

ANNUAL REPORT 2022

NSAI TECHNICAL COMMITTEE NSAI/TC 49/SC 02 – ADDITIVE MANUFACTURING



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1 Committee Chair

NSAI

In 2020 Dr Noel Harris was appointment Chairman of this Committee by NSAI. Dr Harris is a Mechanical Engineering Lecturer at NUI Galway with teaching and research interests in Advanced Manufacturing and Materials (including Additive Manufacturing) and he is also a Funded Investigator in I-Form (SFI Advanced Manufacturing Research Centre).

2 Introduction

The ISO Standards Technical Committee <u>ISO/TC 261</u> was created in 2011 following an agreement with the American Industrial Standards Organisation (ASTM), and the European Standards Organisation (CEN), to have one global suite of Additive Manufacturing (AM) Standards. <u>ISO/TC 261</u> and the <u>ASTM F42</u> work in parallel to produce the AM Standards. The Secretariat of <u>ISO/TC 261</u> is held by the German National Standards Body (DIN).

These are first ever Standards to be

developed for Additive Manufacturing

The Standards being developed at present are the first generation of Standards for Additive Manufacturing.

3 Scope of TC

Standardization activities in the field of Additive Manufacturing are concern with processes, terms and definitions, process chains (Hard and Software), test procedures, quality parameters, supply agreements and a variety of fundamentals.

This Committee does not produce indigenous Irish Standards, instead the national committee is focussed on participating in the development of International Standards at an ISO level.

The International Standards published by ISO will then be adopted as European Standards. NSAI will adopt these European Standards as Irish Standards.

Committee Name	Committee Title
CEN/TC 438	Additive Manufacturing
ISO/TC 261	Additive Manufacturing
ISO/TC 261/WG 1	Terminology
ISO/TC 261/WG 2	Processes, systems and materials
ISO/TC 261/WG 3	Test methods and quality specifications
ISO/TC 261/WG 4	Data and Design
ISO/TC 261/WG 6	Environment, health and safety
ISO/TC 261/JWG 10	Joint ISO/TC 261 - ISO/TC 44/SC 14 WG Additive manufacturing
	in aerospace applications
ISO/TC 261/JWG 11	Joint ISO/TC 261 - ISO/TC 61/SC 9 WG, Additive manufacturing
	for plastics
ISO/IEC JTC 1/WG 12	3D Printing and Scanning

The committee mirrors the following European & international committees:

4 Structure and Membership

4.1 Structure

The Figure below illustrates the structure of the National Committee:



4.2 Members

The list below are the member organisations for the year 2022:

Organisation	Role
NSAI	Secretary
National University of Galway	Chairman
Boston Scientific	Committee member
SFI Confirm	Committee member
DePuy Synthetics	Committee member
Dromone Engineering	Committee member
Dublin City University	Committee member
НР	Committee member
Health Products Regulatory Authority	Committee member
SFI I-Form	Committee member
Irish Manufacturing Research	Committee member
Atlantic Technological University Sligo	Committee member
South East Technological University	Committee member
Johnson & Johnson	Committee member
Laser Prototype Europe (LPE)	Committee member
Nammo Ireland	Committee member
Neratek	Committee member
NSAI National Metrology Laboratory	Committee member
Rapid Innovation Unit (University of Limerick and the University Hospital Limerick Group)	Committee member
St James Hospital	Committee member
SteriPack Contract Manufacturing	Committee member
Stryker	Committee member
Technological University Dublin	Committee Member
Trinity College Dublin	Committee member

University College Dublin	Committee member
University of Limerick	Committee member
Zimmer Biomet	Committee Member
Inspire 3D	Committee Member

5 Summary of 2022 Activities

5.1 National

5.1.1 Meetings

The meetings were conducted via web-conferencing meeting facilities following on from the COVID-19 Pandemic, as well as to reduce the burden and environmental impact of travel for members. Committee members attended the following national meetings as follows:

Meeting No.	Date	Minutes Reference ** optional**
1	10 th March 2022	N 232
2	09 th September 2022	N 257

5.1.2 National Work

The Standards Committees does not draft National Standards, instead, the Committee is focussed on international standards development. All of the ISO/TC 261 Standards are being adopted as European Standards and will therefore be published as Irish Standards.

