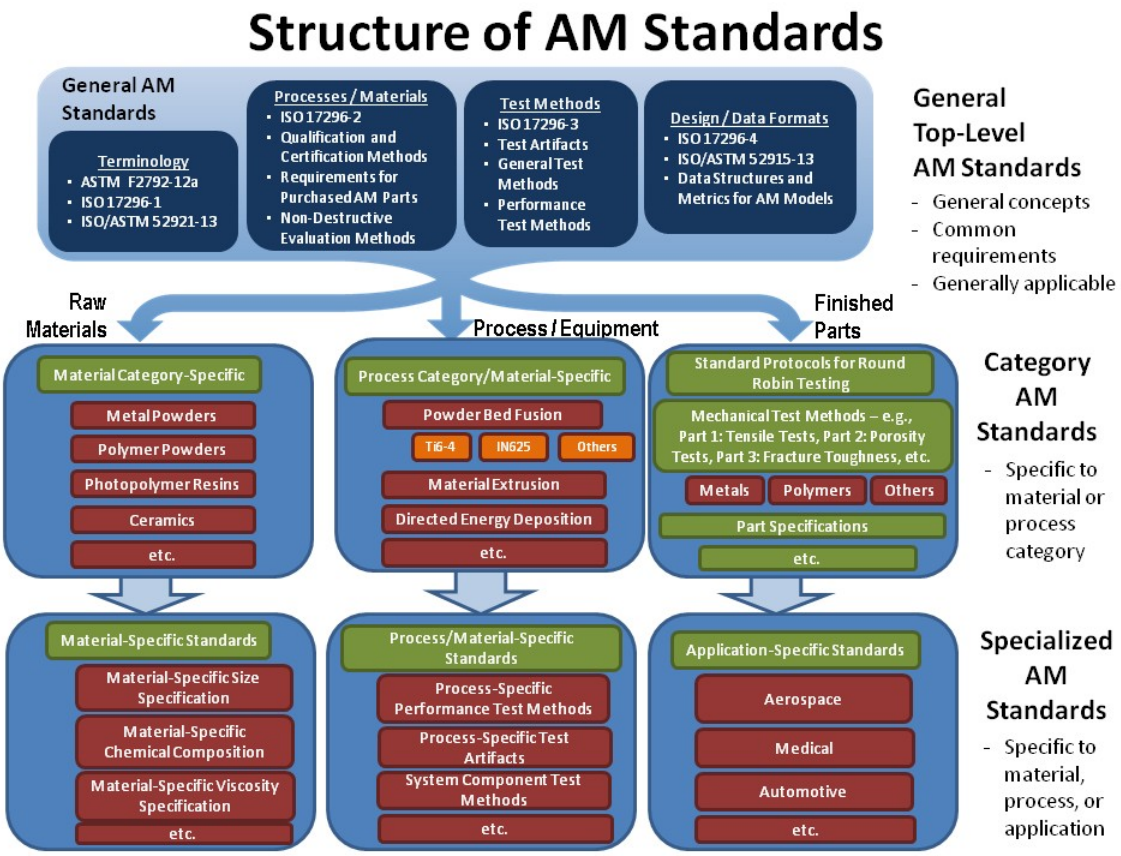

Figure 4 – Structure of Additive Manufacturing standards

Joint Groups (JG) have been set up, under agreement between both ISO/TC 261 and ASTM F42. These agreements have no precedence in the ISO standardization process, and therefore solutions have to be found and developed on short notice in cases where conflicts in the existing processes are being noticed.

Drafting of Standards is not being done in ISO WGs (Where experts are nominated by their National Standards Body.), but in JGs. The amount of JG experts is restricted, and the nomination is done by the ISO/TC 261 Technical Committee.

The high speed of drafting, achieved by having short (but many) web-conferences in the JG, complicates the normal feedback procedure where the ISO experts in JGs would like to get the feedback from other ISO experts outside the JG, and necessitates a good cooperation of ISO experts in different JGs in order to ensure that the work in the JGs has a similar direction (just think "terminology").

Requests of ASTM (e.g. for new Joint Groups) require answers much quicker than can be obtained by the ISO/TC 261 Technical Committee (both by plenary meeting and by correspondence).

The relatively small amount of ISO experts in a JG makes it more likely that the draft resulting from a JG is not familiar enough among the other experts of ISO, so that the commenting and voting might achieve a negative result.

A Coordination Group has been established (members being the ISO experts in the JGs), which meets mainly by web-conference, and which intends, among other things, to achieve a quick flow of information from one JG to the other (at least for the ISO experts in the JGs), a quick response to questions from ASTM and quick nomination of additional ISO experts to new JGs (a formal approval by the ISO/TC at the next opportunity would nevertheless also be necessary)

Additionally, the different JGs are allocated to the existing ISO WGs, as shown in Table 1. The different draft versions of the JG are to be distributed in the WG, and the WGs have the task of the technical discussion and commenting of the JG activities from the ISO side.

WORKING GROUPS WITHIN ISO/TC 261

ISO/TC 261/WG 1 -- Terminology

ISO/TC 261/WG 2 -- Processes, systems and materials

ISO/TC 261/WG 3 -- Test methods and qualification specification

ISO/TC 261/WG 4 -- Data and design

ISO/TC 261/WG 6 -- Environment, health and safety

ISO/TC 261/JWG 10 -- Aerospace applications

ISO/TC 261/JWG 11 -- Additive manufacturing for plastics

ISO/TC 261/AG 1 -- Coordination Group

ISO/TC 261/AHG 5 -- Content of 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

Scope of ISO/TC 261/WG 1 – Terminology

Standardization of terms and definitions as well as fundamental concepts in the field of additive manufacturing (AM*), as defined in the International Standard ISO/ASTM 52900.

ISO/ASTM 52921:2013 - Standard terminology for additive manufacturing — Coordinate systems and test methodologies

Scope of ISO/TC 261/WG 2 -- Processes, systems and materials

Standardization in the field of additive manufacturing (AM*) processes, hardware and software, materials, including but not limited to:

- Material (feedstock) characteristics, production, transport, storage, treatment, reuse;

- Hardware characteristics, qualification, operation, maintenance; and

- Process definitions, specifications, monitoring.

ISO/TC 261/WG 2 closely collaborates with the other Working groups, especially WG 3. Special attention is turned on all kind of AM qualification procedures.

