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Varnost strojev - Integrirani proizvodni sistemi - Osnovne zahteve (ISO/DIS 11161:2024)

Safety of machinery - Integration of machinery into a system - Basic requirements (ISO/DIS 11161:2024)

Sécurité des machines - Intégration de machines dans un système - Exigences fondamentales (ISO/DIS 11161:2024)

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25.040.01	Sistemi za avtomatizacijo v industriji na splošno	Industrial automation systems in general

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Safety of machinery — Integration of machinery into a system — Basic requirements

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 199, *Safety of machinery*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 114, *Safety of machinery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11161:2007), which has been technically revised. It also incorporates the Amendment ISO 11161:2007/Amd1:2010.

The changes are as follows:

- the document title has been changed;
- the document has been completely revised and restructured;
- new Annexes have been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Integrated machinery systems (see [3.1.1](#)) can be different in terms of size and complexity, and can incorporate different technologies that require diverse expertise and knowledge.

An integrated machinery system (IMS) is considered to be a whole new and different machine. Ideally, the entities which individually know only a part of the IMS will cooperate with the integrator. Manufacturing, as a stand-alone application or connected with other domains in the context of smart manufacturing, have tasks, which can be internal or external to the IMS. For frequent manual intervention(s) to parts of the IMS (e.g. inspections, maintenance, cleaning, set-up, observation), minimal downtime and prompt restart are essential to lessen the motivation to defeat risk reduction measures. This can be accomplished by safeguarding for these intervention tasks and use of "task zones".

This document describes how to apply the requirements of ISO 12100 in the context of an IMS.

Some examples of integration of machinery into a system are included in [Annex A](#).

The structure of safety standards in the field of machinery is as follows:

- a) **Type-A standards** (basic safety standards) give basic concepts, principles for design and general aspects that can be applied to machinery;
- b) **Type-B standards** (generic safety standards) dealing with one or more safety aspect(s), or one or more type(s) of safeguards that can be used across a wide range of machinery:
 - type-B1 standards on particular safety aspects (for example, safety distances, surface temperature, noise);
 - type-B2 standards on safeguards (for example, two-hands control devices, interlocking devices, pressure-sensitive devices, guards);
- c) **Type-C standards** (machine safety standards) dealing with detailed safety requirements for a particular machine or group of machines.

This document is a type-B1 standard as stated in ISO 12100.

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- machine manufacturers (e.g. small, medium and large enterprises);
- health and safety bodies (e.g. regulators, accident prevention organisations, market surveillance).

Others can be affected by the level of machinery safety achieved with the means of the document by the above-mentioned stakeholder groups:

- machine users/employers (e.g. small, medium and large enterprises);
- machine users/employees (e.g. trade unions, organizations for people with special needs);
- service providers, e.g. for maintenance (small, medium and large enterprises);
- consumers (in case of machinery intended for use by consumers).

