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Robotics — Safety requirements —

Part 2: Industrial robot applications and robot cells

Robotique — Exigences de sécurité —

Partie 2: Applications robotisées industrielles et cellules robotisées

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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 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 299, *Robotics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 310, *Advanced automation technologies and their applications,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10218-2:2011), which has been technically revised.

The main changes are as follows:

— emphasising robot application and not robot system, as the robot application includes the workpieces, task program, and the machinery and equipment to support the application and intended tasks;

— incorporating safety requirements for collaborative applications (formerly, the content of ISO/TS 15066);

— clarifying requirements for functional safety;

— adding requirements for cybersecurity to the extent that it applies.

A list of all parts in the ISO 10218 series can be found on the ISO website.

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

This document has been created in recognition of the hazards that are presented by robots when they are integrated and installed with end-effectors into robot applications and robot cells. ISO 10218-1 addresses robots as partly completed machinery, while this document addresses robots integrated into completed machinery for specific robot applications.

This document is a type-C standard according to ISO 12100.

This document is of relevance for the following stakeholder groups representing the market players regarding safety of robot applications and robot cells:

— robot manufacturers (small, medium and large enterprises);

— robot application integrators (small, medium and large enterprises);

— health and safety bodies (regulators, accident prevention organisations, market surveillance, etc).

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

— robot application users/employers (small, medium and large enterprises);

— robot application users/employees (e.g. trade unions);

— service providers, e.g. for maintenance (small, medium and large enterprises);

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

Robot applications, and the extent to which hazards, hazardous situations and events, are covered and indicated in the Scope of this document.

When provisions of a type-C standard are different from those which are stated in type-A or type-B standards, the provisions of the type-C standard take precedence over the provisions of the other standards for machines that have been designed and built in accordance with the provisions of the type-C standard.

Hazards associated with robot applications are well recognized, but the sources of the hazards are frequently unique to each robot application. The number and type(s) of hazard(s) are directly related to the nature of the automation process and the complexity of the application. The risks associated with these hazards vary with the robot used, its safety functions, and the integration, installed, programs, use, and maintenance. This document provides requirements for safety in the integration of robots into robot applications and robot cells. The requirements include safeguarding of operators during integration, commissioning, functional testing, programming, operation, maintenance and repair. Requirements for the robot can be found in ISO 10218-1.

The ISO 10218 series deals with robotics in an industrial environment, which is comprised of workplaces where the public is excluded or restricted from access and the allowed people (operators) are working adults. Other standards cover such topics as general characteristics, coordinate systems and axis motions, mechanical interfaces, performance criteria and related testing methods, and end-effectors.

There are a broad range of robot applications and robot cell(s). Therefore, it is not possible to provide a list of all significant hazards, hazardous situations or events into which a robot application can be integrated. Moreover, the same kind of applications can have different levels of risk, resulting from different designs which correspond to the intended application (e.g. paint spraying on large or small parts, handling of a small harmful payload like a hot metal bolt or a large harmless payload like a box of paper tissues).

Other standards can be applicable to associated machinery and equipment in robot applications and robot cells.

For ease of reading this document, the words “robot”, “robot system” and “robot application” refer to “industrial robot”, “industrial robot system” and “industrial robot application” as defined in ISO 10218-1 and this document.

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This document has been updated based on experience gained since the release of the first edition of ISO 10218-2 in 2011. This document remains aligned with minimum requirements of a harmonized type-C standard for robot applications and robot cells in an industrial environment. Providing for a safe robot application and a safe robot cell depends on the cooperation of a variety of “stakeholders”. Stakeholders can include designers, manufacturers, suppliers and integrators. Users are the entity responsible for using robot applications and robot cells. Users can also be any of the other stakeholder roles.

Where appropriate, ISO/TS 15066:2016 on the safety of collaborative robot applications was added to the ISO 10218 series. Because human-robot collaboration relates to the application and not to the robot alone, most of the requirements of ISO/TS 15066 have been incorporated into this document. Safety functions that enable a collaborative application can be part of the robot (e.g. PFL), or can be provided by a protective device, or a combination.

It is important to emphasize that the term “collaborative robot” is not used in this document. Only the application can be developed, verified, and validated as a collaborative application. In addition, the term “collaborative operation” is not used in this document.

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Robotics — Safety requirements —

Part 2: Industrial robot applications and robot cells

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1 Scope

This document specifies requirements for the integration of industrial robot applications and industrial robot cells. The following are addressed:

— the design, integration, commissioning, operation, maintenance, decommissioning and disposal;

— integration of machines and components;

— information for use for the design, integration, commissioning, operation, maintenance, decommissioning and disposal.

This document is not applicable to the following uses and applications of industrial robots:

— underwater;

— law enforcement;

— military (defence);

— airborne and space, including outer space;

— medical;

— healthcare of a person;

— prosthetics and other aids for the physically impaired;

— service robots, which provide a service to a person and as such the public can have access;

— consumer products, as this is household use to which the public can have access;

— lifting or transporting people;

— multi-purpose lifting devices or machinery, e.g. cranes, forklift trucks.

NOTE Applications for the automation of laboratories are not considered as medical or healthcare of a person.

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 by the integrator.