ISO 17296-2:2015 - *Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock*

ISO/ASTM 52904:2019 *Additive manufacturing — Process characteristics and performance — Practice for metal powder bed fusion process to meet critical applications*

ISO/ASTM 52907:2019 *Additive manufacturing — Feedstock materials — Methods to characterize metal powders*

ISO/ASTM 52903-1:2020 -- *Additive manufacturing Material extrusion based additive manufacturing of plastic materials — Part 1: Feedstock materials*

ISO/ASTM 52903-2:2020 -- *Additive manufacturing Material extrusion based additive manufacturing of plastic materials — Part 2: Process equipment*

Scope of ISO/TC 261/WG 3 -- Test methods and qualification specification

Standardization in the field of tests methods related to Additive Manufacturing; including but not limited to:

- Characterization of samples representing AM technologies;

- Characterization of mechanic properties of samples build with AM (plastic, metallic and ceramic);

- Round robin tests;

- Quality requirements for parts made by AM;

- Characterization and description of geometries for parts build with AM; and

- Test codes for machines in AM.

ISO 17296-3:2014 - *Additive manufacturing -- General principles – Part 3: Main characteristics and corresponding test methods*

ISO/ASTM 52901:2017 - *Additive manufacturing — General principles — Requirements for purchased AM parts*

ISO/ASTM 52902:2019 - *Additive manufacturing — Test artifacts — Geometric capability assessment of additive manufacturing systems*

Scope of ISO/TC 261/WG 4 -- Data and design

Standardization in the field of Data and Design related to Additive Manufacturing; including but not limited to:

- Data processing and data exchange specifying terms, definitions, file types and relevant data formats; and

- Additive Manufacturing Format (AMF) providing key parameters for AMF as an interchange format that uses an extensible mark-up language (XML), being capable of addressing the current and future data requirements of Additive Manufacturing technology.

ISO/TC 261/WG 4 has an active liaison with ISO/IEC JTC 1 for aspects related to Information Technology.

ISO 17296-4:2014 - *Additive manufacturing -- General principles -- Part 4: Overview of data processing*

ISO/ASTM 52910:2018 - *Additive manufacturing — Design — Requirements, guidelines and recommendations*

ISO/ASTM 52911-1:2019 - *Additive manufacturing — Design — Part 1: Laser-based powder bed fusion of metal*

ISO/ASTM 52911-2:2019 - *Additive manufacturing — Design — Part 2: Laser-based powder bed fusion of polymers*

ISO/ASTM TR 52912:2020 - *Additive manufacturing — Design — Functionally graded additive manufacturing*

ISO/ASTM 52915:2020 - *Specification for additive manufacturing file format (AMF) Version 1.2*

ISO/ASTM 52950:2021 - *Additive manufacturing — General principles — Overview of data processing*

Scope of ISO/TC 261/WG 6-- Environment, health and safety

Standardization in the field of Environment, health and safety related to Additive Manufacturing; including but not limited to:

- application, operation, inputs and outputs of the various AM processes. These include:

- the use and disposition of materials, mainly powders (metals, polymers and ceramic);

- the use of concentrated sources of energy (such as Lasers and Electron Beams);

- the use of inert gases;

- the operation of equipment, including installation, the loading/unloading of parts;

maintenance and cleaning;

- the use of postprocessing to obtain a final part; and

Excluded is the usage of products designed and fabrication via an AM Method.

Scope of ISO/TC 261/JWG 10 -- Aerospace applications

Joint Working Group with ISO/TC 261 and ISO/TC 44/SC 14 (Welding and allied processes/ Welding and brazing in aerospace).
Standardization in the field of Additive manufacturing in aerospace applications

including but not limited to:

- Process specification and quality requirements for aerospace hardware produced with AM;
- qualifying machine operators of powder bed-based laser beam machines;
- test method for acceptance of powder bed fusion machines for metallic materials;
- calibration of Metal Powder Bed Fusion Machines and Subsystems; and
- directed energy deposition using wire and arc, wire and beam and laser blown powder.

ISO/ASTM 52941:2020 - *Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application*

ISO/ASTM 52942:2020 - *Additive manufacturing — Qualification principles — Qualifying machine operators of laser metal powder bed fusion machines and equipment used in aerospace applications*

ISO/ASTM CD 52926-1: - *Additive manufacturing of metals — Qualification principles — Part 1: General qualification of machine operators*

ISO/ASTM CD 52926-2: - *Additive manufacturing of metals — Qualification principles — Part 2: Qualification of machine operators for PBF-L*

ISO/ASTM CD 52926-3: - *Additive manufacturing of metals — Qualification principles — Part 3: Qualification of machine operators for PBF-EB*

ISO/ASTM CD 52926-4: - *Additive manufacturing of metals — Qualification principles — Part 4: Qualification of machine operators for DED-LB*

ISO/ASTM CD 52926-5: - *Additive manufacturing of metals — Qualification principles — Part 5: Qualification of machine operators for DED-Arc*

ISO/ASTM CD 52935: - *Additive manufacturing of metals — Qualification principles — Qualification of coordinators for metallic parts production*

ISO/ASTM AWI 52937: - *Additive manufacturing of metals — Qualification principles — Qualification of designers*

ISO/ASTM PWI 52943-1: - *Additive manufacturing for aerospace — Process characteristics and performance — Part 1: Directed energy deposition using wire and laser beam*

ISO/ASTM NP 52943-2: - *Additive manufacturing for aerospace — Process characteristics and performance — Part 2: Directed energy deposition using wire and arc*

ISO/ASTM PWI 52943-3: - *Additive manufacturing for aerospace — Process characteristics and performance — Part 3: Directed energy deposition using laser blown powder*

ISO/ASTM PWI 52943-4: - *Additive manufacturing for aerospace — Process characteristics and performance — Part 4: Directed energy deposition using wire and electron beam*

ISO/ASTM PWI 52944: - *Additive manufacturing — Process characteristics and performance — Standard specification for powder bed processes in aerospace applications*

Scope of ISO/TC 261/JWG 11 -- Additive manufacturing for plastics

Joint Working Group between ISO/TC 261 and ISO/TC 61/SC 9, set up to revise

ISO 27547-1:2010 - *Plastics — Preparation of test specimens of thermoplastic materials using mouldless technologies — Part 1: General principles, and laser sintering of test specimens*

ISO/TC 61 - *Plastics*

ISO/TC 61/SC 9 - *Thermoplastic materials*

ISO/ASTM DIS 52924 - *Additive manufacturing of polymers — Feedstock materials — Qualification of materials for laser-based powder bed fusion of parts*

