

ANNUAL REPORT 2023

NSAI CONSULTATIVE COMMITTEE NSAI/TC 49 – MANUFACTURING & MACHINERY



Contents

| 1 | C | hai | r2 |
|-------------|-----|-------|--|
| 2 | I | ntro | duction2 |
| 3 | S | Сор | e of SCC |
| 4 | S | Struc | cture and Membership4 |
| | 4.1 | | Structure |
| | 4.2 | - | Members5 |
| 5 | S | Sum | mary of 2023 Activities5 |
| | 5.1 | | National5 |
| | 5 | 5.1.1 | Meetings |
| | 5 | 5.1.2 | 2 National Work |
| | 5.2 | - | International/Regional6 |
| | 5 | 5.2.1 | Meetings 6 |
| | 5 | 5.2.2 | 2 International/Regional Work 6 |
| | 5 | 5.2.3 | 3 International/Regional Standards Reviewed7 |
| | 5 | 5.2.4 | International/Regional Voting Results7 |
| | 5.3 | ; | Regulatory Development/Update 7 |
| 6 Irish Pul | | rish | Publications/Reviews |
| | 6.1 | | Publications |
| | 6.2 | - | Reviews 10 |
| 7 | V | Vork | c programme for 2024 onwards 10 |
| 8 | А | ddit | tional Information 10 |



1 Chair

In 2020 NSAI offered the position of Chairman to Dr Matt Cotterell, who accepted the role and chaired the first meeting of the Committee on the 2021-11-17.

Dr Matt Cotterell is Head of the Munster Technological University (MTU) School of Mechanical, Process & Electrical Engineering. Dr Cotterell is involved in the development and management of programmes and research within the constituent Departments in the School: Mechanical, Biomedical & Manufacturing Engineering; Process, Energy & Transport Engineering; Electrical & Electronic Engineering and the Centre of Craft Studies.

2 Introduction

The Manufacturing and Machinery Standards Consultative Committee was established by the Board of NSAI to facilitate and manage this sector of Industry. This Consultative Committee can propose the establish of a Technical Committee or Sub-Committee where it deems it necessary to track the standardization activities in a specific area. It provides a strategic direction on new opportunities and challenges arising from Industry 4.0 for standardization, including priority areas for NSAI national mirror committees to focus on for maximum national impact. In 2019, Future Jobs Ireland acknowledged these challenges and opportunities, by publishing Ireland's Industry 4.0 Strategy 2020-2025 the Government's economic pathway to ensure that Ireland is well placed to prosper in a rapidly changing global economy. This Consultative Committee advise and provide guidance on the key strategics actions assigned to NSAI in this National Strategy.

As Industry 4.0 is critical to developing Ireland's manufacturing sector while helping to maintain it competitiveness. Standards are a key enabler for the digitisation of the manufacturing industry. Ensuring that Ireland is at the forefront of emerging technologies, they help provide indigenous companies and academia with a voice on the European and International Standardization Platforms. As manufacturing processes are now being digitized there is a significant opportunity for Ireland and NSAI to help shape the future of the sector which is heavily dependent on standards.

According to the Central Statistics Office figures, in 2019 the industrial economy in Ireland contributed more than one third of Gross Value Added (GVA) 34.9% vs. the EU average of 19.7% while the previous year performance shows a continuation of 35.1% vs. EU average of 19.5%. The top 10 industrial enterprises accounted for 51.7% of all production in Ireland in 2019. While the top 50 industrial enterprises in Ireland represented 75.4% of the overall NSV with a value of €101.5 billion ¹.

This Consultative Committee have the opportunity for additional representation in the standardization programme by National Technical Bodies, against the background of national importance and developments in the sector.

 $^{^{1}}$ Irish Industrial Production by Sector 2019 - CSO - Central Statistics Office

3 Scope of SCC

This Manufacturing & Machinery Standards Consultative Committee focuses on supporting Irish business through optimising a standards vision to provide the Irish manufacturing community with relevant standards related information and information on current and future standardization activities.