This document provides basic requirements for industrial robot applications, but does not cover the hazards related to the following:

— emission of airborne noise;

— severe conditions (e.g. extreme climates, freezer use, strong magnetic fields) outside of manufacturer's specifications;

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— underground use;

— use that has hygienic requirements;

— processing of any material (e.g. food, cosmetics, pharmaceutical, metal);

— use in nuclear environments;

— use in potentially explosive environments;

— mobility when robots or manipulators are integrated with driverless industrial trucks;

— mobility when robots or manipulators are integrated with mobile platforms;

— use in environments with hazardous ionizing and non-ionizing radiation levels;

— hazardous ionizing and non-ionizing radiation;

— handling loads the nature of which could lead to dangerous situations (e.g. molten metals, acids/bases, radiating materials);

— when the public or non-working adults have access.

Emission of acoustic noise could be identified to be a significant hazard, but emission of noise 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 3864-1:2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 3864-2:2016, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 3864-3:2024, *Graphical symbols — Safety colours and safety signs — Part 3: Design principles for graphical symbols for use in safety signs*

ISO 3864-4:2011, *Graphical symbols — Safety colours and safety signs — Part 4: Colorimetric and photometric properties of safety sign materials*

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 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 8995-1:2002, *Lighting of work places — Part 1: Indoor*

ISO/CIE 8995-3:2018, *Lighting of work places — Part 3: Lighting requirements for safety and security of outdoor work places*

ISO 10218-1:2025, *Robotics – Safety requirements – Part 1: Industrial robots*

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

ISO 13732-1:2006, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces*

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ISO 13732-3:2005, *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 13854:2017, *Safety of machinery — Minimum gaps to avoid crushing of parts of the human body*

ISO 13855:2010, *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

ISO 13856:2013, *Safety of machinery — Pressure-sensitive protective devices*

ISO 13857:2019, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

ISO 14118:2017, *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 14120:2015, *Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards*

ISO 14122:2016, *Safety of machinery — Permanent means of access to machinery*

ISO 14738:2002, *Safety of machinery — Anthropometric requirements for the design of workstations at machinery*

ISO 15534-1:2000, *Ergonomic design for the safety of machinery — Part 1: Principles for determining the dimensions required for openings for whole-body access into machinery*

ISO 15534-2:2000, *Ergonomic design for the safety of machinery — Part 2: Principles for determining the dimensions required for access openings*

ISO 19353:2019, *Safety of machinery — Fire prevention and fire protection*

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

ISO 20643:2005, *+ AMD1:2021, Mechanical vibration — Hand-held and hand-guided machinery — Principles for evaluation of vibration emission*

IEC 60073:2002, *Basic and safety principles for man-machine interface, marking and identification — Coding principles for indication devices and actuators*

IEC 60204-1:2016, *+ AMD1:2021, Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

IEC 60825-1:2014, *Safety of laser products — Part 1: Equipment classification and requirements*

IEC 60947-5-8:2020, *Low-voltage switchgear and controlgear — Part 5-8: Control circuit devices and switching elements — Three-position enabling switches*

IEC 61000-6-7:2014, *Electromagnetic compatibility (EMC) — Part 6-7: Generic standards — Immunity requirements for equipment intended to perform functions in a safety-related system (functional safety) in industrial locations*

IEC 61310:2007, *Safety of machinery — Indication, marking and actuation*

IEC 61496-1:2020, *Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests*

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IEC 61508-2:2010, *Functional safety of electrical/electronic/programmable electronic safety-related systems — Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems*

IEC 62046:2018, *Safety of machinery — Application of protective equipment to detect the presence of persons*

IEC 62061:2021, *Safety of machinery — Functional safety of safety-related control systems*

3 Terms, definitions, symbols and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 12100:2010 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/

3.1 Terms and definitions

3.1.1 Robot, robot system, robot application, robot cell - related

3.1.1.1
industrial environment
workplace where the public is restricted from access or not reasonably expected to be present for the intended tasks and *robot application(s)* (3.1.1.4)

Note 1 to entry: This includes manufacturing, laboratory, pharmaceutical, warehousing, logistics, and more.

3.1.1.2
industrial robot
robot
automatically controlled, reprogrammable multipurpose *manipulator(s)* (3.1.2.7), programmable in three or more *axes* (3.1.2.1), which can be either fixed in place or fixed to a *mobile platform* (3.1.2.10) for use in automation *applications* (3.1.1.5) in an *industrial environment* (3.1.1.1)

Note 1 to entry: The industrial robot includes:

— the *manipulator* (3.1.2.7), including *robot actuators* (3.1.2.12) controlled by the robot control;

— the robot control; and

— the means to teach or program the robot, including any communications interface (hardware and software).

Note 2 to entry: This includes any axes that are integrated into the kinematic solution.

Note 3 to entry: A mobile robot consists of a *mobile platform* (3.1.2.10) with an integrated *manipulator* (3.1.2.7) or robot.

3.1.1.3
industrial robot system
robot system
industrial robot (3.1.1.2), an *end-effector(s)* (3.1.2.3), any *end-effector* sensors and equipment needed to support the *end-effector(s)* (3.1.2.3)

Note 1 to entry: Examples of equipment are vision systems, adhesive dispensing, weld control.

3.1.1.4
robot application
industrial robot application
machine comprising an *industrial robot system* (3.1.1.3), workpieces, *task program* (3.1.4.1), and machinery and equipment to support the *application* (3.1.1.5) and the intended task(s)

Note 1 to entry: The *application* (3.1.1.5) can be a *collaborative application* (3.1.1.6).