ISO/ASTM DIS 52925 - Additive *manufacturing of polymers — Qualification principles — Classification of part properties*

ISO/ASTM DIS 52936-1 - *Additive manufacturing of polymers —powder bed fusion — Part 1: General principles, preparation of test specimens for laser-based PBF*

JG no.	Joint Group with ASTM F 42	WG of ISO/TC 261
51	Terminology	WG 1, Terminology
52	Standard test artifacts	WG 3, Test methods
53	Requirements for purchased AM parts	WG 3, Test methods
54	Design guidelines	WG 4, Data and design
55	Standard Specification for Extrusion Based Additive Manufacturing of Plastic Materials	WG 2, Methods, processes and materials
56	Standard Practice for Metal Powder Bed Fusion to Meet Rigid Quality Requirements	WG 2, Methods, processes and materials
57	Specific design guidelines on powder bed fusion	WG 4, Data and design
58	Qualification, quality assurance and post processing of powder bed fusion metallic parts	WG 3, Test methods
59	NDT for AM parts	WG 3, Test methods
60	Guide for Intentionally Seeding Flaws in Additively Manufactured (AM) Parts	WG 2, Methods, processes and materials
61	Guide for Anisotropy Effects in Mechanical Properties of AM Part	WG 3, Test methods
62	Guide for Conducting Round Robin Studies for Additive Manufacturing	WG 3, Test methods
63	Test Methods for Characterization of Powder Flow Properties for AM Applications	WG 3, Test methods
64	Specification for AMF Support for Solid Modelling: Voxel Information, Constructive Solid Geometry Representations and Solid Texturing	WG 4, Data and design
65	Specification for Additive Manufacturing Stainless Steel Alloy with Powder Bed Fusion	Disbanded
66	Technical specification on metal powders	Dormant
67	Technical report for the design of functionally graded additive manufactured parts	Dormant
68	Environment, Health & Safety for 3D printers	WG 6, E, H & S
69	Environment, Health & Safety for use of metallic materials	WG 6, E, H & S
70	Optimized medical image data	WG 4, Data and design
71	Powder quality assurance	WG 2, Methods, processes and materials
72	Machine - Production process qualification	WG 2, Methods, processes and materials
73	Digital product definition and data management	WG 4, Data and design
74	Personnel qualifications	JWG 10 Aerospace applications
75	Industrial conformity assessment at additive manufacturing centres	WG 2, Methods, processes and materials

JG	Joint Group with ASTM F 42	WG of ISO/TC 261
76	Revision of ISO 17296-3 & ASTM F3122-14	WG 3, Test methods
77	Test method of sand mold for metal casting	WG 3, Test methods
78	Proposal to establish a new JG to deal with type-C	WG 6, E. H & S
79	Qualification for AM processes in automotive applications manufacturing centres	WG 2, Methods, processes and materials
80	"Quality requirements for Additive Manufacturing in Building & Construction (Structural and Infrastructure elements)"	WG 2, Methods, processes and materials
81	Metallic Materials for Additive Manufacturing	WG 2, Methods, processes and materials
82	Characterization of ceramic feedstock materials	WG 2, Methods, processes and materials

Table 1 – Relationship between ASTM F42 Joint Groups and ISO/TC 261 Working GROUPS

