



NSAI

ANNUAL REPORT 2023

NSAI TECHNICAL COMMITTEE
NSAI/TC 128 – SAFETY OF
MACHINERY

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1 Chair

In 2020 the scope of this Committee was changed from an e-Committee to a technical Committee. Due to the change in scope a Chairman was needed, NSAI offered the position of Chairman to Mr Brian Maher, who accepted the role and has Chaired the meetings of NSAI/TC 128.

In 2023, Mr Maher stepped down as Chair of this committee, but is still an active committee member. Mr Jürgen Bukowski was offered to Chair this committee by NSAI and graciously accepted. Mr Bukowski is currently an International Service Project Manager with Pilz and has been with the company for over 10 years. During this time, he has worked as a Technical Consultant and has represented Ireland in Standards Development at an ISO level and has participated as an expert in ISO/TC 199/WG 8 over multiple years.

2 Introduction

The ISO Standards Technical Committee of [ISO/TC 199](#) and the European Technical Committee of [CEN/TC 114](#). The main activity is standardisation of general principles for safety of machinery incorporating terminology and methodology



Standards contribute greatly to urgently addressing global emissions

3 Scope of TC

Standardization of basic concepts and general principles for safety of machinery incorporating terminology, methodology, guards and safety devices within the framework of ISO / IEC Guide 51 and in cooperation with other ISO and IEC technical committees. Excluding product safety standards, as defined in ISO / IEC Guide 51, and which are explicitly covered by the work of other ISO or IEC technical committees.

This committee will not produce indigenous Irish Standards. The national committee will participate in the development of International Standards at an ISO level and at a European Level, participating in the work of a CEN Technical Committee.

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

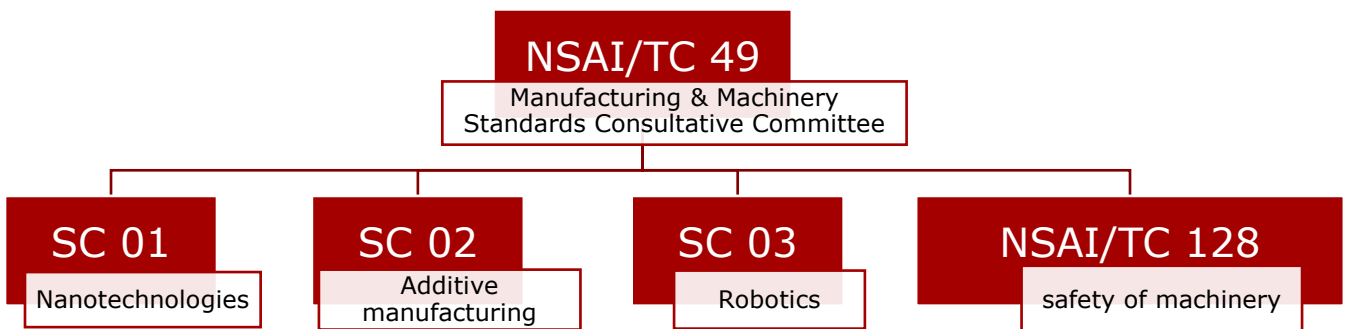
The committee mirrors the following European & international committees:

Committee Name	Committee Title
ISO/TC 199	Safety of machinery
ISO/TC 199/WG 5	General principles for the design of machinery and risk assessment
ISO/TC 199/WG 7	Interlocking devices
ISO/TC 199/WG 8	Safe Control Systems
CEN/TC 114	Safety of machinery
IEC/TC 44	Safety of Machinery – Electrotechnical aspects

4 Structure and Membership

4.1 Structure

The Figure below Illustrates the structure of the National Committee:



The Committee reports to the Manufacturing & Machinery Standards Consultative Committee and the Chairman participates in the work of this group.

4.2 Members

The list below are the members for the year 2023:

Organisation	Role
NSAI	Secretary
Pilz	Chairman
Analog Devices	Committee member
Boston Scientific	Committee member
DPS Arcadis Group	Committee member
Heineken	Committee member
IDA	Committee member
Johnson & Johnson	Committee member
Modular Automation	Committee member
MOOG	Committee member
NeoDyne	Committee member
Project Engineering	Committee member
Rockwell Automation	Committee member

5 Summary of 2023 Activities

5.1 National

5.1.1 Meetings

The meetings were conducted online having regard to reducing the burden and environmental impact of travel for members. Committee members attended the following national meetings:

Meeting No.	Date	Minutes Reference ** optional**
1	27 th January 2023	N 146
2	08 th February 2023	N 156
3	31 st May 2023	N 176
4	07 th September 2023	N 187
5	30 th November 2023	N 199

5.1.2 National Work

The Standards Committee will not draft any National Standards. All of the ISO/TC 199 and CEN/TC 114 Standards that are produced/adopted as European Standards will be published as Irish Standards.

5.2 International/Regional

5.2.1 Meetings

The following meetings were attended by Irish experts:

Committee Name	Location	Date	No. of Attendees
ISO/TC 199/ WG 8	Germany	21 st -22 nd March 2023	1
ISO/TC 199/ WG 8	United States	11 th – 13 th July 2023	1
ISO/TC 199/ WG 8	Germany	14 th – 16 th November	1

5.2.2 International/Regional Work

Ireland is committed to following and inputting into the development of International and European Standards. The National Committee reviews, comments and votes on each of the public comment drafts circulated by ISO/TC 199 & CEN/TC 114.