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3.1.1.5
application
intended use and purpose of the *robot* (3.1.1.2) or *robot application* (3.1.1.4), i.e. the process, the task(s)

EXAMPLE Manipulating, processing, machining, inspection, spot welding, painting, assembly, palletizing.

3.1.1.6
collaborative application
application (3.1.1.5) that contains one or more *collaborative task(s)* (3.1.1.7)

Note 1 to entry: Collaborative applications can include non-collaborative tasks.

3.1.1.7
collaborative task
portion of the robot sequence where both the *robot application* (3.1.1.4) and *operator(s)* (3.1.7.3) are within the same *safeguarded space* (3.1.9.6)

3.1.1.8
robot cell
industrial robot cell
one or more *robot applications* (3.1.1.4), any obstacle or object that has influence on the risk assessment of the intended use and associated *safeguarded space(s)* (3.1.9.6) and *safeguards* (3.1.10.2)

3.1.2 Sub-assemblies and components

3.1.2.1
axis
actuated (e.g. rotating about a pivot, moving linearly) mechanical joint that provides at least one degree of freedom

3.1.2.2
additional axis
axis (3.1.2.1) that is not part of the *manipulator* (3.1.2.7)

Note 1 to entry: Additional axis includes any auxiliary axis as described in ISO 10218-1:2025, 5.1.9.

3.1.2.3
end-effector
device specifically designed for attachment to the *mechanical interface* (3.1.2.9) to enable the *robot application* (3.1.1.4) to perform its task

EXAMPLE Gripper, welding gun, spray gun.

Note 1 to entry: End-effectors are sometimes known as end-of-arm tooling (EOAT).

3.1.2.4
gripper
end-effector (3.1.2.3) designed for seizing and holding workpieces

Note 1 to entry: Various types of grippers and the terms “grip, grasp, grasping and releasing” are defined in ISO 14539:2000.

[SOURCE: ISO 14539:2000, 4.1.2, modified — Note 1 to entry has been added.]

3.1.2.5
fixture
device used to hold in position an item as part of the handling or assembling process in a *robot application* (3.1.1.4), but not as an *end-effector* (3.1.2.3)

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3.1.2.6
manual load/unload station
part of the *robot application* (3.1.1.4) designed for the direct manual intervention for the placement and removal of parts or workpieces for processing by the *robot application* (3.1.1.4)

3.1.2.7
manipulator
mechanism consisting of an arrangement of segments, jointed or sliding relative to one another

Note 1 to entry: *Robot actuators* (3.1.2.12) can constitute parts of a *manipulator*.

3.1.2.8
mass per manipulator
M
mass of all moving parts of the *manipulator* (3.1.2.7)

3.1.2.9
mechanical interface
mounting surface at the end of the *manipulator* (3.1.2.7) to which the *end-effector* (3.1.2.3) is attached

3.1.2.10
mobile platform
assembly of the components which enables locomotion and provides the structure by which to affix or integrate a *manipulator* (3.1.2.7) or *robot* (3.1.1.2)

3.1.2.11
payload
mass of all that is attached to the *manipulator* (3.1.2.7), including the *end-effector* (3.1.2.3) and workpiece

Note 1 to entry: The payload can be attached to, but is not limited to, the *mechanical interface* (3.1.2.9) of the *robot* (3.1.1.2).

3.1.2.12
robot actuator
powered mechanism that converts energy to effect motion

Note 1 to entry: Energy can be electrical, hydraulic, pneumatic or more.

3.1.2.13
tool centre point
TCP
point defined for a given *application* (3.1.1.5) relative to the *mechanical interface* (3.1.2.9) coordinate system

Note 1 to entry: The TCP setting defines the location of the TCP relative to the *mechanical interface* (3.1.2.9).

3.1.3 Controls-related

3.1.3.1
control station
enclosure which contains one or more control devices intended to activate or deactivate functions

Note 1 to entry: The control station can be fixed in place (e.g. control panel) or can be movable [*pendant* (3.1.3.2) or *teach pendant* (3.1.3.3) which is referred to as a portable control station].

Note 2 to entry: The portable or hand-held control station for a *robot* (3.1.1.2) is referred to as a *teach pendant* (3.1.3.3).

3.1.3.2
pendant
hand-held *control station* (3.1.3.1)

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3.1.3.3
teach pendant
pendant (3.1.3.2) with which a *robot* (3.1.1.2) can be programmed, moved, or actuated

Note 1 to entry: Hand-held units or devices which only have the capability of displaying parameters (e.g. no motion and no actuation capabilities), are not considered to be *control stations* (3.1.3.1) or teach pendants.

Note 2 to entry: The *teach pendant* can be linked to the *end-effector* (3.1.2.3) and other parts of the *robot application* (3.1.1.4).

3.1.3.4
local control
state of the system or portions of the system in which operation is effected from a *control station* (3.1.3.1) or *teach pendant* (3.1.3.3) of the individual machine(s) or portions of the machine(s)

Note 1 to entry: An *operator* (3.1.7.3) using the local control(s) usually has a direct view of the *robot cell* (3.1.1.8).