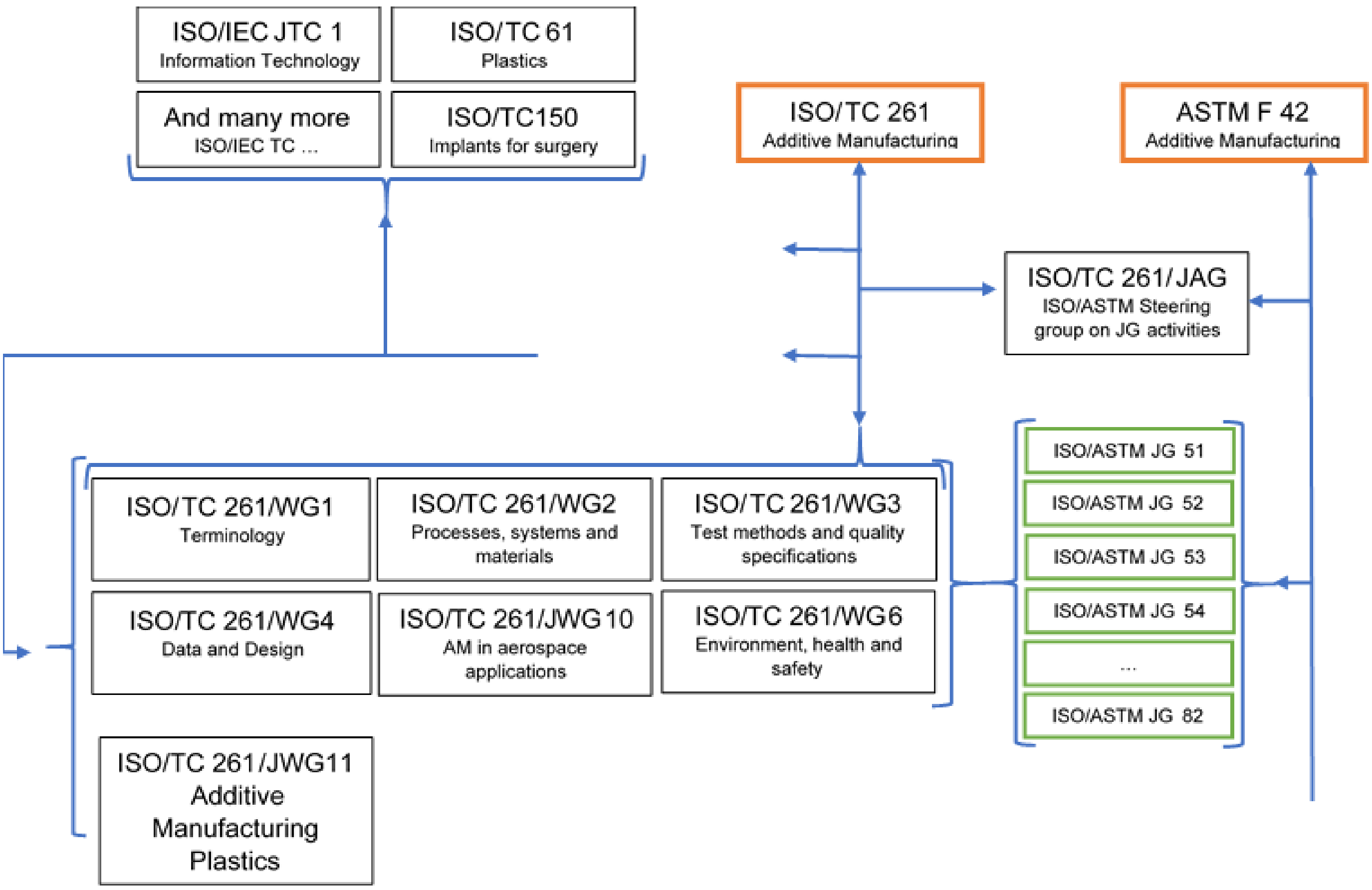

Figure 5 – Process map for functions of ISO/TC 261

JOINT GROUPS OF ISO/TC 261

WG /	ISO/TC 261/WG 1	ISO/TC 261/WG 2	ISO/TC 261/WG 3	ISO/TC 261/WG 4	ISO/TC 261/JWG 10	ISO/TC 261/WG 6
Title	**Terminology**	**Processes, systems and materials**	**Test methods and quality specifications**	**Data and Design**	**Joint ISO/TC 261 - ISO/TC 44/SC 14 WG: Additive manufacturing in aerospace applications**	**Environment, health and safety**
Convenor	Dr. Klas Bovie	Dr. Marius Lakomiec	Verquin Benoît M	Dr Eujin Pei	Dr . -Ing Simon Jahn	Mr François Richard
Secretariat	Sweden (SIS)	Germany (DIN)	France (AFNOR)	United Kingdom (BSI)	Germany (DIN)	Canada (SCC)
Mirroring of ISO/ASTM Joint Groups (JG) in the right hand columns	JG 51	JG 55 JG 56 JG 60 JG 66 JG 71 JG 72 JG 75 JG 79 JG 80 JG 81 JG 82	JG 52 JG 53 JG 58 JG 59 JG 61 JG 62 JG 63 JG 76 JG77	JG 54 JG 57 JG 64 JG 70 JG 73	--JG-74	JG 68 JG 69 JG 78
Mirroring, drafting and maintenance of ISO & ISO/ASTM documents	ISO/ASTM FDIS 52900	ISO/ASTM PWI 52914 ISO/ASTM CD 52904 ISO/ASTM CD 52903-2 ISO/ASTM CD DTR 52906 ISO/ASTM DIS 52920 ISO/ASTM CD 52928 ISO/ASTM TS 52930 ISO/ASTM AWI 52939 ISO/ASTM PWI 52940 ISO/ASTM NP 52945 ISO/ASTM PWI 52946 ISO/ASTM PWI 52947	ISO/ASTM CD 52902 ISO/ASTM DTR 52905 ISO/ASTM CD 52908 ISO/ASTM CD 52909 ISO/ASTM DTR 52913-1 ISO/ASTM DTR 52917 ISO/ASTM AWI 52919-1 ISO/ASTM AWI 52919-2 ISO/ASTM DIS 52921 ISO/ASTM CD 52927 ISO/ASTM AWI 52938-1	ISO/ASTM CD 52910 ISO/ASTM AWI 52911-3 ISO/ASTM PWI 52914 ISO/ASTM PRF TR 52916 ISO/ASTM CD/TR 52918 ISO/ASTM PWI 52922 ISO/ASTM PWI 52923 ISO/ASTM PWI 52951	ISO/ASTM CD 52926-1 ISO/ASTM CD 52926- 2 ISO/ASTM CD 52926-3 ISO/ASTM CD 52926-4 ISO/ASTM CD 52926-5 5ISO/ASTM CD 52935 ISO/ASTM AWI 52937	ISO/ASTM DIS 52931 ISO/ASTM CD 52932 ISO/ASTM AWI 52933

Joint Group 51 - Terminology

JG51 is a Joint Group for Terminology, developing standards that establishes and defines terms as well as fundamental concepts relevant within the field of additive manufacturing (AM). JG51 is responsible for the maintenance and continuous revision of the International Standard ISO/ASTM 52900, including the development of definitions for new terms as well as necessary amendments, emerging from the ongoing work within ISO/TC 261 and ASTM F42.

ISO/ASTM DIS 52900 -- *Additive manufacturing — General principles — Fundamentals and vocabulary*

Joint Group 52 - Standard test artifacts

JG52 is a Joint Group for Standard Test Artefacts for Additive Manufacturing, developing standards that describe test piece geometries using quantitative and qualitative measurements to assess the performance of an Additive Manufacturing (AM) system. The primary characterization of AM systems obtained by this standard is to use geometric accuracy, surface finish, and minimum feature sizes of the test piece.

ISO/ASTM 52902:2019 -- *Additive manufacturing — test artifacts — Geometric capability assessment of additive manufacturing systems*

Joint Group 53 – Requirements for purchased AM parts

JG53 is a Joint Group for Requirements for Purchased AM Parts, developing standards to specify the elements to be exchanged between the customer and the part provider or vendor, such as the order information, part definition data, raw material requirements, final part characteristics and properties, inspection requirements, and part acceptance methods, to ensure that the resulting part meets the customers' requirements. The standard allows for any AM process and any material type, considering different requirements based on the classification of the criticality and the expected end use of the parts. (DORMANT)

ISO/ASTM 52901:2017 -- *Additive manufacturing — General principles — Requirements for purchased AM parts*

Joint Group 54 - Fundamentals of Design

Develop the general design guidelines standard to homogenize the fundamental design-process-material correlations within Additive Manufacturing (AM) processes. Design rules are prescriptive guidelines or explicit constraints that provide an insight into manufacturability during the design and planning process. The design rules contain knowledge and provide both experts and non-experts with a way of making meaningful changes to part geometries without compromising manufacturability, and as a means to constrain a design space, defining the boundaries of a design feature for given processes and material parameters.

ISO/ASTM CD 52910 -- *Additive manufacturing — Design — Requirements, guidelines and recommendations*

ISO/ASTM PWI 52922 -- *Additive manufacturing — Design — Directed energy deposition*

ISO/ASTM PWI 52923 -- *Additive manufacturing — Design decision support*

Joint Group 55 – Standard Specification for Extrusion Based Additive Manufacturing of Plastic Materials

JG55 is a Joint Group for Extrusion Based Additive Manufacturing of Plastic Materials, developing standards for feedstock materials (Part 1); process-equipment (Part 2), and final part specification (Part 3). The standard describes the requirements for plastic materials used in extrusion based Additive Manufacturing (AM) processes such as unfilled, filled, special additives (e.g. flame retardants, stabilizers, etc.) and reinforced plastic materials. It also describes the requirements and assuring component integrity for plastic parts created using material extrusion-based AM processes, including the process, equipment, and operational parameters.

