ANNUAL REPORT 2023

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

Contents

1 Chair

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 ISO/TC 261 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 AM Standards. ISO/TC 261 and the ASTM F42 work in parallel to produce the AM Standards. The Secretariat of ISO/TC 261 is held by the German National Standards Body (DIN).

These are the 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 in the field of Additive Manufacturing (AM) is concerned with processes, terms and definitions, process chains (Hard and Software), test procedures, quality parameters, supply agreements and various fundamentals.

This committee does not produce indigenous Irish Standards. The national committee's role is to participate in the development of International Standards at an ISO level.

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

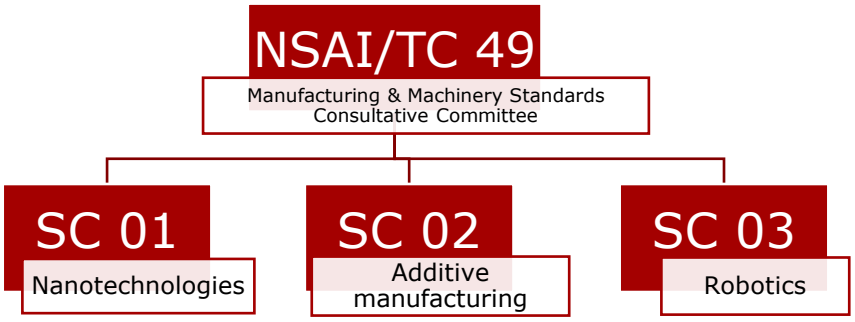
The committee mirrors the following European & international committees:

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

Structure and Membership

3.1 Structure

The Figure below illustrates the structure of the National Committee:



3.2 Members

The list below are the members for the year 2023:

Organisation	Role
NSAI	Secretary
National University of Galway	Chairman
Boston Scientific	Committee member
Atlantic Technological University	Committee member
Confirm	Committee member
Croom Medical	Committee member
DePuy Synthetics	Committee member
Dromone Engineering	Committee member
Dublin City University	Committee member
HP	Committee member
HPRA	Committee member
Harcourt Technologies Ltd	Committee member
IDA	Committee member
I-Form	Committee member
Irish Manufacturing Research	Committee member
Johnson & Johnson	Committee member
Laser Prototype Europe (LPE)	Committee member
Nammo Ireland	Committee member
Neratek	Committee member
NSAI NML	Committee member
Rapid Innovation Unit	Committee member
Richard Nolan Civil Engineering	Committee member
South East Technological University	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

Summary of 2023 Activities

3.3 National

3.3.1 Meetings

The meetings were conducted via web-conferencing meeting facilities in order to maximise attendance, 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	22nd March 2023	N 330
2	13th September 2023	N 343

3.3.2 National Work

The Standards Committees does not draft any National Standards. All of the ISO/TC 261 Standards are being adopted as European Standards and will therefore be published as Irish Standards.

3.4 International/Regional

3.4.1 Meetings

Committee members attended international meetings as follows:

Committee Name	Location	Date	No. of Attendees
ISO/TC 261	Penn State University (USA)	31st March 2023	0
ISO/TC 261	Incheon Korea	23rd September 2023	0

The above meetings took place in person. Experts from the committee attended ASTM F42 meetings as through the ASTM International Additive Manufacturing Centre of Excellence, they have funded research that feeds directly into ISO/ASTM proposed work items.

3.4.2 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, ISO/IEC JTC 1, there is a Working Group, WG 12 focused on 3D printing and Scanning. Ireland is following this work.

3.4.3 International/Regional Standards Reviewed

ISO/ASTM 52902:2023, *Additive manufacturing — Test artefacts — Geometric capability assessment of additive manufacturing systems*

ISO/ASTM TR 52905:2023, *Additive manufacturing of metals — Non-destructive testing and evaluation — Defect detection in parts*

ISO/ASTM TR 52908:2023 Additive manufacturing of metals — Finished part properties — Post-processing, inspection and testing of parts produced by powder bed fusion

ISO/ASTM 52920:2023, *Additive manufacturing — Qualification principles — Requirements for industrial additive manufacturing processes and production sites*

ISO/ASTM FDIS 52924:2023, *Additive Manufacturing of polymers — Qualification principles — Part 1: General qualification of operators*

ISO/ASTM 52926-*1:2023, Additive Manufacturing of metals — Qualification principles — Part 1: General qualification of operators*