3.1.3.5
span-of-control
predetermined portion of the *robot* (3.1.1.2), *robot application* (3.1.1.4), *robot cell* (3.1.1.8) or machinery that is under control of a specific device for a *safety function* (3.1.8.1)

Note 1 to entry: *Protective devices* (3.1.10.5) and *emergency stop devices* could initiate a stop of a machine, a portion of a machine, or partly completed machinery, i.e. a *robot* (3.1.1.2).

3.1.3.6
simultaneous motion
motion, of two or more *robots* (3.1.1.2) at the same time under the control of a single robot control, which can be coordinated or can be synchronous

3.1.3.7
singularity
occurrence whenever the rank of the Jacobian matrix becomes less than full rank

Note 1 to entry: Mathematically, in a singular configuration, the joint velocity in joint space can become infinite to maintain Cartesian velocity. In actual operation, motions defined in Cartesian space that pass near singularities can produce high axis speeds. These high axis speeds can be unexpected to an *operator* (3.1.7.3).

[SOURCE: ISO 10218-1:2025, 3.1.3.6]

3.1.3.8
mode
operating mode
characterization of the way and the extent to which the *operator* (3.1.7.3) interacts with the control equipment

Note 1 to entry: Mode refers to the control state, e.g. *manual mode* (3.1.3.9), *automatic mode* (3.1.3.10).

3.1.3.9
manual mode
control state that allows control directly by an *operator* (3.1.7.3)

Note 1 to entry: Sometimes this is referred to as teach mode where program points, program logic and attributes are set.

3.1.3.10
automatic mode
control state that allows executing programmed tasks

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3.1.4 Program-related

3.1.4.1
task program
set of instructions for motion and auxiliary functions that define the specific intended task of the *robot application* (3.1.1.4)

Note 1 to entry: This type of program is generated by the *integration* (3.1.7.1) or use.

Note 2 to entry: The task program can include functions of other machinery within the *robot application* (3.1.1.4).

3.1.4.2
teach
programming of the task manually by positioning of the *manipulator* (3.1.2.7), or by using a *teach pendant* (3.1.3.3) to move the *robot* (3.1.1.2) through the desired positions, or program without causing motion, or by using an external device for off-line programming

Note 1 to entry: Manually positioning can be referred to as "lead-through teaching" using hand-guided control (HGC).

3.1.4.3
program verification
execution of a *task program* (3.1.4.1) for confirming the robot path and process performance

Note 1 to entry: Program verification can include the total path traced by the *tool centre point* during the execution of a *task program* (3.1.4.1) or a segment of the path. The instructions can be executed in a single instruction or continuous instruction sequence. Program verification is used in new *applications* (3.1.1.5) and in fine-tuning/editing of existing *applications* (3.1.1.5).

3.1.5 Power-, energy-related

3.1.5.1
drive power
energy enabling the *robot actuators* (3.1.2.12) to apply force or torque

3.1.5.2
energy source
electrical, mechanical, hydraulic, pneumatic, chemical, thermal, potential, kinetic or other type of source that is capable of supplying power

3.1.6 Hazard-related

3.1.6.1
hazard
potential source of harm

Note 1 to entry: The term “hazard” can be qualified in order to define its origin (for example, mechanical hazard, electrical hazard) or the nature of the potential harm (for example, electric shock hazard, cutting hazard, toxic hazard, fire hazard).

Note 2 to entry: The hazard envisaged by this definition either

— is permanently present during the intended use of the machine (for example, motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature), or

— can appear unexpectedly (for example, explosion, crushing hazard as a consequence of an unintended/unexpected start-up, ejection as a consequence of a breakage, fall as a consequence of acceleration/deceleration).

[SOURCE: ISO 12100:2010, 3.6, modified — Note 3 has been deleted.]

3.1.6.2
hazardous motion
movement that can cause personal physical injury or damage to health

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3.1.6.3
hazardous situation
circumstance in which a person is exposed to at least one *hazard* (3.1.6.1)

Note 1 to entry: The exposure can result in harm immediately or over a period of time.

[SOURCE: ISO 12100:2010, 3.10.]

3.1.7 Role-related

3.1.7.1
integration
act of combining a *robot* (3.1.1.2) with other equipment or another machine including additional *robot applications* (3.1.1.4) to form a *robot cell* (3.1.1.8) capable of performing useful work

Note 1 to entry: This act of machine building can include the requirements for the installation of the machinery and equipment associated with the *application* (3.1.1.5).

3.1.7.2
integrator
entity that designs, provides, manufactures, or assembles *robot applications* (3.1.1.4) or *robot cells* (3.1.1.8) and oversees the safety strategy, including the *protective measures* (3.1.10.1), control interfaces and interconnections of the control system(s)

Note 1 to entry: The integrator can be referred to as the "manufacturer" of the supplied *robot application* (3.1.1.4) or *robot cell* (3.1.1.8). The role of the integrator can be provided by the manufacturer, assembler, engineering company or the *user* (3.1.7.4).

3.1.7.3
operator
person using, operating, adjusting, maintaining, cleaning, repairing, troubleshooting, transporting, commissioning and disassembling

Note 1 to entry: This definition includes person or persons who can be expected at or near machinery, even if not performing a task associated with the specific machinery.