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

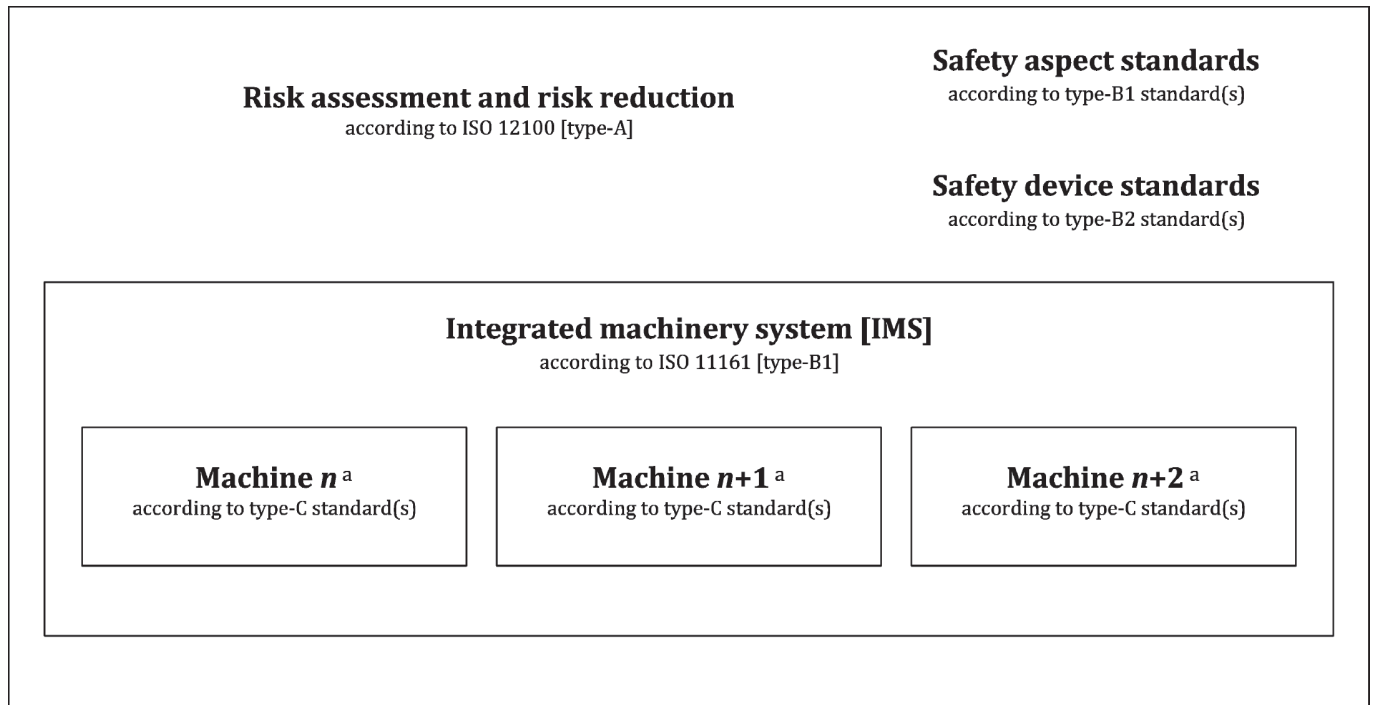
In addition, this document is intended for standardization bodies elaborating type-C standards.

The requirements of this document can be supplemented or modified by a type-C standard.

For machines which are covered by the scope of a type-C standard and which have been designed and built according to the requirements of that standard, the requirements of that type-C standard take precedence.

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Figure 1 shows the relationship between the safety standards relating to machines and their integration into a system.



^a Use applicable type-B standard(s) if no type-C standard exists; see ISO/TR 22100-1:2021, Figure 4.

Figure 1 — Relationship between the safety standards relating to machines and their integration into a system

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Safety of machinery — Integration of machinery into a system — Basic requirements

1 Scope

This document specifies the safety requirements for the integration of machinery into a system. It gives requirements and recommendations for inherently safe design, safeguarding and complementary protective measures, and information for use of an integrated machinery system (IMS).

NOTE In the context of this document, the term "system" refers to an IMS which can also collaborate with other domains within the supply chain(s) of an enterprise (e.g. smart manufacturing). See also [4.3.2](#).

This document is not intended to cover safety aspects of individual machines and equipment that can be covered by standards specific to those machines and equipment. Therefore, it deals only with those safety aspects for the safety-relevant interconnection of the machines and components. Where component machines of an IMS are operated separately or individually, the safety requirements of the relevant safety standards for these machines and equipment apply.

This document is also applicable when a modification of an existing IMS results in a new configuration, function, capability or location.

This document deals with the significant hazards, hazardous situations or hazardous events when used as intended and under specified conditions of misuse which are reasonably foreseeable. This document also provides requirements for IMS used in applications such as the following, but does not cover the hazards related to them:

- underground use;
- nuclear environments;
- potentially explosive environments;
- hazards due to the lifting of persons;
- use of IMS in environments with hazardous ionizing and non-ionizing radiation levels;
- when the public have access.

Emission of acoustic noise can be identified as a significant hazard. The reduction of acoustic noise emissions is not covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4413:2010, *Hydraulic fluid power — General rules and safety requirements for systems and their components*

ISO 4414:2010, *Pneumatic fluid power — General rules and safety requirements for systems and their components*

ISO 4871, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 11553 (all parts), *Safety of machinery — Laser processing machines*