5.2 International/Regional

5.2.1 Meetings

Committee members attended international meetings as follows:

Committee Name	Location	Date	No. of Attendees
ISO/TC 261	Online	1 st April 2022	2
ISO/TC 261	Online	23 rd September 2022	1

COVID-19 and environmental considerations impacted on Irish delegates travelling to the ISO/TC 261 meetings in 2022.

5.2.2 International/Regional Work

Ireland is committed to following and inputting into the development of the AM ISO/ASTM Standards. The National Committee reviews, comments and votes on each of the public comment drafts circulated by ISO/TC 261.

Ireland has several experts participating in the Working Groups that are drafting the Standards.

Within the International Joint Technical Committee for Information Technology, <u>ISO/IEC JTC 1</u>, there is a Working Group, WG 12 focused on 3D Printing and Scanning. Ireland is following this work.

5.2.3 International/Regional Standards Reviewed

ISO/ASTM TR 52906:2022, Additive manufacturing — Non-destructive testing — Intentionally seeding flaws in metallic parts

ISO/ASTM 52909:2022, Additive manufacturing of metals — Finished part properties — Orientation and location dependence of mechanical properties for metal powder bed fusion

ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data

ISO/ASTM 52925:2022, Additive manufacturing of polymers — Feedstock materials — Qualification of materials for laser-based powder bed fusion of parts

ISO/ASTM DIS 52908, Additive manufacturing of metals — Finished Part properties — Postprocessing, inspection and testing of parts produced by powder bed fusion

ISO/ASTM DIS 52927, Additive manufacturing — General principles — Main characteristics and corresponding test methods

ISO/ASTM DIS 52926-1, Additive Manufacturing of metals — Qualification principles — Part 1: General qualification of operators

ISO/ASTM DIS 52926-2, Additive Manufacturing of metals — Qualification principles — Part 2: Qualification of operators for PBF-LB

ISO/ASTM DIS 52926-3, Additive Manufacturing of metals — Qualification principles — Part 3: Qualification of operators for PBF-EB

ISO/ASTM DIS 52926-4, Additive Manufacturing of metals — Qualification principles — Part 4: Qualification of operators for DED-LB

ISO/ASTM DIS 52910.2, Additive manufacturing — Design — Requirements, guidelines and recommendations

ISO/ASTM DIS 52904.2, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications

ISO/ASTM DIS 52939, Additive Manufacturing for construction — Qualification principles — Structural and infrastructure elements

ISO/PWI 27548, Additive manufacturing of plastics — Environment, health and safety — Test method for determination of particle and chemical emission rates from desktop 3D printer material extrusion

ISO/ASTM PWI 52929, Additive manufacturing of metals — Powder bed fusion — Presentation of material properties in material data sheets

ISO/ASTM PWI 52948, Additive manufacturing for metals — Non-destructive testing and evaluation — Imperfections classification in PBF parts

5.2.4 International/Regional Voting Results

The committee voted on 48 out of the 81 international votes in 2022.

5.3 Regulatory Development/Update

3D Printers – also known as Additive Manufacturing machinery are a means of production that can be used to manufacture various products for different applications. 3D printers are among the so-called 'harmonised products' for which there is specific EU product harmonisation legislation in place. In particular, they fall under the definition of machinery under the Machinery Directive 2006/42/EC. Thus, manufacturers must ensure the compliance of 3D Printers with the



applicable essential health and safety requirements of the Machinery Directive, compose a technical file and affix the CE-marking before placing them on the EU internal market.

EU Legislation impacting on 3D Printers

Besides the Machinery Directive, other EU pieces of legislation may apply to 3D printers; i.e. the Electromagnetic Compatibility Directive 2014/30/EC, and EU legislation on chemicals, WEEE2012/19/EU, RoHS II 2011/65/EU Directive and Directive (EU) 2017/2102, and REACH 1907/2006/EU.

In particular, on 15 December 2022, negotiators from European Parliament and Council of the EU reached a provisional political agreement on a new Machinery Regulation¹, adapting the rules to new market developments and risks originating from emerging technologies.