ISO/ASTM 52903-1:2020 -- *Additive manufacturing Material extrusion based additive manufacturing of plastic materials — Part 1: Feedstock materials*

ISO/ASTM CD 52903-2 -- *Additive manufacturing Material extrusion based additive manufacturing of plastic materials — Part 2: Process equipment*

ISO/ASTM PWI 52914 -- *Additive manufacturing of polymers — Design — Material extrusion of thermoplastics*

Joint Group 56 - Standard Practice for Metal Powder Bed Fusion to Meet Rigid Quality Requirements

JG56 is a Joint Group for developing a Standard Practice for Metal Powder Bed Fusion Process to Meet Critical Applications, describing the operation and production control to meet rigid quality requirements such as commercial aerospace components and medical implants. The requirements contained herein are applicable to production components and mechanical test specimens produced using either laser or electron beam.

ISO/ASTM CD 52904 -- *Additive manufacturing — Process characteristics and performance — Metal powder bed fusion process to meet critical applications*

Joint Group 57 - Process-specific design guidelines and standards

JG57 is a Joint Group for process specific Design Guidelines and Standards. In focus is the designing of parts that need to be manufactured by means of additive manufacturing processes to support first time right production. It includes recommendations and best practices to achieve build accuracy and integrated features, as well as design recommendations such as allowing for powder removal, achieving adequate wall thickness, minimizing warpage, etc**.**

ISO/ASTM 52911-1:2019 -- *Additive manufacturing — Design Part 1: Laser-based powder bed fusion of metals*

ISO/ASTM 52911-2:2019 -- *Additive manufacturing — Design Part 2: Laser-based powder bed fusion of polymers*

ISO/ASTM WD 52911-3 -- *Additive manufacturing — Design Part 3: Electron beam powder bed fusion of materials*

Joint Group 58 - Qualification, quality assurance and post processing of powder bed fusion metallic parts

JG58 is a Joint Group for Qualification, Quality Assurance, and Post- Processing of Powder Bed Fusion Metallic Parts, developing standards for methods and procedures for testing and qualification of various characteristics of Additive Manufactured metal parts. The standard specifies the qualification of feedstock material such as particle size distribution, flowability, chemical composition and morphology and also defines testing procedures and values to be obtained to meet defined quality levels.

ISO/ASTM CD 52908 -- *Additive Manufacturing of Metals — Post-processing methods — Quality assurance and post processing of powder bed fusion metallic parts*

Joint Group 59 - Non-destructive Testing for Additive Manufactured Parts

JG59 is a Joint Group for Non-destructive Testing of Additive Manufactured Parts, developing a guide that will include post-process NDT of Additive Manufacturing (AM) for metallic parts. It will cover several sectors and a similar framework can be applied to other materials such as ceramics and polymers, etc. This guide will present current capabilities to detect Additive Manufacturing (AM) flaws and those that require new standards using a selection tool. In-process NDT and metrology standards will also be

referenced in the guide. New NDT methods that arise will be referenced in this standard via document updates.

ISO/ASTM DTR 52905 -- *Additive manufacturing of metals — Nondestructive testing and evaluation — Defect detection in parts*

Joint Group 60 - Guide for intentionally seeding flaws in additively manufactured (AM) parts

JG60 is a Joint Group for Intentionally Seeding Flaws in Additively Manufactured (AM) Parts, developing standards for best practices to intentionally seed components with flaws of prescribed geometry and location to confirm that non-destructive testing methods are capable of detecting those defects.

ISO/ASTM DTR 52906 -- *Additive manufacturing — Non-destructive testing and evaluation — Intentionally seeding flaws in parts*

Joint Group 61 - Mechanical properties characterization of additively manufactured metallic materials

JG61 is a Joint Group focusing on the measurement of Orientation and Location Dependence Mechanical Properties for Metal Additive Manufacturing, developing standards for the field of mechanical testing of metals made by Additive Manufacturing. Vendors and manufacturers will use the standard to partially qualify parts and components to meet certain load bearing capability, damage tolerance, fracture and fatigue properties. In addition, standard practices for location and orientation specific mechanical property measurement is provided.

ISO/ASTM CD 52909 -- *Additive manufacturing — Finished part properties — Orientation and location dependence of mechanical properties for powder bed fusion*

ISO/ASTM DIS 52921 -- *Additive manufacturing — General principles — Part positioning, coordinates and orientation*

Joint Group 62 - Guide for conducting round robin studies for additive manufacturing

JG62 is a Joint Group for developing specifications and guidance on how to conduct and interpret results of round robin testing in Additive Manufacturing to enable the acquisition of reliable and high-quality data. The goal of Design of Experiments (DOE) for round robin testing is to minimize the variability in the feedstock, sequence of manufacturing operations and part test methods such as mechanical properties, chemical composition and geometric tolerances

ISO/ASTM DTR 52917 -- *Additive manufacturing — Round Robin Testing — Guidance for conducting Round Robin studies*

Joint Group 63 - Test methods for characterization of powder flow properties for AM applications

JG63 is a Joint Group for Test Methods for the Characterization of Powder Flow Properties for Additive Manufacturing Applications, developing standards for evaluating the flow properties of powders intended for Additive Manufacturing (AM), considering factors that influence powder behavior and introducing test methodologies and protocols for characterizing the flow properties of powders to create consistency across all applications and sectors. It is intended to provide guidance to all users in the AM process

from powder producers and suppliers through to machinery manufacturers and end-users.

ISO/ASTM DTR 52913-1 -- *Additive manufacturing — Feedstock materials — Part 1: Parameters for characterization of powder flow properties*

Joint Group 64 - AMF Additive Manufacturing File Format (AMF)

JG64 is a joint group for Additive Manufacturing File Format (AMF) and AMF Solid Modelling Support, i.e. Voxel Information, Constructive Solid Geometry Representations and Solid Texturing, working on further evolutions to the AMF standard. In addition to these activities, the Joint Group coordinates standard activities with ISO/TC 292 "Security and resilience" on AMF authentication and security applications.