Ireland has two experts participating in the Working Groups that are drafting Standards at an International level.

Within IEC there is a Technical Committee, TC 44 focused on Standardization of electrotechnical equipment and systems relating to the safeguarding of persons from hazards of the machinery, its associated equipment and the environment. Ireland is participating in this standardisation work.

5.2.3 International/Regional Standards Reviewed

ISO/DIS 11161 (Ed 3), *Safety of machinery – Integration of machinery into a system – Basic requirements*

prEN ISO 11161, *Safety of machinery - Integration of machinery into a system - Basic requirements (ISO/DIS 11161:2023)*

EN 12198-2:2002+A1:2008, *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery - Part 2: Radiation emission measurement procedure*

EN 12198-3:2002+A1:2008, *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery - Part 3: Reduction of radiation by attenuation or screening*

ISO 13849-2:2012 (Ed 2, vers 2), *Safety of machinery – Safety-related parts of control systems – Part 2: Validation*

ISO 13856-1:2013 (Ed 2, vers 2), *Safety of machinery – Pressure-sensitive protective devices – Part 1: General principles for design and testing of pressure-sensitive mats and pressure-sensitive floors*

ISO 13856-2:2013 (Ed 2, vers 2), *Safety of machinery – Pressure-sensitive protective devices – Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars*

5.2.4 International/Regional Voting Results

The Committee voted on nine out of the 13 international votes in 2023.

5.3 Regulatory Development/Update

In April 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.

On 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 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 in developing 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 \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2023/1230/oj)

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 products¹.

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://health.ec.europa.eu/system/files/2020-09/md_mdmcg_qa_3d_ppp_covid-19_en_0.pdf [Accessed on: 05th January,2023]

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.

Moreover, the requirements in the AI Act address the safety risks presented by AI systems used in control safety functions in machinery, complementing certain specific requirements in the Machinery Directive with the AI Act will ensure that an AI system is integrated in a safe way into the whole machine, ensuring that the safety of the machine as a whole is not compromised. In order to define obligations and provide a uniform legal framework for the development, marketing and use of AI systems in safety systems through a risk-based approach, in combination with the Machinery Regulation.

Once high-risk AI system for products covered by the AI Act is placed on the market or put into service, with the product manufactured in accordance with the AI Act, the manufacturer of the product shall assume responsibility for the conformity of the AI system and shall be subject to obligations in relation to the AI system as a supplier under the AI Act.

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

It has been agreed by ISO/TC 199 and CEN/TC 114, that they will not duplicate work. Only in the case the other organization is not interested, or the European Commission submits a Standardization request to CEN, will standards be developed "alone" at EU level.

The Safety of Machinery Committee currently reports to the Manufacturing and Machinery Consultative Committee.

7 Work programme for 2024 onwards

7.1 ISO/TC 199

ISO/AWI 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO/AWI 13849-2, *Safety of machinery — Safety-related parts of control systems — Part 2: Guidance for the design and validation*

ISO/AWI TR 13849-3, *Safety of machinery — Safety-related parts of control systems — Part 3: Markov model-based PFH calculation*

ISO/AWI 14122-1, *Safety of machinery — Permanent means of access to machinery — Part 1: Choice of fixed means of access between two levels*

ISO/AWI 14159, *Safety of machinery — Hygiene requirements for the design of machinery*

ISO/CD TR 21260, *Safety of machinery — Mechanical safety data for physical contacts between moving machinery or moving parts of machinery and persons*

7.2 CEN/TC 114 – Safety of machinery

prEN ISO 11161 rev, *Safety of machinery - Integration of machinery into a system - Basic requirements*

prEN ISO 12895, *Safety of machinery -- Identification of whole body access and prevention of derived risks*

FprEN ISO 13849-1, *Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO/DIS 13849-1:2021)*

prEN ISO 13855, *Safety of machinery - Positioning of safeguards with respect to the approach of the human body*

prEN ISO 14119, *Safety of machinery - Interlocking devices associated with guards - Principles for design and selection (ISO/DIS 14119:2021)*

7.3 IEC/TC 44 – Safety of machinery - Electrotechnical aspects

IEC 60204-1 ED7, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

IEC 61496-3 ED4, *Safety of machinery - Electro-sensitive protective equipment - Part 3: Particular requirements for active opto-electronic protective devices responsive to diffuse Reflection (AOPDDR)*

IEC 62046 ED2, *Safety of machinery - Application of protective equipment to detect the presence of persons*

IEC 62061/AMD1 ED2, *Safety of machinery - Positioning of safeguards with respect to the approach of the human body*

IEC 62745 ED2, *Safety of machinery - Requirements for cableless control systems of machinery*

8 Additional Information

The committee has an expert who is actively participating in the revision of ISO 13849-2:2015, *Safety of machinery – Safety-related parts of control systems – Part 2: Guidance for the design and validation*. The Irish expert regularly attends ISO/TC 199/WG 8 -- Safe control system meetings and provides detail reports at committee meetings.

ISO 13849-1:2023 was published last year and is expected to be Harmonized with the current Machinery Directive this year. This is an important standard that provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS for high demand and continuous mode, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery.

This year ISO is looking into the revision of ISO 12100:2010 - *Safety of machinery — General principles for design — Risk assessment and risk reduction* specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective, which is of great interest to the national committee. ISO 12100:2010 is a harmonised standard with the machinery directive and aspects of the standard will need to be revised in order for it to be harmonised with the proposed new Machinery Regulation.