3.1.7.4
user
entity that uses *robot applications* (3.1.1.4) and *robot cells* (3.1.1.8) and is responsible for the *operator(s)* (3.1.7.3) associated with the *robot applications* (3.1.1.4) and *robot cells* (3.1.1.8)

3.1.8 Functional safety-related

3.1.8.1
safety function
function of the machine whose failure can result in an immediate increase of the risk(s)

[SOURCE: ISO 13849-1:2023, 3.1.27]

3.1.8.2
emergency stop
emergency stop function
function which is intended to

— avert arising or reduce existing *hazards* (3.1.6.1) to persons, damage to machinery or to work in progress, and

— be initiated by a single human action

[SOURCE: ISO 12100:2010, 3.40]

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3.1.8.3
protective stop
interruption of operation intended to reduce risks

3.1.8.4
monitored-standstill
safety function (3.1.8.1) that monitors the absence of motion while drive power is active

Note 1 to entry: Previously, "monitored-standstill" was called “safety-rated monitored stop”.

3.1.8.5
monitored-speed
safety function (3.1.8.1) that limits the speed to a configured value

3.1.8.6
reduced-speed
safety function (3.1.8.1) that limits the speed to be no greater than 250 mm/s

3.1.8.7
single-point-of-control
single source of control
ability to operate such that initiation of motion is only possible from one source of control and cannot be overridden from another initiation source

3.1.8.8
software-based limiting
safety function(s) (3.1.8.1) with monitored limit(s) placed on the range of motion of the *robot* (3.1.1.2) or other equipment

3.1.8.9
safety function input
input signal having a specified safety-related performance

3.1.8.10
safety function output
output signal having a specified safety-related performance

3.1.9 Spaces, zones and distances

3.1.9.1
space
three-dimensional volume

Note 1 to entry: See Annex B for illustrations of *spaces*.

3.1.9.2
maximum space
space (3.1.9.1) that can be reached by the moving parts of the *robot* (3.1.1.2)

Note 1 to entry: In the context of this document, *maximum space* refers to the *robot application* (3.1.1.4) which includes the *space* (3.1.9.1) reached by the *end-effector* (3.1.2.3) and workpiece(s).

Note 2 to entry: In the context of *mobile platforms* (3.1.2.10), *maximum space* is indeterminate.

3.1.9.3
operating space
portion of the *restricted space* (3.1.9.4) that is used while performing all motions commanded by the *task program* (3.1.4.1)

Note 1 to entry: In the context of this document, *operating space* refers to the *robot application* (3.1.1.4) which includes the *space* (3.1.9.1) reached by the *end-effector* (3.1.2.3) and workpiece(s).

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3.1.9.4
restricted space
portion of the *maximum space* (3.1.9.2) restricted by *limiting devices* (3.1.9.5)

Note 1 to entry: When the *restricted space* refers to the *robot system* (3.1.1.3), this includes the *space* (3.1.9.1) reached by the *end-effector* (3.1.2.3).

Note 2 to entry: When the *restricted space* refers to the *robot application* (3.1.1.4), this includes the *space* (3.1.9.1) reached by the *end-effector* (3.1.2.3) and workpiece(s).

3.1.9.5
limiting device
limiting function
means that reduces the range of motion to a portion of the *maximum space* (3.1.9.2), resulting in the *restricted space* (3.1.9.4)

Note 1 to entry: The ISO 12100:2010 definition of a *limiting device* is broader, encompassing more than motion. In ISO 12100, it is a device that prevents a machine or hazardous machine condition(s) from exceeding a designed limit (space limit, pressure limit, load moment limit, etc.).

Note 2 to entry: *Limiting device(s)* can be fulfilled by *safety function(s)* (3.1.8.1), e.g. *software-based limiting* (3.1.8.8). See *safeguard* (3.1.10.2).

3.1.9.6
safeguarded space
space (3.1.9.1) where *safeguards* (3.1.10.2) are active or where the *perimeter safeguard* (3.1.10.3) provides protection

Note 1 to entry: This sometimes refers to the space within *perimeter safeguarding* (3.1.10.3).

Note 2 to entry: This can change dynamically.

3.1.9.7
hazard zone
any *space* (3.1.9.1) within and/or around machinery in which a person can be exposed to a *hazard* (3.1.6.1)

[SOURCE: ISO 12100:2010, 3.11]

3.1.9.8
task zone
any predetermined *space* (3.1.9.1) within and/or around the *robot application* (3.1.1.4) in which *operators* (3.1.7.3) can perform a specified activity

3.1.9.9
detection zone
zone within which a specified test piece will be detected by the *sensitive protective equipment* (3.1.10.6)

Note 1 to entry: The *detection zone* can also be a point, line or plane.

[SOURCE: IEC 61496-1:2020, 3.4, modified — addition of the note to entry and deletion of “electro-” before “sensitive”]

3.1.9.10
separation distance
shortest permissible distance between any moving hazardous part of the *robot application* (3.1.1.4) and any *operator* (3.1.7.3)

Note 1 to entry: This value can be fixed or variable.

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3.1.10 Risk reduction measures

3.1.10.1
protective measure
measure intended to achieve risk reduction, implemented

— by the designer (inherently safe design, safeguarding and complementary protective measures, information for use); and/or

— by the *user* (organization: safe working procedures, supervision, permit-to-work systems; provision and use of additional safeguards; use of personal protective equipment; training).