ISO/ASTM 52915:2020 -- *Specification for additive manufacturing file format (AMF) Version 1.2*

ISO/ASTM CD TR 52918 -- *Additive manufacturing — Data formats — File format support, ecosystem and evolutions*

Joint Group 66 – Technical specifications on metal powders

JG66 is a Joint Group for Technical Specification on Metal Powders, compiling standards for documentation and traceability, sampling, particle size distribution, chemical composition, characteristic densities, morphology, flowability, thermal characteristics, cleanliness, and packaging and storage. It does not cover safety aspects but provides specific requirements for used metallic powders in Additive Manufacturing.

ISO/ASTM 52907:2019 -- *Additive manufacturing — Feedstock Materials-Methods to characterize metal powders*

Joint Group 67 - Technical report for the design of functionally graded additive manufactured parts

JG67 is now dormant after it has completed its work and produced a Technical Report which clarifies the definition of terms, current software that can simulate FGAM materials with discrete or continuous variation of mechanical properties, outlines key manufacturing processes, providing examples of materials that have been used to produce FGAM parts, as well as identifying potential applications.

ISO/ASTM 52950:2021 -- *Additive manufacturing — General principles — Overview of data processing*

ISO/ASTM TR 52912:2020 -- *Additive manufacturing — Design — Functionally graded additive manufacturing*

Joint Group 68 - EH&S for 3D printers

JG68 is a Joint Group that specifies a test method to determine the emissions of Fine particles, Ultrafine Particles and the other hazardous substances from Material Extrusion (ME) additive manufacturing processes, which builds three dimensional parts by selectively dispensing melted thermoplastic filaments through a nozzle.

ISO/ASTM CD 52932 -- *Additive manufacturing — Environmental health and safety -- Standard test method for determination of particle emission rates from desktop 3D printers using material extrusion*

ISO/ASTM WD 52933 -- Additive manufacturing — Environment, health and safety — Consideration for the reduction of hazardous substances emitted during the operation of the non-industrial ME type 3D printer in workplaces, and corresponding test method

Joint Group 69 - EH&S for use of metallic materials

JG69 is a Joint Group developing guidelines related to Environment, Health and Safety (EHS) aspects in all Additive Manufacturing processes that use metallic materials in powder or wire form, consisting from the supply of feedstock to the delivery of parts. The guidelines include, but are not limited to the identification of hazards, risk assessment, recommendations for protective and preventive measures, verification protocols, and waste disposal management.

ISO/ASTM DIS 52931 -- *Additive manufacturing of metals — Environment, health and safety — General principles for use of metallic materials*

Joint Group 70 - Optimized medical image data

JG70 is a Joint Group that develops guidelines for the standard specification for optimized medical image data for Additive Manufacturing. The data is generated from static modalities such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT), Positron Emission Tomography (PET), Single-Photon Emission Computed Tomography (SPECT); as well as Dynamic modalities such as ultrasound and optical image data. This Joint Group addresses medical-specific data quality requirements and approaches for medical image data acquisition to obtain accurate medical models and devices based on real human information. This data can also be applicable for veterinary surgery.

ISO/ASTM PRF DTR 52916 -- *Additive Manufacturing — Data formats — Optimized medical image data*

Joint Group 71 - Powder Quality Assurance

JG71 is a Joint Group developing guidelines related to the feedstock for metal Powder Bed Fusion (PBF) processes to comply to the Nadcap PBF accreditation checklist. This covers the purchasing specifications, powder lifecycle management in terms of receiving, storage and disposal, and the reuse of metal powders. The guidelines include specifying the attributes of metal powders that affect the performance of the PBF processes which influences part quality, procedures for feedstock reuse in metal PBF, as well as different re-use schemas in terms of how many times the powder can be reused, powder sieving techniques, storage, handling prior to reuse, batch control, traceability and the effects of the PBF process on powder.

ISO/ASTM CD 52928 -- *Additive manufacturing — Feedstock materials — Powder life cycle management*

Joint Group 72 - Machine- Production Process Qualification

JG72 is a Joint Group developing guidelines related to the operating procedures of metal Powder Bed Fusion (PBF) machines, including best practices for cleaning the machines after routine build changes, when changing material types and periodic maintenance. Additionally, this guide covers the initial quality requirements and metrics for metal PBF machines and identifies key machine attributes that affect part quality. The guidelines cover how to establish upper and lower limits for each parameter to create fixed processes for machine qualification, guidelines for risk assessment for Critical to Quality (CTQ) machine attributes for initial qualification, operational qualification and part qualification.

ISO/ASTM TS 52930 -- *Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment*

Joint Group 73 - Digital product definition and data management

JG73 is a Joint Group developing guidelines related to digital data configuration control, data integrity checks, and enterprise work flow for files used in the metal Powder Bed Fusion (PBF) process. The guideline covers digital product data workflows, file formats used for printing, automated and manual methods for receiving digital data and build cycle information in the PBF process that can be used for product quality assurance. The guidelines cover saving and storing the build cycle data in order to meet quality system requirements.

ISO/ASTM PWI 52951 -- *Additive Manufacturing — Data — Data packages for AM parts*

Joint Group 74 – Personnel Qualifications

JG74 is a Joint Group developing guidelines related to establish a comprehensive training program for the different roles necessary for the metal Powder Bed Fusion (PBF) process. This includes powder technicians, build set-up engineers, machine operators and other personnel necessary for the production of metal PBF parts. This JG liaises with ISO/TC 44/SC 14 which focuses on standards on welding, brazing and structural soldering for aerospace applications.

ISO/ASTM CD 52926-1 -- *Additive manufacturing of metals — Qualification principles — Part 1: General qualification of machine operators*

ISO/ASTM CD 52926-2 -- *Additive manufacturing of metals — Qualification principles — Part 2: Qualification of machine operators for PBF-LB*

ISO/ASTM CD 52926-3 -- *Additive manufacturing of metals — Qualification principles — Part 3: Qualification of machine operators for PBF-EB*

ISO/ASTM CD 52926-4 -- *Additive manufacturing of metals — Qualification principles — Part 4: Qualification of machine operators for DED-LB*

ISO/ASTM CD 52926-5 -- *Additive manufacturing of metals — Qualification principles — Part 5: Qualification of machine operators for DED-Arc*

ISO/ASTM CD 52935 -- *Additive manufacturing of metals — Qualification principles — Qualification of coordinators for metallic parts production*

ISO/ASTM AWI 52937 -- *Additive Manufacturing of metals — Qualification principles — Qualification of designers*

Joint Group 75 - Industrial conformity assessment at additive manufacturing centers

JG75 is a joint group developing a standard related on performance levels for industrial additive manufacturing centers. The document will include quality assurance control throughout the entire manufacturing workflow. The standard focus on the AM specifics to achieve high quality serial production in additive manufacturing centers. NOTE: Once the AM standard on performance levels is established the JG75 planning to elaborate a standard on conformity assessment.