The new Regulation envisages that six categories of machinery will be included in Annex I, thereby subject to third party conformity assessment, supported by strong procedures for updating the Annex with additional categories. The new Regulation will apply from 42 months after entry force, thus giving companies time to adjust to the new requirements.

Products designed and manufactured in accordance with the Machinery Directive 2006/42/EC can circulate freely throughout the internal market and Member States may not introduce additional and/or diverging requirements regarding the manufacturing and placement on the market of such products².

Other standards in development impacting on 3D Printers

EN 13445-14, Unfired pressure vessels -Part 14: Additional requirements for pressure equipment and pressure components fabricated with additive manufacturing method which is under preparation. This standard is expected to be harmonised with the Pressure Equipment Directive.

ISO/ASTM AWI 52938-1, AM of metals — Environment, health and safety — Part 1: Safety requirements for PBF-LB machines, will be harmonized with Machinery Directive.

6 Irish Publications/Reviews

6.1 Publications

National Standards are not produced by this committee as it is focussed on the development of International Standards, which will be published as European Standards and then adopted as Irish Standards.

6.2 Reviews

The Committee reports to the Manufacturing & Machinery Standards Consultative Committee and the Chairman participates in the work of this group. It was 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 a Joint Group (JG). Only in case the other organization is not interested, the standard will be developed "alone".

¹ European Commission, "Regulation on Machinery Products", 2021, [Online]. Available on: https://eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021PC0206&from=EN. [Accessed on: 08th February 2023]

² European Commission, "Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19?", 2020. [Online]. Available on: https:// https://health.ec.europa.eu/system/files/2020-09/md_mdcg_qa_3d_ppp_covid-19_en_0.pdf [Accessed on: 05th January,2022]

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.

7 Work programme for 2023 onwards

7.1 ISO/TC 261

NSAI

ISO/CD 27548, Additive manufacturing of plastics — Environment, health and safety — Test method for determination of particle and chemical emission rates from desktop 3D printer material extrusion

ISO/ASTM DIS 52902, Additive manufacturing — Test artifacts — Geometric capability assessment of additive manufacturing systems

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

ISO/ASTM DIS 52904, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications

ISO/ASTM DTR 52905, Additive manufacturing of metals — Non-destructive testing and evaluation — Defect detection in parts

ISO/ASTM DIS 52908, Additive manufacturing of metals — Finished Part properties — Postprocessing, inspection and testing of parts produced by powder bed fusion

ISO/ASTM DIS 52909, Additive manufacturing — Finished part properties — Orientation and location dependence of mechanical properties for metal powder bed fusion

ISO/ASTM DIS 52910, Additive manufacturing — Design — Requirements, guidelines and recommendation

ISO/ASTM DIS 52911-3, Additive manufacturing — Design — Part 3: PBF-EB of metallic materials

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

ISO/ASTM AWI 52919, Additive manufacturing — Qualification principles — Test method for sand molds for metal casting

ISO/ASTM DIS 52920, Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing processes and production sites

ISO/ASTM DIS 52924, Additive manufacturing of polymers — Qualification principles — Classification of part properties

ISO/ASTM AWI 52919, Additive manufacturing — Qualification principles — Test method of sand mold for metal casting

ISO/ASTM DIS 52926-1, Additive Manufacturing of metals — Qualification principles — Part 1: General qualification of operators

ISO/ASTM DIS 52926-2, Additive Manufacturing of metals — Qualification principles — Part 2: Qualification of operators for PBF-LB

ISO/ASTM DIS 52926-3, Additive Manufacturing of metals — Qualification principles — Part 3: Qualification of operators for PBF-EB



ISO/ASTM DIS 52926-4, Additive Manufacturing of metals — Qualification principles — Part 4: Qualification of operators for DED-LB

ISO/ASTM DIS 52926-5, Additive Manufacturing of metals — Qualification principles — Part 5: Qualification of operators for DED-Arc

ISO/ASTM DIS 52927, Additive manufacturing — General principles — Main characteristics and corresponding test methods

ISO/ASTM DIS 52926-3, Additive Manufacturing of metals — Qualification principles — Part 3: Qualification of operators for PBF-EB