[SOURCE: ISO 12100:2010, 3.19]

3.1.10.2
safeguard
guards or *protective devices* (3.1.10.5)

Note 1 to entry: *Protective devices* (3.1.10.5) include a broad range of means by which to reduce or control risks, for example:

— interlocking devices for guards,

— *sensitive protective equipment (SPE)* (3.1.10.6),

— *safety functions* (3.1.8.1) that replace a *protective device* (3.1.10.5),

— *limiting devices* (3.1.9.5),

— limited movement control device.

[SOURCE: ISO 12100:2010, 3.26, modified — Note 1 to entry has been added.]

3.1.10.3
perimeter safeguard
safeguard (3.1.10.2) that surrounds one or more *safeguarded space(s)* (3.1.9.6)

Note 1 to entry: A perimeter safeguard can encompass portion(s) of or an entire *robot application* (3.1.1.4), *robot cell* (3.1.1.8) or machine, and can consist of guards and *protective devices* (3.1.10.5).

3.1.10.4
impeding device
any physical obstacle (low barrier, rail, fixture, etc.) which, without totally preventing access to a *hazard zone* (3.1.9.7), reduces the probability of access to this zone by offering an obstruction to free access

[SOURCE: ISO 12100:2010, 3.29, modified — "fixture" has been added.]

3.1.10.5
protective device
safeguard (3.1.10.2) other than a guard

Note 1 to entry: Examples of types of *protective devices* are provided in 3.28.1 to 3.28.9 of ISO 12100:2010.

[SOURCE: ISO 12100:2010, 3.18, modified — Note 1 to entry has been adapted.]

3.1.10.6
sensitive protective equipment
SPE
equipment for detecting persons or parts of persons which generates an appropriate signal to the control system to reduce risk to the persons detected

[SOURCE: ISO 12100:2010, 3.28.5, modified — Note 1 to entry has been deleted.]

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3.1.10.7
presence-sensing device
PSD
sensitive protective equipment (3.1.10.6) that creates a sensing field, area or plane for detecting the presence of a body part or the whole of a person

Note 1 to entry: *Pressure-sensitive protective devices* (3.1.10.9) can be used as tripping devices as well as presence-sensing devices, as mentioned in ISO 12100:2010, 3.28.5 NOTE to entry.

[SOURCE: ISO 13856-3:2013, 3.2]

3.1.10.8
electro-sensitive protective equipment
ESPE
assembly of devices and/or components working together for protective tripping or presence-sensing purposes and comprising at a minimum:

— a sensing device;

— controlling/monitoring devices;

— output signal switching devices and/or a safety-related data interface

Note 1 to entry: The safety-related control system associated with the ESPE, or the ESPE itself, can further include a secondary switching device, muting functions, stopping performance monitor, etc. (see Annex A).

Note 2 to entry: A safety-related communication interface can be integrated in the same enclosure as the ESPE.

[SOURCE: IEC 61496-1:2020, 3.5 modified — "may" changed to "can" in Note 1 to entry.]

3.1.10.9
pressure-sensitive protective device
PSPD
sensitive protective equipment (3.1.10.6) of the "mechanically activated trip" type intended to detect the touch of a person or body part of a person

Note 1 to entry: A *pressure-sensitive protective device* consists of a sensor or sensors, which generates a signal when pressure is applied to part of its outer surface, and a control unit, which responds to the signal from the sensor and generates an output signal(s) to the control system of a machine.

Note 2 to entry: *Pressure-sensitive protective devices* can be used as tripping devices as well as *presence-sensing devices* (3.1.10.7), as mentioned in ISO 12100:2010, NOTE in 3.28.5.

Note 3 to entry: For the definitions of *sensitive protective equipment* (3.1.10.6) and *impeding device* (3.1.10.4), see ISO 12100:2010, 3.28.5 and 3.29, respectively.

[SOURCE: ISO 13856-3:2013, 3.1]

3.1.11 Verification and validation

3.1.11.1
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: *Verification* determines if the design meets its specification, e.g. through review, measurement, analysis, or inspection.

[SOURCE: ISO 9000:2015, 3.8.12, modified — Notes 1, 2, 3 to entry have been deleted and a new Note 1 to entry has been added.]

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3.1.11.2
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or *application* (3.1.1.5) have been fulfilled

Note 1 to entry: *Validation* determines if the specification accomplishes what was intended, e.g. that a specified limit is acceptable for its purpose. *Validation* includes functional testing.

[SOURCE: ISO 9000:2015, 3.8.13, modified — Note 1 to entry has been added.]

3.1.12 Contact-related

3.1.12.1
body model
representation of the human body consisting of individual body segments characterized by biomechanical properties

3.1.12.2
compliant
exhibiting deformation of material or mechanism when subjected to a force

Note 1 to entry: The reciprocal of stiff (e.g. compliant linkage, compliant surface).

3.1.12.3
quasi-static contact
contact to an *operator* (3.1.7.3) from moving part(s) of a *robot application* (3.1.1.4), where the body part can be clamped between a moving part of the *robot application* (3.1.1.4) and another fixed or moving part of the *application* (3.1.1.5)

Note 1 to entry: This includes contact from the *manipulator* (3.1.2.7), moving parts attached to the *manipulator* (e.g. cables, hoses), *end-effector* (3.1.2.3), and workpiece.