The Manufacturing & Machinery Standards Consultative Committee is dedicated in providing NSAI with expert advice on general strategy, industry trends relating to Manufacturing and Industry 4.0 and how standards can support the Irish manufacturing industry. This will create a strategic framework for prioritizing standards development work and resource deployment.

The Manufacturing & Machinery Standards Consultative Committee does not produce indigenous Irish Standards. This Consultative Committee gives guidance on the development of a coherent NSAI standards development strategy in Advanced Manufacturing and Industry 4.0 by advising on alignment and linkages with other relevant national policy initiatives and academic and enterprise developments. The Consultative Committee is tasked with the following:

The Consultative Committee works to understand the overview of International and European standardization in 'Advanced Manufacturing', including Smart / Digital Manufacturing (aka 'Industry 4.0'), IIoT, Robotics, Additive Manufacturing and enabling technologies such as Cloud Computing and Distributed Platforms and Artificial Intelligence:

- Consider European and international advanced manufacturing technology standardization programmes and national participation in such programmes;
- ✓ Advice and support NSAI on matters, relevant to Manufacturing and Industry 4.0 standardization;
- ✓ Aid NSAI on its dissemination of information of significant value to the Irish manufacturing industry and relevant stakeholders;
- ✓ Assist NSAI in matters of strategic importance by providing guidance of tactical relevance on operational matters, European Regulations and National Positioning ballots;
- Contribute to the development of national policies and strategies, by providing recommendations linked to current standardisation activities, during the public consultation phase.

The Consultative Committee monitors the activities of NSAI Standards Committees within the Manufacturing Sector. Recommendations can be made to NSAI highlighting specific areas of standardization that may be strategical beneficial for the Irish Manufacturing Sector.

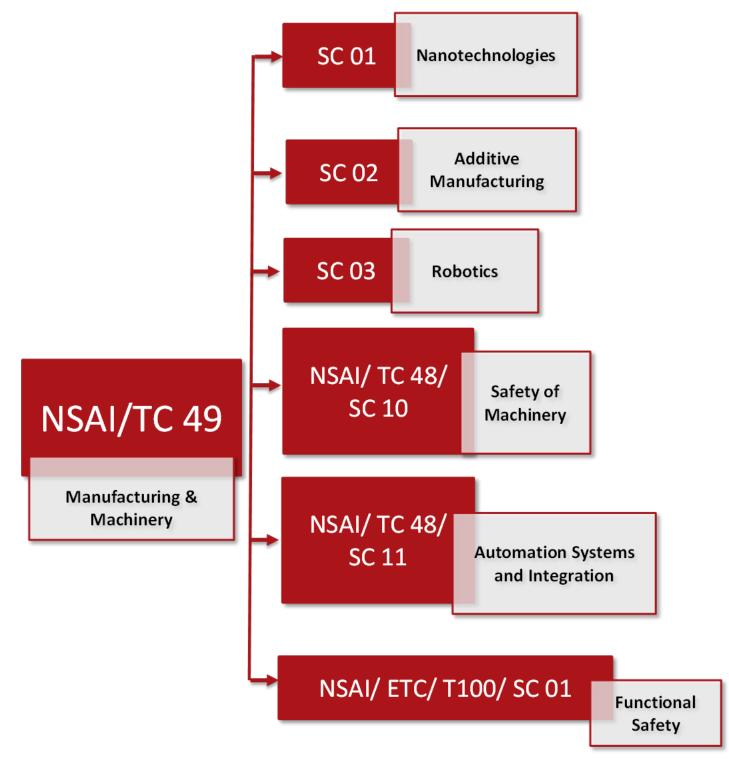
The Consultative Committee advises NSAI in implementing the strategic actions from applicable Irish Government Strategies and Ireland's Industry 4.0 Strategy 2020-2025, see Annex A.

The Consultative Committee plays an advisory role to NSAI providing standards related information that will increase Irish manufacturing companies and SME readiness for future production, while seeking to take full advantage of the evolving transformation opportunities for Industry 4.0 and adopting new manufacturing advancements.