ISO/ASTM DIS 52926-4, Additive Manufacturing of metals — Qualification principles — Part 4: Qualification of operators for DED-LB

ISO/ASTM DIS 52926-5, Additive Manufacturing of metals — Qualification principles — Part 5: Qualification of operators for DED-Arc

ISO/ASTM DIS 52927, Additive manufacturing — General principles — Main characteristics and corresponding test methods

ISO/ASTM DIS 52928, Additive manufacturing of metals— Feedstock materials — Powder life cycle management

ISO/ASTM AWI 52929, Additive manufacturing of metals — Powder bed fusion — Presentation of material properties in material data sheets

ISO/ASTM CD 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

ISO/ASTM DIS 52935, Additive manufacturing of metals – Qualification principles – Qualification of AM coordination personnel

ISO/ASTM 52936-1, Additive manufacturing of polymers — Qualification principles — Part 1: General principles and preparation of test specimens for PBF-LB

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

ISO/ASTM DIS 52939, Additive Manufacturing for construction — Qualification principles — Structural and infrastructure elements

ISO/ASTM CD 52940, Additive manufacturing of ceramics — Feedstock materials — Characterization of ceramic slurry in vat photopolymerization

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

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

ISO/ASTM AWI 52948, Additive manufacturing for metals — Non-destructive testing and evaluation — Imperfections classification in PBF parts

ISO/ASTM DTR 52952, Additive Manufacturing of metals — Feedstock materials — Correlating of rotating drum measurement with powder spreadability in PBF-LB machines

ISO/ASTM PWI 52947, Additive Manufacturing – Feedstock materials – Nickel alloy UNS N06625 for Powder bed fusion

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

ISO/ASTM PWI 52952, Additive Manufacturing of metals — Feedstock materials — Correlating of rotating drum measurement with powder spreadability in PBF-LB machines

ISO/ASTM PWI 52953, Additive manufacturing – Data – Registration of Process-Monitoring and Quality-Control Data

7.2 ISO/IEC JTC 1/WG 12 – 3D Printing & Scanning

ISO/IEC FDIS 3532-1, Information technology — Medical image-based modelling for 3D printing — Part 1: General requirements

ISO/IEC DIS 3532-2, Information technology — Medical image-based modelling for 3D printing — Part 1: General requirements

ISO/IEC AWI 8801, Information Technology — 3D Printing and Scanning-- 3D scanned and labeled data Standard Operating Procedure (SOP) for evaluation of modelling from 3D scanned data

ISO/IEC AWI 8803, Information Technology — 3D Printing and Scanning — accuracy and precision evaluation process for modeling from 3D scanned data

ISO/IEC AWI 16466, Information Technology — 3D Printing and scanning — Assessment methods of 3D scanned data for 3D printing model

8 Additional Information

Ireland was due to host ISO/IEC JTC1 between the 09th to the 13th of May 2022 however, due to Covid-19 Pandemic restrictions, this event is cancelled.

The Secretary worked with members of the committee to produce a document informative in nature and providing 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). The document is entitled *Introduction to NSAI/TC 49/SC 2 & standardization for Additive Manufacturing*.

The document takes into consideration the findings of the Organization for Economic Cooperation and Development (OECD) on the importance of engaging in standards development for SMEs, and stresses on the importance of standards by emphasizing the connections and benefits achievable through standards, that can positively affect innovation.

In order to showcase the importance of standards for innovation, a case study is included in this document, demonstrating 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.

This document is publicly available from the NSAI website at <u>Introduction to NSAI/TC 49/SC 2</u> & standardization for Additive Manufacturing.

Also of relevance is the Amaze Project, which is an explainer Horizon 2020 project that has formed the basis of new standards development including a new benchmarking process based on a "suite" of test artefacts to assess: geometrical accuracy, surface finish, resolution, density, microstructure and productivity - ASTM-F42/ISO-TC 261 Joint Group 52 and standards for NDT



of AM parts being developed in the - ASTM-F42/ISO-TC 261 Joint Group 59. The Amaze Exploitable plan was even broken down into 7 themes, one of which included engagement with Standards Bodies.