3.1.12.4
transient contact
brief contact to an *operator* (3.1.7.3) from moving part(s) of a *robot application* (3.1.1.4) where the body part is not clamped and can recoil or retract from the moving part of the *robot application* (3.1.1.4)

Note 1 to entry: This includes contact from the *manipulator* (3.1.2.7), moving parts attached to the *manipulator* (3.1.2.7) (e.g. cables, hoses), *end-effector* (3.1.2.3), and workpiece.

3.2 Abbreviated terms and symbols

Abbreviated term or symbol	Term	Occurrence
2D/ 3D	Two-dimensional / three-dimensional	4.2
3P	Three-position [enabling device]	5.7.6, 5.7.7
A	Surface area (2-dimensional) of contact	Annex M, M.1, M.2, M.3.4, Figure M.2, Formulae M.1, M.5, M.6
A	Ampere, unit of electrical current	Annex C, Table C.2
A1	Avoidable	Annex C, C.2.1.4.1, Annex E, Tables C.7, E.1, E.2, E.5
A2	Reasonably avoidable	Annex C, C.2.1.4.1, Annex E, Tables C.7, E.1, E.2, E.5
A3	Not avoidable	Annex C, C.2.1.4.1, Annex E, Tables C.7, E.1, E.2, E.5
AIS	Abbreviated Injury Scale	Annex M, M.3.1, Table M.2, footnote b
AIS 1	Abbreviated Injury Scale 1	Annex M, M.3.1, Table M.2, footnote b

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Abbreviated term or symbol	Term	Occurrence
AOPD	Active Opto-electronic Protective Device	5.8.6.1, 5.8.10, Annex J, J.2.3, J.2.9, Annex K, K.2.3, Figures J.4, J.5, J.6, K.3,
AOPDDR	Active Opto-electronic Protective Devices Responsive to Diffuse Reflection	5.8.6.1, Annex J, J.2.9, Annex K, K.2.3, Figures J.7, K.4,
AP	Possibility of avoidance	Annex C, C.2.1.4.1, C.2.1.4.2, Tables C.6, C.7
Av	Probability of avoiding or limiting harm, denoted as Av1, Av3 or Av5	Annex E, E.2.2; Tables E.1, E.3, E.4; Formula E.1
C	Intrusion distance	5.8.9.1, Annex L, Formula L.1, Figure L.1
°C	Degrees in Celsius, unit of temperature	Annex C, Table C.2
cm	Centimetre, unit of distance	Annex N, Figure N.6,
Cat.	Category, as in stop category or functional safety architecture, denoted as B, 1, 2, 3, or 4	5.5.3, Annex C, C.1, Annex D, Annex E, E.2.1, Tables D.1, E.2
CL	Claim Limit (of a SIL)	Annex E, E.2.2, Table E.4
CNC	Computer numerical control machine	Annex D, Table D.1
D	Distance	Annex L, Figure L.1
D	Dominant body side	Annex M, Table M.1
D	Duration of a single exposure in minutes	Annex C, C.2.1.3.4, Formula C.1
DCavg	Average diagnostic coverage	5.5.3
DL	[Harm/] Damage likelihood	Annex C, C.2.1.3.5.4, Table C.5
E	Transfer energy	Annex M, Table M.5, Formulae M.1, M.2
E	Exposure (to a hazard)	Annex C, C.2.1.3.4, Formula C.1
E0	Exposure prevented	Annex E, E.2.3, Tables E.1, E.5
E1	Low exposure to hazard	Annex C, C.2.1.3.2, Annex E, Tables E.1, E.2, E.5
E2	High exposure to hazard	Annex C, C.2.1.3.2, Annex E, Tables E.1, E.2, E.5
EMC	Electromagnetic compatibility	5.5.10
EOAT	End-of-arm tooling	3.1.2.3
ESPE	Electro-sensitive protective equipment	3.1.10.8, 5.8.1, 5.8.6.1, 5.8.9.1, Annex J, J.2.6, Annex K, K.1, K.2.3, Annex L, Figure L.2
F	Frequency, denoted as F1 or F2	Annex C, C.2.1.3.4, Formula C.1, Annex E, Formula E.1
Fr	Frequency and duration of exposure, denoted as Fr3 or Fr5	Annex E, E.2.2, Tables E.3, E.4, Formula E.1
F_{max}	Threshold force, quasi-static contact	Annex M, Table M.2, Annex N, N.2.4.6, Figure N.7, Formulae M.1, M.6
F_T	Threshold force, transient contact *(multiplier of quasi-static force)*	Annex M, Annex N, N.2.4.6, Table M.3, Figure N.7, Formulae M.2, M.5
F_{SA}	Actual maximum force, quasi-static contact	Annex N, N.2.4.6, Figure N.7
F_{TA}	Actual maximum force, transient contact	Annex N, N.2.4.6, Figure N.7
F_{Trig}	Trigger force	Annex N, N.2.4.6
h	Hour	5.5.2, 5.5.3, Annex C, Table C.1, Table C.3
H	1 000 mm minimum height of impeding device	Annex J, Figure J.6
HFT	Hardware fault tolerance	5.5.2, 5.5.3, Annex D, Table D.1