ISO/ASTM 52926-2:2023*, Additive Manufacturing of metals — Qualification principles — Part 2: Qualification of operators for PBF-LB*

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

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

ISO/ASTM FDIS 52933*, Additive manufacturing — Environment, health and safety — Test method for the hazardous substances emitted from material extrusion type 3D printers in the non-industrial places*

FprEN SO/ASTM 52933*, Additive manufacturing — Environment, health and safety — Test method for the hazardous substances emitted from material extrusion type 3D printers in the non-industrial places*

ISO/ASTM FDIS 52935, *Additive Manufacturing of metals — Qualification principles — Qualification of coordination personnel*

FprEN ISO/ASTM 52935, *Additive Manufacturing of metals — Qualification principles — Qualification of coordination personnel*

prEN ISO ASTM 52937, *Additive manufacturing of metals — Qualification principles — Qualification of designers*

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

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

ISO/ASTM 52945:2023 *Additive manufacturing for automotive — Qualification principles — Generic machine evaluation and specification of key performance indicators for PBF-LB/M processes*

ISO/ASTM AWI 52953, *General principles — Registration of geometric data acquired from process-monitoring and for quality control*

ISO/ASTM 52960, *Additive manufacturing — Qualification principles — Optical properties of fixed resolution UV engine*

prEN ISO/ASTM 52960, *Additive manufacturing — Qualification principles — Optical properties of fixed resolution UV engine*

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

3.4.4 International/Regional Voting Results

The committee voted on 30 out of the 91 international votes in 2023.

3.5 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.

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.

On the 29th June 2023 the Machinery Regulation (Regulation (EU) 2023/1230) was published.

This text replaces Machinery Directive 2006/42/EC. The Machinery Regulation intends to better cover new technologies such as autonomous mobile machinery (robots), internet of things with connected equipment, or artificial intelligence (AI), where specific modules of AI using learning techniques ensure safety functions.

The new text will enter into force 42 months after its publication, which means **20 January 2027**. Exceptions pertain to some rules applying to Member States, such as the notification of conformity assessment bodies, definitions of penalties from each EU, etc. There are no transitional provisions between the Machinery Directive and the Machinery Regulation. This means that manufacturers will have to comply with the Machinery Directive until 19 January 2027 and with the new Machinery Regulation as of the following day.

Main changes:

The Machinery Regulation introduces relevant changes, among which:

- Legal status: as a Regulation, the Machinery Regulation provides more harmonisation as well as direct application throughout the EU. Manufacturers will not need to wait for each country's transposition in national law, which may introduce stronger national requirements.
- New Legislative Framework: the Machinery Regulation follows the principles of the New Legislative Framework, which sets out the main rules for the accreditation of conformity assessment bodies and for the market surveillance framework.
- Paperless: manufacturers can provide product instructions in digital format. If the machine is intended for non-professional users, a paper document containing the main safety information needs to be provided.
- Common specifications: the Machinery Regulation gives rules for the development of common specifications, in case there are issues to develop a harmonised standard for a specific machine.

- Substantial modification: the notion of 'substantial modification' is introduced, targeting evolutions/modifications brought out by the final user, and which generate a change of the significant hazards associated with the modified machine.
- Conformity Assessment: the general principle for the conformity assessment of the machinery is self-compliance. Machinery indicated in a list included in the Regulation must undergo validation through notified bodies (external accredited centres). Under the Machinery Directive there was the possibility to apply for self-compliance when an existing harmonised standard covers all its relevant hazards; under the Machinery Regulation this possibility was revoked for some specific machinery or components. In particular, power take-off (PTO) drive shafts and their guards or simply guards to PTOs, when they are placed alone on the market, will need to be validated by a notified body.
- Machine learning: systems containing 'fully or partially self-evolving behaviour containing machine learning approaches' are now in the list of machinery requiring the validation by a notified body. The upcoming AI Regulation, when published, will consider these systems as high-risk Artificial Intelligence and impose additional requirements.
- Partly completed machinery will need to comply with the requirements of the Machinery Regulation before they are incorporated in the whole machinery.

Technical Requirements:

The technical requirements are gathered in a specific annex to the Machinery Regulation. Compared to the Machinery Directive, the numbering remains unchanged. Here below is an overview of the main changes.

Protection against corruption/Safety and reliability of control systems: The Machinery Regulation extends the protection against external influences, when they would result in a dangerous behaviour of the machine. This impacts both the protection of the machinery and the behaviour of control systems (cybersecurity). The manufacturer is required to identify key data or key software, the versions of the software installed, the proof of interventions. The upcoming publication of the Cyber-Resilience Act should cover this in detail. On remote controls, a communication or a connection failure must not lead to a dangerous situation either.