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 members for the year 2023:

| Organisation | Role |
|------------------------------------|------------------|
| NSAI | Secretary |
| MTU | Chairman |
| Enterprise Ireland | Committee member |
| IBEC | Committee Member |
| IDA | Committee member |
| Pilz | Committee member |
| IMR | Committee member |
| Dromone Engineering Limited | Committee member |
| SFI Confirm | Committee member |
| NUI Galway | Committee member |
| Analog Devices | Committee member |
| Johnson & Johnson | Committee member |
| DETE | Committee member |

5 Summary of 2023 Activities

5.1 National

5.1.1 Meetings

In 2023 there were no committee meetings as the following critical actions needed to be fulfilled in order to support the progress of the committee and further develop its strategic work and maximise its effectiveness:

- Throughout 2023, the Secretary focused on enhancing the membership of this committee by growing the external stakeholders to include key people of critical importance to industrial policy.
- The Secretary developed a repository of informative technology reports, research projects, emerging EU Legislation, draft standardisation requests, policy documents, presentations, and trend reports, with the intention of boosting the knowledge valorisation of the committee, thus enabling the Irish Manufacturing base to create a compelling and distinctive reputation. This knowledge valorisation process organically grew the membership of the committee and strengthened its reputation, through providing key stakeholders with the information they need when they need it.
- The Chair and Secretary regularly meet through 2023 to identify key personnel and support key Industry 4.0 events and members linked to the Irish Manufacturing Council, I-Forum, IBEC's Engineering Industries Ireland and Universities.
- Lectures were provided to undergraduates on current standardisation activities, emerging legislation and how to engage in the standardisation process, all of which is of tactical importance to supporting the manufacturing Industry by preparing students for critical roles. The presentations given also promoted European priorities such as the <u>code of practice on standardization for researchers</u>, that has the potential to generate through scalable value from standardisation for Irish Manufactures, involved in innovative projects with Researchers.

5.1.2 National Work

The Standards Committee will not draft any National Standards. The Manufacturing & Machinery Standards Consultative Committee is dedicated in providing NSAI with expert advice on general strategy, Industry trends relating to Manufacturing and Industry 4.0 and how standards can support the Irish manufacturing industry. This creates a strategic framework for prioritizing standards development work and resource deployment.

5.2 International/Regional

5.2.1 Meetings

The Standards Committee is not a National Mirror Committee for any ISO, CEN or IEC Committee. This Committee is a Standards Consultative Committee and is dedicated in providing NSAI with expert advice on general strategy, Industry trends relating to Manufacturing and Industry 4.0 and how standards can support the Irish manufacturing industry.

5.2.2 International/Regional Work

The Secretary produced a Sectoral Study of Standards in Manufacturing to assist the Consultative Committee that provides an overview of the Industry 4.0 from a standards perspective, following the structure of 15 areas of focus.

It starts with a summary on what the "fourth industrial revolution" is, followed by an overview of the manufacturing sector in Ireland in 2019 and information on Ireland's digital transformation. It highlights European Policies and National Strategies and their potential impact on the industry as well as enabling changes to the current landscape.

The report highlights the importance of standards by emphasizing on the links and benefits achievable through standards and innovation, that can positively affect standardization. It also mentions some of the current funding mechanism that are available to support this action. The German Standardization Roadmap is referred to for its overview of standards and specifications relevant to Industry 4.0 with some strategic recommendations to address gaps and normative inconsistencies.

The relationship between standards and regulations is then detailed, exploring also how standards can support organizations' objectives. Specific attention is given to the Machinery Directive, where a comprehensive view into the latest ICT and emerging technologies from the "Impact assessment study on the revision of Directive 2006/42/EC on machinery" is listed along with its current shortcomings. The future revision of the directive is then examined through the recommendations of the Machinery Working Group.

The current standards and standardization process is then comprehensively examined and eleven enabling technologies are listed. The current and future applications of these technologies are investigated and linked to standards committees. The key relationships between emerging technologies and standardization are addressed and links are provided to published standards and current standardization activities.

Finally, this document maps the standardization activities of the European standards setting organizations, the International Organization for Standardization, and the International Electrotechnical Commission with respect to NSAI's National Mirror Committees.

