



SLOVENSKI STANDARD
oSIST prEN ISO 11161:2023
01-junij-2023

Varnost strojev - Integrirani proizvodni sistemi - Osnovne zahteve (ISO/DIS 11161:2023)

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

Sicherheit von Maschinen - Integrierte Fertigungssysteme - Grundlegende Anforderungen (ISO/DIS 11161:2023)

Sécurité des machines - Systèmes de fabrication intégrés - Exigences fondamentales (ISO/DIS 11161:2023)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

This third edition cancels and replaces the second edition (ISO 11161:2007 including AMD 1:2010), which has been technically revised.

The main changes compared to the previous edition 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.

Introduction

An integrated machinery system (IMS, see [3.1.1](#)) can be very different in terms of size and complexity, and can incorporate different technologies that require diverse expertise and knowledge.

An integrated machinery system 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, set-up, observation), minimal downtime and prompt restart are essential to lessen the motivation to defeat protective/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 (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organisations, market surveillance etc.)

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 (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.

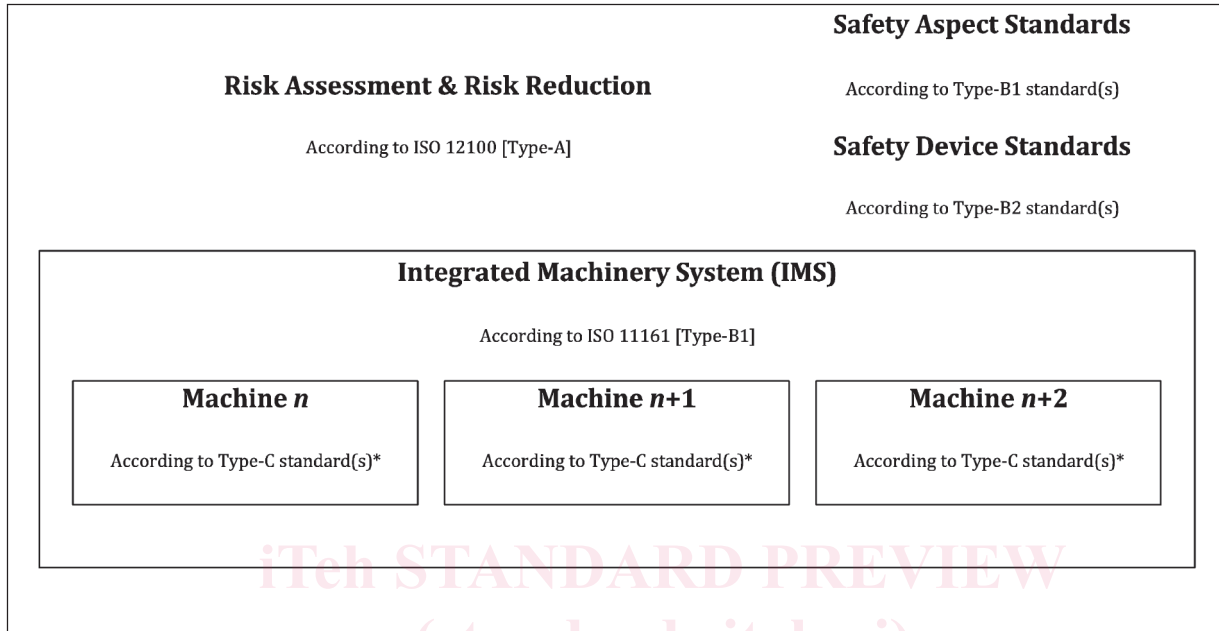
In addition, this document is intended for standardization bodies elaborating type-C standards.

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

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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.

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



* 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

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 manufacturing 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 [5.2.2](#).

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 integrated machinery system 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 as following, but does not cover the hazards related to

- 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 could be identified to be a significant hazard but the reduction of 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 11553 (all parts), *Safety of machinery — Laser processing machines*

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

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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 14119:2023, *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 60204-1:2016, *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 terminological 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/>

3.1.1**integrated machinery system**

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.

3.1.3**integrator**

entity who designs, provides, manufactures or assembles an integrated machinery system and the safety strategy, including the protective/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 portions of the system in which operation is affected from a specific control panel or pendant

3.1.5**blinking**

optional function that permits an object of a size greater than the detection capability of the ESPE 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 – Acronym OSSD has been replaced by output signal switching device.]

3.1.6**muting**

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

[SOURCE: ISO 13849-1:2023, 3.1.8] [IST prEN ISO 11161:2023](https://standards.iteh.ai/catalog/standards/sist/247fe0f1-2ebb-4e71-bc12-1ff53a5c080d/osist-pren-iso-11161-2023)

3.1.7**safeguarded space**

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

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 could initiate a stop of a machine or a portion of a machine. For example, an emergency stop pushbutton could cause a local stop or global stop (see ISO 13850).

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. See also [Annex C](#).

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. In this document the terms “detection zone” and “effective sensing area” are used synonymously.

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[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 [3.1.15](#), IMS mode.

3.1.15**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 3691-4:2020, 3.46]

3.1.17**operational stop**

safety-related stop function that does not cut off the energy supplied to the actuators and monitors and maintains the stop condition in order to perform specific operations

3.1.18**whole body access**

situation where a person can be completely inside a safeguarded space

3.1.19**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.

Note 2 to entry: In addition to manufacturing, other enterprise domains can include engineering, logistics, marketing, procurement, sales or any other domains identified by the enterprise.

[SOURCE: ISO/TR 22100-4:2019, 3.16]

3.1.20 equipment

tools or objects required to accomplish a task related the machine and single items or assemblies for the utilization of electricity, pneumatic or hydraulic power by machines or component machines.

Note 1 to entry: Equipment itself is not a component machine (e.g., a welding current transformer, weld gun).

Note 2 to entry: Examples of equipment are piping components, fixtures for workpieces, luminaires, cable trays.

3.1.21 visual line-of-sight

condition in which the operator maintains direct unaided visual contact with the span-of-control

3.2 Abbreviated terms

AGV	automatic guided vehicle
AOPD	active opto-electronic protective device
AOPDDR	active opto-electronic protective device responsive to diffuse reflection
ESPE	electro-sensitive protective equipment
HMI	human machine interface
IMS	integrated machinery system
OSSD	output signal switching device
PL	performance level
PL _r	required performance level
SPE	sensitive protective equipment
SRP/CS	safety-related part of a control system
VLOS	visual line-of-sight

4 Strategy for risk assessment and risk reduction

4.1 General

Component machines shall comply with the requirements of ISO 12100 and applicable type-B and type-C standards.

Risk assessment and risk reduction of an IMS shall be in accordance with ISO 12100.

Risk assessment shall also identify tasks or hazards which can arise due to influences external to the IMS (e.g., Smart Manufacturing, network connections, see [7.11.3](#)).

Risk reduction shall be done when integrating the component machines into the IMS to achieve adequate risk reduction. Information for use of the IMS shall be in accordance with [Clause 8](#).

The IMS shall be designed to facilitate manual intervention(s), including maintenance. Where multiple configurations and modifications are foreseeable, the IMS shall be designed for each intended functionality. For some manual intervention(s) where it is impractical to stop the whole IMS, segregated zone(s) with safety functions including span(s)-of-control shall be established where operators can perform their tasks safely.