ANNUAL REPORT 2024

NSAI TECHNICAL COMMITTEE NSAI/TC 128 – SAFETY OF MACHINERY

Contents

1 Chairman's Statement

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

Mr Maher stepped down as Chair of this committee in 2023 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.

During 2024 the committee's most strategically important item was the adoption of EN ISO 13849- 1:2023 as a harmonised standard under the Machinery Directive. This standard is critically important as it provides safety requirements for the design and integration of safety-related parts of control systems. By enabling machinery to meet high safety standards, it helps reduce the risk of accidents and injuries, which is particularly important in industries where machinery malfunctions can lead to severe consequences. The committee had actively involved the development of this standard since its revision started in 2017.

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 Safety

3 Scope of TC

Standardisation 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.

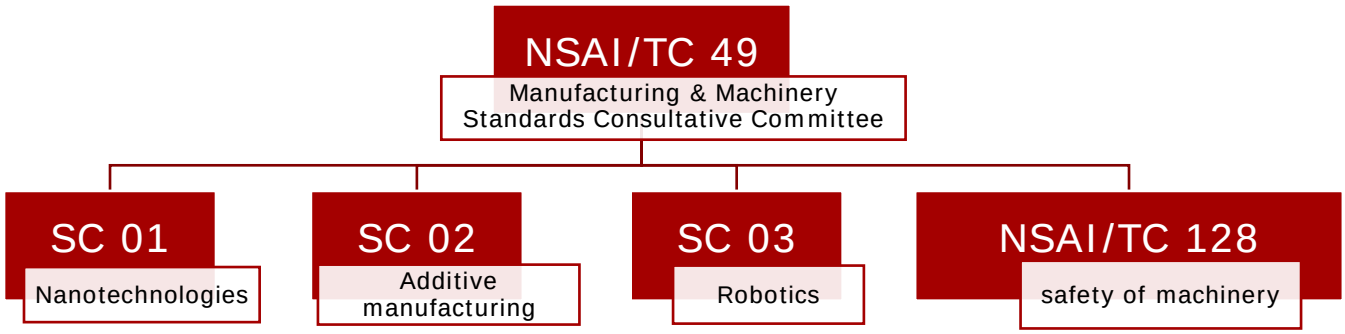
The committee mirrors the following European & international committees:

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 2024:

Organisation	Role
NSAI	Secretary
Pilz	Chairman
Analog Devices	Committee member
Boston Scientific	Committee member
CPS	Committee Member
Dairy Master	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 2024 Activities

5.1 National

5.1.1 Meetings

The meetings were held via web-conferencing facilities with the committee's consensus, aiming to minimise both the time burden and environmental impact associated with travel for members. Committee members attended the following national meetings as follows:

Meeting No.	Date	Minutes Reference ** optional**
1	15th February 2024	N 201
2	02nd May 2024	N 214
3	21st August 2024	N 226
4	29th November 2024	N 232

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.

In 2024, the Chair collaborated closely with the Standards Development Manager to promote the successful harmonisation of ISO 13849-1:2023 with the Machinery Directive to a wider audience. They also informed key stakeholders about the Machinery Regulation through a targeted social media campaign and an article in NSAI's Ezine magazine. This regulation will impact all standards currently harmonised with the Machinery Directive and lead to the creation of new standards to address the added essential requirements. For more details, refer to the article written by the Chair of NSAI/TC 128, Mr. Jürgen Bukowski, in the March 2024 issue of NSAI's Ezine magazine.

On May 1st, Engineering Industries Ireland were delighted to partner with the National Standards Authority of Ireland (NSAI), and the Department of Enterprise, Trade and Employment on a recent webinar to discuss the Machinery Regulation and General Product Safety Regulation (GPSR). Register to view the IBEC for Irish Business webinar.