This document is publicly available from NSAI's website at the following link <u>Sectoral Study of</u> <u>Standards in Manufacturing</u>.

5.2.3 International/Regional Standards Reviewed

The Standards Committee is not a National Mirror Committee for any ISO, CEN or IEC Committee. This Committee is a Standards Consultative Committee and is dedicated in providing NSAI with expert advice on general strategy, Industry trends relating to Manufacturing and Industry 4.0 and how standards can support the Irish manufacturing industry.

5.2.4 International/Regional Voting Results

The Committee is an advisory Committee and does not vote on international standards.

5.3 Regulatory Development/Update

In 2021, the European Commission presented its proposal for a new Regulation on machinery products. The main legal changes are the transformation of the legislation into a Regulation, with alignment to the New Legislative Framework. The regulation will facilitate the homogenous application throughout the EU. and an alignment with the horizontal rules on the responsibilities of economic operators, market surveillance, accreditation, as well as the role of notified bodies and conformity assessment procedure.

In 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 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
- 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 products².

Cyber-resilience:

The Cyber Resilience Act is a first ever EU-wide legislation of its kind: it introduces common cybersecurity rules for manufacturers and developers of products with digital elements, covering both hardware and software. It will ensure that wired and wireless products that are connected to the internet and software placed on the EU market are more secure and that manufacturers remain responsible for cybersecurity throughout a product's life cycle. It will also allow the customers of these products to be properly informed about the cybersecurity of the products they buy and use.

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,2023]

6 Irish Publications/Reviews

6.1 Publications

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

6.2 Reviews

The Committee will review the standardization activities of each of the Technical Committees as outlined in the reporting structure of the Committee in 4.1.

7 Work programme for 2024 onwards

The Consultative Committee will understand the overview of International and European standardization in 'Advanced Manufacturing', including Smart / Digital Manufacturing (aka 'Industry 4.0'), IIoT, Robotics, Additive Manufacturing and enabling technologies such as Cloud Computing and Distributed Platforms and Artificial Intelligence:

- Consider European and international advanced manufacturing technology standardization programmes and national participation in such programmes;
- ✓ Advise and support NSAI on matters, relevant to Manufacturing and Industry 4.0 standardization;
- ✓ Aid NSAI in its dissemination of information of significant value to the Irish manufacturing industry and relevant stakeholders;
- ✓ Assist NSAI in matters of strategic importance by providing guidance of tactical relevance on operational matters, European Regulations and National Positioning ballots;
- ✓ Formally agree on updated Terms of Reference;
- ✓ Develop a Strategic business plan, to bring about a clarity of intent and provide members with the focus needed to accomplish its mission.

8 Additional Information

As manufacturing processes are now being digitized there is a significant opportunity for Ireland and NSAI to help shape the future of the sector which is heavily dependent on standards. NSAI's Board has approved the establishment of a Sectoral Consultative Committee which is tasked with serving the needs of the Manufacturing Sector through the use of standards for the firm adoption of Industry 4.0 Technologies.

The Irish Government is committed to supporting the Manufacturing Sector. Ireland's Industry 4.0 Strategy 2020-2025 sets out the Government's new economic pathway to ensure that Ireland is well placed to prosper in a rapidly changing global economy. NSAI is assigned strategic actions to help in the implementation of the strategy where by 2025 Ireland will be a competitive, innovation-driven manufacturing hub at the frontier of the fourth industrial revolution. This

The Consultative Committee advises NSAI in implementing these key actions from applicable Irish Government Strategies and Ireland's Industry 4.0 Strategy 2020-2025.



The CEN-CENELEC-ETSI Coordination Group on Smart Manufacturing (SMa-CG) was created to coordinate the European standardization activities relating to new technologies in the field of manufacturing. It is a joint group of CEN, CENELEC and ETSI which advises the CEN-CENELEC Technical Boards and the ETSI Board. At the 8th meeting of the CEN-CENELEC-ETSI Coordination Group, the Secretary gave a detailed presentation on NSAI's Sectoral Study of Standards in Manufacturing. The presentation was well received, and members requested links to download the document.