ISO/ASTM DIS 52920 -- *Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing sites*

Joint Group 76 – Revision of ISO 17296-3 & ASTM F3122-14

The main objective of JG76 is to adapt existing test procedures for additive manufacturing. This group identifies existing standards in terms of procedures (mechanical tests, metrology,...) applicable to AM. Information will have to be determined in order to take into account the test analysis from samples carried out by AM: orientation, location of build, manufacturing strategy, surface finish, heat treatment, volume of the build job,...This work will lead JG76 to define the best appropriate test procedure link to the final part and collect necessary information for data reporting. This JG76 activity covers metal, polymer and ceramic material

ISO/ASTM CD 52927 -- *Additive manufacturing — General principles — Main characteristics and corresponding test methods*

Joint Group 77 – Test method of sand mold for metalcasting

JG77 is a Joint Group for testing sand mold for metalcasting produced by binder jetting and powder bed fusion additive manufacturing processes, developing standards to define specified methodologies to measure properties of sand mold for metalcasting made by AM, such as bending strength and gas permeability, etc. The standards enable to provide appropriate means evaluating AM made mold property to be shared by international stakeholders such as AM machine supplier, castings foundry and casting products user.

ISO/ASTM AWI 52919-1 -- *Additive manufacturing — Qualification principles — Part 1: Mechanical properties of sand mold for metalcasting*

ISO/ASTM AWI 52919-2 -- *Additive manufacturing — Qualification principles — Part 2: Physical properties of sand mold for metalcasting*

Joint Group 78 -Safety regarding AM-machines (relating to harmonized European Standards, Type C-Standard)

JG78 is in charge of drafting safety standards for additive manufacturing machines used for the 7 processes as identified in ISO 17296-2 and using all different types of materials (e.g. metals, polymers and ceramics) as feedstock. The purpose of this group is to draft standards to be harmonized regarding the European Machinery Directive in order to give presumption of conformity to this Directive for the essential requirements covered by the standard

ISO/ASTM AWI 52938-1 -- *Additive manufacturing of metals — Environment, health and safety — Part 1: Safety requirements for PBF-LB machines*

Joint Group 79 - Qualification for AM processes in automotive applications

JG79 is a joint group dedicated to the qualification of AM processes for automotive applications. Projects assigned to JG79 will address topics related to performance and production KPI definitions for M-L-PBF processes. Furthermore, JG79 aims for standardizing a basis of AM-machine acceptance criteria and processes in automotive applications.

ISO/ASTM NP 52945 -- *Additive manufacturing for Automotive — Qualification principles — Generic machine evaluation and specification of Key Performance Indicators for PBF-LB/M processes*

Joint Group 80 - Quality requirements for Additive Manufacturing in Building & Construction (Structural and Infrastructure elements)

JG80 defines the requirements for building and construction projects in which additive manufacturing techniques are used. The requirements are independent of the material and fabrication method used. The JG specifies the criteria for additive manufacturing processes and quality-relevant characteristics and factors along the process chain and defines activities and sequences within an additive manufacturing site/project. The JG covers all additive manufacturing technologies in building & construction of structural and infrastructure building elements for residential and commercial applications and follows an approach oriented to the manufacturing process.

ISO/ASTM PWI 52939 -- *Additive manufacturing for construction — Qualification principle — structural and infrastructure elements*

Joint Group 81 - Metallic Materials for Additive Manufacturing

JG 81 is a Joint Group for developing normative documents for metallic materials, defining their properties and specifying user requirements for additive manufacturing considering the different processes. The normative documents developed by JG 81 are intended for the use of all stakeholders for defining the minimum acceptance requirements of additively manufactured metallic components." Note: This JG does not deal with topics already covered by JG 56 and JG 58 but can refer to the standards developed within those JG or other ones.

ISO/ASTM PWI 52946 -- *Additive manufacturing — Feedstock materials — Stainless steel alloy UNS S31603 for Powder bed fusion*

ISO/ASTM PWI 52947 -- *Additive manufacturing — Feedstock materials Nickel alloy UNS N06625 for Powder bed fusion*

Joint Group 82 - Characterization of ceramic feedstock materials

JG 82 is a Joint Group for defines requirements for the characterization of ceramic feedstock materials such as fine ceramic powders, ceramic slurry, ceramic paste and ceramic feedstock materials with binder intended to be used in Additive Manufacturing, for example: - properties with regard to morphology (shape, crystallinity, particle size distribution);- physical properties (density, viscosity, compaction property, flowability);- chemical composition (purity, contents of trace elements).Referring to existing ISO and ASTM standards for testing, the documents developed in this JG provide additional requirements, recommendations and information required for Additive Manufacturing.

ISO/ASTM PWI 52940 -- *Additive manufacturing of ceramics – Feedstock materials – Characterization of ceramic slurry in vat photopolymerization*

ISO/TC 261 ADDITIVE MANUFACTURING PUBLISHED STANDARDS

Below is a list of recently published standards from ISO/TC 261. For a complete up to date list of published standards please see the following link.

ISO/ASTM 52950:2021	Additive manufacturing — General principles — Overview of data processing
ISO/ASTM 52942:2020	Additive manufacturing — Qualification principles — Qualifying machine operators of laser metal powder bed fusion machines and equipment used in aerospace applications
ISO/ASTM 52941:2020	Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
ISO/ASTM 52915:2020	Specification for additive manufacturing file format (AMF) Version 1.2
ISO/ASTM TR 52912:2020	Additive manufacturing — Design — Functionally graded additive manufacturing
ISO/ASTM 52911-1:2019	Additive manufacturing — Design — Part 1: Laser-based powder bed fusion of metals
ISO/ASTM 52911-2:2019	Additive manufacturing — Design — Part 2: Laser-based powder bed fusion of polymers
ISO/ASTM 52907:2019	Additive manufacturing — Feedstock materials — Methods to characterize metal powders
ISO/ASTM 52903-1:2020	Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 1: Feedstock materials
ISO/ASTM 52901:2017	Additive manufacturing — General principles — Requirements for purchased AM parts

STANDARDS + INNOVATION CASE STUDY

The Irish Manufacturing Research is a leading Research and Technology Organisation providing a portfolio of research, training and consultancy services to Industry across 4 thematic pillars: Digitisation, Sustainable Manufacturing, Design for Manufacturing, Automation and Advanced Control.