While in June NSAI presented at the National Manufacturing & Supply Chain Conference & Exhibition 2024. NSAI's Standards Development Manager Barry Cox, delivered an informative presentation on the Machinery Regulation and CE Marking. For further information please visit our webpage LINK

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	Web Meeting	25th January -	1
ISO/TC 199/ WG 8	Milan, Italy	16th – 18th September 2024	1
ISO/TC 199/ WG 8	Web Meeting	29th November 2024	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 standardisation 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

SO/DIS 12100 (Ed 2), *Safety of machinery — General principles for design — Risk assessment and risk reduction*

FprEN ISO 14119, *Safety of machinery - Interlocking devices associated with guards - Principles for design and selection (ISO/FDIS 14119:2024)*

ISO 13851:2019 (Ed 2), *Safety of machinery - Two-hand control devices — Principles for design and selection*

ISO 13857:2019 (Ed 2), *Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs*

ISO 19353:2019, (Ed 3) *Safety of machinery - Fire prevention and fire protection*

ISO 20607:2019, *Safety of machinery — Instruction handbook — General drafting principles*

ISO 29042-2:2009 (vers 3), *Safety of machinery — Evaluation of the emission of airborne hazardous substances — Part 2: Tracer gas method for the measurement of the emission rate of a given pollutant*

ISO 29042-3:2009 (vers 3), *Safety of machinery — Evaluation of the emission of airborne hazardous substances — Part 3: Test bench method for the measurement of the emission rate of a given pollutant*

ISO 29042-4:2009 (vers 3), *Safety of machinery — Evaluation of the emission of airborne hazardous substances — Part 4: Tracer method for the measurement of the capture efficiency of an exhaust system*

ISO/TS 19837:2018 (vers 2), *Safety of machinery — Trapped key interlocking devices — Principles for design and selection*

5.2.4 International/Regional Voting Results

The Committee voted on eighteen out of the thirty-three international votes in 2024.

5.3 Regulatory Development/Update

On 21st 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 **20th 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 Country. 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 19th 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.

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 are 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.

Harmonised Standards

Currently, over 800 harmonised standards are listed in the Official Journal of the European Union under the Machinery Directive. CEN/CENELEC Technical Committees are reviewing these standards to identify those that do not meet the new requirements of the Machinery Regulation. Any "gaps" identified by the committees could then be noted as restrictions in the Official Journal before January 20th, 2027.

Additionally, on July 4th, 2024, the European Commission published a draft standardisation request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) regarding machinery and related products. This request supports Regulation (EU) 2023/1230 of the European Parliament and of the Council, aiming to draft new harmonised standards and European standardisation deliverables. Furthermore, it specifies requirements for revising existing harmonised standards and European standardisation deliverables. The Draft Standardisation request can be view at the following LINK.

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 does not report to any National Steering Committee but offers strategic information on the development of standards to the Manufacturing and Machinery Consultative Committee. It was agreed by ISO/TC 199 and CEN/TC 114, that it will not repeat work. Only in the case where the other organisation is not interested, or the European Commission submits a Standardisation Request to CEN will the standard be developed "alone".

7 Work programme for 2025 onwards

7.1 ISO/TC 199

ISO/DIS 11161, *Safety of machinery — Integration of machinery into a system — Basic requirements*

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

ISO/DIS 12895, *Safety of machinery — Identification of whole-body access and prevention of associated risk(s)*

ISO/CD 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/DIS 20607, *Safety of machinery —Instruction handbook — General drafting principles*

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 12100, *Safety of machinery - Identification of whole body access and prevention of derived risks - Risk assessment and risk reduction (ISO/DIS 12100:2024)*

prEN ISO 12895, *Safety of machinery - General principles for design -*

prEN ISO 13849-2 Rev, *Safety of machinery - Safety-related parts of control systems - Part 2: Validation*

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

prEN ISO 14159 rev, *Safety of machinery - Hygiene requirements for the design of machinery*

prEN ISO 20607 rev, *Safety of machinery - Instruction handbook – General drafting principles*

FprEN 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 61496-1 ED5, *Safety of machinery - Electro-sensitive protective equipment - Part 1: General requirements and tests*

IEC 61496-2 ED45 *Safety of machinery - Electro-sensitive protective equipment - Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs)*

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

IEC 62998-1 ED1, Safety of machinery - Safety-related sensors used for the protection of persons

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.

The committee wish to highlight ISO 13849-1:2023 was Harmonized with the current Machinery Directive last 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 new Machinery Regulation.