Manufacturers of **mobile machinery** will need to:

- Provide a filtered cab for machines with ride-on driver, when the main use of the machine is the application of hazardous substances. This is typically the case for self-propelled sprayers.
- Provide an audible and visual warning when the seat belt is not fastened on machines presenting a risk of overturning. Additionally, where there is a significant risk of roll or tip over and its restraint system is not used it shall not be possible for the machinery to move.
- Take into account the possibility of contact with overhead power lines. Manufacturers will need to do this firstly with measures to avoid the contact or the creation of an electric arc, and secondly through solutions to prevent electrical hazards in case the contact occurs.

For **autonomous mobile machinery**, a set of new requirements was introduced:

- The possibility to have a supervisor and a related supervisory function. This role intends to monitor the actions of the robot when it is in autonomous mode. The robot must send information and alerts to the supervisor who has the possibility to stop, re-start the machine in autonomous mode, or to bring it to a safe position.

- The robot must travel safely in a defined working area (also for the automatic charging of the batteries), using either a physical borders or obstacle detection.

Finally, for **machines fitted with fully or partially self-evolving logic or behaviour**, the risk assessment will need to take into account the behaviour of the machine after it is placed on the market. This measure targets in particular the movement space and the tasks it will perform. The manufacturer will need to ensure good connection between the operator and the machinery, when it comes to communication and to forces used to carry out a task. Finally, the data related to a software of a safety function taking decision will have to be stored each time a decision is taken.

Next steps:

Now that the text of the Machinery Regulation has been published there are two important steps that will follow:

- Development of the Application Guide of the Machinery Regulation, in order to avoid diverging interpretations of the text
- Update of the harmonised standards. Each standard will need at least the addition of an annex making the link between the requirements of the Regulation and the requirements of the standards. The European Commission is working with standardisation instances on a Standardisation Request to officially allow this work.

The full text of the Machinery Regulation can be read in all the official languages of the EU at this link:

EUR-Lex - 32023R1230 - EN - EUR-Lex (europa.eu)

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 products[1].

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.

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

[1] 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,2023]

4 Irish Publications/Reviews

4.1 Publications

National Standards will not be produced by this committee as the International Standards will be published as European Standards adopted as Irish Standards.

4.2 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. Only in case the other organization is not interested, the standard will be developed "alone".

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.

5 Work programme for 2024 onwards

5.1 ISO/TC 261

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

ISO/ASTM FDIS 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 recommendations*

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

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

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

ISO/ASTM AWI 52922, *Additive manufacturing — Design — Directed energy deposition of metals*

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

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

ISO/ASTM FDIS 52933, *Additive manufacturing — Environment, health and safety — Test method for the hazardous substances emitted from material extrusion type 3D printers in the non-industrial places*

ISO/ASTM CD 52937, *Additive Manufacturing of metals — Qualification principles — Qualification of designers*

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

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

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

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

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

ISO/ASTM WD TS 52949 Additive manufacturing of metals — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-EB equipment

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

ISO/ASTM DIS 52953, Additive manufacturing for metals — General principles — Registration of geometric data acquired from process-monitoring and for quality control

ISO/ASTM CD 52957, Additive Manufacturing — Design — Parts using ceramic materials

ISO/ASTM CD TR 52958, Additive Manufacturing of Metals — Powder Bed Fusion (PBF) — Best Practice for In-Situ Flaw Detection and Analysis for Laser-based PBF

ISO/ASTM DIS 52959, Additive Manufacturing of metals — Test artefacts — Compression validation coupons for lattice designs

ISO/ASTM AWI 52965, Additive manufacturing for metals — Qualification principles — Test method for indentation plastometry

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

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

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

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

ISO/IEC AWI 23955, *Information technology — 3D Printing and Scanning — Technical requirements for product data protection of Additive Manufacturing Service Platform (AMSP)*

ISO/IEC NP 24956, *Information Technology — 3D Printing and Scanning — Phantom-based evaluation methods for 3D printing modeling software*

6 Additional Information

The Secretary worked with members of the committee to produce a document informative in nature, which 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).

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

The findings are linked to the Organization for Economic Co-operation and Development (OECD) on the importance of engaging in standards development for SMEs, which report stresses 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 employed, in this document 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 Amaze project is showcased in the document as an exemplar 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.