Atlantic Prosthetic and Orthotic Services are a specialist clinical prosthetics and orthotics provider operating throughout Ireland. They manufacture and fit specific prosthetic and orthotic devices for clients with a wide range of pathologies. Based at Westlink Oranmore, their main facility is only a short drive from Galway city. They also conduct other clinics throughout the West of Ireland, Midlands, Mid-West and Dublin. APOS Ltd employs internationally experienced, registered clinicians qualified in both prosthetics and orthotics.

Atlantic Prosthetic and Orthotic Services, together with Irish Manufacturing Research are collaborating to develop a digital workflow for Computer Aided Design (CAD) and Additive Manufacture (AM) for transtibial (through the shin) prosthetic sockets from scanned patient data.

The state of the art for this device is a ceramic reinforced polymer or thermoplastic formed over a modified casting taken from the patient's limb. Best practice for manufacture has been developed over decades, and individual clinical expertise is earned through many years of training and practice. The challenge is that assessment of structural integrity and confidence of fit of socket for current product is based on decades of clinical experience, which is not available for 3D printed product. A body of evidence of structural performance of the new material and geometric deviation for the new manufacturing process must be developed. Also, specification of the new manufacturing process is required.

In this collaboration, Standardized Management Systems, Manufacturing Specifications, Test Methods, and Product Specifications were all leveraged to develop the body of evidence that allowed clinicians to sign off on the patient matched medical devices.

All testing work needed to be relevant, and to be captured in an appropriate framework. The management system ISO 14971 was used to identify, control, and monitor risks to patient associated with development work. Risks to patient and to product performance were identified, and design requirements developed to control these risks. Corresponding Standards were identified and leveraged to determine measurable Critical to Quality design parameters (CTQ's).

Product Specifications for equivalent, 'off the shelf' (CE marked) devices provided useful detail on how to meet material related risks, specifically biocompatibility and flammability. Standardized test methods for structural integrity of CE marked product provided a foundation for engineers to develop and validate test methods for 'worst case' loading conditions identified in risk assessment.

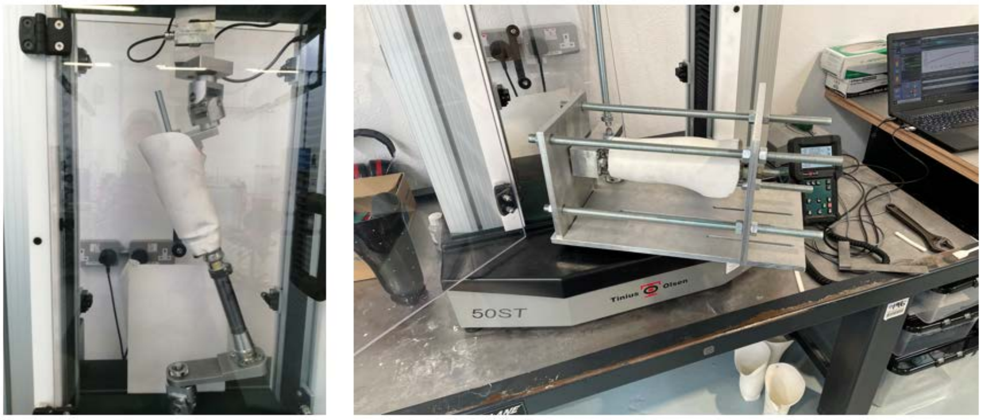

Figure 6 – Various tests based on or according to Standardized test methods. From left: Structural static proof strength test (16.2 ISO 10328), Structural torsional test (16.xx ISO 10328*)*

Having identified and verified adequate test methods see figure 6, to determine the capability of the design to meet patient needs, the second half of the project examined how to control the manufacturing process to meet the design intent. Control is achieved through verification and documentation of best practice for specific AM equipment, materials, data storage. A process map outlined in figure 7 was created during development, which became progressively more detailed as materials, technology, and software were identified.

Figure 7 – Process map created during development to help identify applicable standards

Standards applicable to each step of the process were identified, broken down, and mapped to each process step. This allowed development of operating procedures, including definition of best practice for operators, methods to track manufacturing process, and product inspection methods.

Standardization of Additive Manufacturing is under intense development, and AM standards specific to this project are (at the time of writing) informative. However, extant standards have been of substantial support. The AM Standards below were of particular value:

- ISO /ASTM 52950:2021 – Overview of data processing. This Standard supported identification of best practice for data handling;
- ISO/ASTM 52902:2019 – Geometric accuracy of a Manufacturing Process. This Standard supported qualification of machines used to build test coupons and product, and provided useful tools for ongoing process control;
- ISO/ASTM 52901:2017 – General requirements of AM parts. This standard supported risk control activities during design development and process validation; and
- ISO/ASTM 52921:2013 - Standard terminology for additive manufacturing — Coordinate systems and test methodologies. This standard supported communication and documentation of best practice clearly and unambiguously.

In summary, the potential for deviation and risk within a new design and manufacturing process was quantified, controlled, and documented by direct application and indirect leverage of a range of Standards. These results allow clinicians insight into the limits of additive manufacture material and digital design process with respect to the current state of the art, and to adopt technology with a high degree of confidence that risk to patient and product performance is controlled to an acceptable level.

CONCLUSION

Additive Manufacturing is poised to transform the manufacturing industry, due to Its extreme flexibility that not only allows for easy customization of goods but also eliminates assembly and inventories and enables products to be redesigned for higher performance. This impacts the carbon footprint of products by reducing material waste to negligible amounts. In recent times there has been an uptake of Additive Manufacturing by the Aerospace, Medical, Transportation and Energy Industries which is set to continue.

"***Thanks to disruptive technologies like 3D printing, Europe also needs to make the most of localisation as an opportunity to bring more manufacturing back to the EU in some sectors.***[9]"

Standards are one of the key drivers for this innovation, helping SME's and start-ups take advantage of the reducing costs in purchasing AM equipment and helping them to scale up through the use of standards resources such as technical reports, technical specifications, publicly available specifications and standards by technical committees at a regional European and further international level. This work will help enable the uptake and use of Additive Manufacturing to improve business processes, production systems and support the European Green Deal to make Europe climate neutral in 2050 by helping to mobilize the manufacturing industry towards a clean and circular economy.

[9] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A New Industrial Strategy for Europe

APPENDIX

Figure 8 – Lifecycle of a Standard

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