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- ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*
- ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*
- ISO 13732-3, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 3: Cold surfaces*
- ISO 13849-1:2023, *Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design*
- ISO 13850:2015, *Safety of machinery — Emergency stop function — Principles for design*
- ISO 13851, *Safety of machinery — Two-hand control devices — Principles for design and selection*
- ISO 13856 (all parts), *Safety of machinery — Pressure-sensitive protective devices*
- ISO 14118, *Safety of machinery — Prevention of unexpected start-up*
- ISO 14119:2024, *Safety of machinery — Interlocking devices associated with guards — Principles for design and selection*
- ISO 14120, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*
- ISO 14122 (all parts), *Safety of machinery — Permanent means of access to machinery*
- ISO 14159, *Safety of machinery — Hygiene requirements for the design of machinery*
- ISO 19353, *Safety of machinery — Fire prevention and fire protection*
- ISO 20607:2019, *Safety of machinery — Instruction handbook — General drafting principles*
- IEC 60204-1:2021¹⁾, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*
- IEC 61496-1:2020, *Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests*
- IEC 62046:2018, *Safety of machinery — Application of protective equipment to detect the presence of persons*
- IEC/TS 62998-1, *Safety of machinery — Safety-related sensors used for the protection of persons*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12100 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

1) i.e. Edition 6.1 which combines IEC 60204-1:2016 and Amendment 1, AMD 1:2021.

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3.1.1

integrated machinery system

IMS

two or more machines, capable of operating independently of each other, which are interconnected by controls and act together in a coordinated manner

Note 1 to entry: An integrated machinery system is typically used for the purpose of fabrication, production, treatment, processing or packaging of discrete parts or assemblies as part of an enterprise's supply chain.

Note 2 to entry: An integrated machinery system can be linked by a material-handling system.

3.1.2

component machine

individual machine which is part of an integrated machinery system

Note 1 to entry: A component machine can be stationary or mobile during intended use or operation.

Note 2 to entry: A component machine can also be machinery which cannot perform a specific task before being integrated into an IMS.

3.1.3

integrator

entity who designs, provides, manufactures or assembles an integrated machinery system and the safety strategy, including the risk reduction measures, control interfaces, interconnections of the control system and instruction for use

Note 1 to entry: The integrator can be a manufacturer, assembler, engineering company or the user.

3.1.4

local control

state of the system or portion of the system in which operation is affected from a control unit which is within visual line-of-sight of the span-of-control

3.1.5

blanking

function that permits an object of a size greater than the detection capability of the electro-sensitive protective equipment to be located within the detection zone without causing an OFF-state of the output signal switching device(s)

[SOURCE: IEC 62046:2018, 3.1.4, modified – Delete “optional” from the beginning of the definition.]

3.1.6

muting

temporary automatic suspension of a safety function(s) by the SRP/CS

[SOURCE: ISO 13849-1:2023, 3.1.15, modified – Acronym SRP/CS spelled out as safety-related part of a control system.]

3.1.7

safeguarded space

area or volume where guards and/or protective devices are intended to protect persons from a hazard(s)

3.1.8

span-of-control

predetermined portion of the machinery under control of a specific device or safety function

Note 1 to entry: A protective device can initiate a stop of a machine or a portion of a machine. For example, an emergency stop pushbutton can cause a local stop or global stop (see ISO 13850).

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3.1.9

zone

space within machinery or an integrated machinery system

Note 1 to entry: An integrated machinery system can be segmented for specific purposes into zones.

3.1.10

control zone

identified portion of machinery or an integrated machinery system coordinated by the control system

3.1.11

detection zone

zone within which a specified test piece will be detected by the sensitive protective equipment

Note 1 to entry: ISO 13856-1 uses the term “effective sensing area” when describing pressure-sensitive mats and floors.

[SOURCE: IEC 61496-1:2020, 3.4, modified – “electro-” has been removed before “sensitive protective equipment” and Note 1 to entry has been added.]

3.1.12

task zone

predetermined space within or around machinery or an integrated machinery system in which personnel can perform a specified activity

3.1.13

user

entity who utilizes the machinery

3.1.14

manual mode

control state that requires an operator to initiate and/or maintain operation of the machine by use of actuating control

Note 1 to entry: The operation can be of the IMS, portions of the IMS, component machines or portions of machines.

Note 2 to entry: See also *integrated machinery system mode* (3.1.15).

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3.1.15

integrated machinery system mode

IMS mode

mode specific to the integration of machinery into a system

Note 1 to entry: See also 7.6 and [Annex D](#).

3.1.16

protective stop

safety-related stop function initiated by a protective device

[SOURCE: ISO 3691-4:2023, 3.45]

3.1.17

operational stop

stop function of machinery for functional purposes only

3.1.18

smart manufacturing

manufacturing that improves its performance aspects with integrated and intelligent use of processes and resources in cyber, physical and human spheres to create and deliver products and services, which also collaborates with other domains within enterprises' value chains

Note 1 to entry: Performance aspects include agility, efficiency, safety, security, sustainability or any other performance indicators identified by the enterprise.