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Abbreviated term or symbol	Term	Occurrence
HGC	Hand-guided control	4.3.1, 5.5.7.1, 5.14.3, 5.14.4, 5.14.4.1, 5.14.4.2, Annex C, Annex I, I.3.1, Table C.1, Figure I.1
HP	Hazard perception	Annex C, C.2.1.4.2, C.2.1.4.3, C.2.1.4.4; Tables C.6, C.7
Hz	Hertz, unit of alternating current or electromagnetic wave frequency	Annex N, N.1.4
I/O	Input(s)/Output(s)	Annex F, Table F.1
IH	Incident history	Annex C, C.2.1.3.5.4, Table C.5
IMS	Integrated manufacturing system	5.3.1, 5.3.5
J	Joule, unit of energy	Annex M, Table M.4
K	Effective spring constant (stiffness) for a specific body region	Annex M, Table M.3 Formulae M.1, M.2, M.5, M.6, Annex N, N.1.1, N.1.5, N.5.2, Table N.1, Figure N.1
kg	Kilogram, unit of mass	Annex M, Table M.3, Annex N, Table N.1
kHz	Kilohertz, unit of alternating current or electromagnetic wave frequency	Annex N, N.1.4
kPa	Kilopascal, unit of pressure and stress	Annex C, Table C.2
lx	Lux, unit of light intensity per unit of area	5.15.4, Annex H
M	Mass per manipulator	3.1.2.8, Annex M, Figure: M.3, Formula: M.4
m	Metre, unit of distance	7.5.19, Annex L, L.2
m_H	Effective mass of the human body region and the effects of that body region being connected to other body regions	Annex M, Annex N, M.3.4, M.3.4.1, N.2.4.1.2, Tables : M.3, N.1 Figure: M.2, Formula: M.3
m_L	Effective mass of the payload for the robot application (specified maximum payload of the application)	Annex M, M.3.4, Figures: M.2, M.3, Formula M.4
m_R	Effective mass of the moving parts of the robot as a function of robot posture and motion	Annex M, M.3.4, M.3.4.1, Table M.2, Figures: M.4, Formulae: M.3, M.4
mA	Milliampere, unit of electrical current	Annex C, Table C.2
mm	Millimetre, unit of distance	3.1.8.6, 5.5.6.1, 5.5.6.2, 5.7.2.3.2, 5.7.7.2, 5.8.5.1, 5.12.2.1, 5.12.2.2, Annex M, Annex N, Table M.5, Table N.1
$MTTF_D$	Mean time to failure dangerous	5.5.3
N	Newton, unit of force	Annex C, Table C.2, Annex M, Annex N, Figure N.6, N.7, N.8
ND	Non-dominant body side	Annex M, Table M.1
n_{op}	Mean number of annual operations	Annex D, Table D.1
Nr	Factor for the number of persons exposed	Annex C, C.2.1.3.4, Formula C.1
O1	Probability of occurrence – low	Annex C, C.2.1.3.5.1, Annex E, E.2.1, Tables: C.5, E.1, E.2
O2	Probability of occurrence – medium	Annex C, C.2.1.3.5.1, Annex E, E.2.1, Tables: C.5, E.1, E.2
O3	Probability of occurrence – high	Annex C, C.2.1.3.5.1, C.2.1.3.5.2, Annex E, E.2.1, Tables: C.5, E.1, E.2
OS	Operator skill / information	Annex C, C.2.1.4.2, Tables: C.6, C.7
P_{max}	Threshold pressure, quasi-static contact	Annex M, Annex N, M.3.4.1, N.2.4.6, Table M.2, Figure N.7, Formulae: M.1, M.6

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Abbreviated term or symbol	Term	Occurrence
P_T	Threshold pressure, transient contact, a multiplier of quasi-static pressure	Annex M, Annex N, N.2.4.6, Table M.2, Figure N.7, Formula M.5
P_{SA}	Actual maximum pressure, quasi-static contact	Annex N, N.2.4.6, Figure N.7
P_{TA}	Actual maximum pressure, transient contact	Annex N, N.2.4.6, Figure N.7
P_{Trig}	Trigger pressure	Annex N, N.2.4.6
PFH	Average frequency of a dangerous failure per hour	5.5.2, 5.5.3, Annex D, Table D.1
PFL	Power and force limiting	4.3.1, 5.5.6.1, 5.7.7, 5.9.4, 5.14.3, 5.14.4.1, 5.14.5.1, 5.14.6, 5.14.6.1, 5.14.6.3, Annex B, Figure B.6, Annex C, Annex I, Annex J, Annex M, Annex N, I.3.2, J.2.1, M.1, M.2, M.3.2, N.1.1, N.2.1, N.4, N.4.3, Table C.1, Figure I.2,
PFMD	Pressure and/or Force Measuring Device	Annex M, Annex N, M.3.4, N.1.1, N.1.2, N.2.3, N.2.4, N.2.4.1.1, N.2.4.1.2, N.2.4.2, N.2.4.3, N.2.4.4, N.4.2, N.5, N.5.2, N.5.3, N.5.4, Figures: N.1, N.2, N.3, N.4
PL	Performance Level, denoted as PL a, PL b, PL c, PL d or PL e	4.1, 5.5.2, 5.5.3, Annex C, C.1, Annex D, Annex E, E.1, E.2, Tables: C.1, D.1, E.1 (footnote), E.2, E.5
PL_r	Required Performance Level	4.1, 5.5.3, Annex C, Annex E, Annex I, C.1, E.1, E.2.1, E.2.3, I.3.2, Tables: C.1, E.1 (footnote), E.2, E.5
PLC	Programmable logic controller	Annex D, Table D.1
PPE	Personal protective equipment	Annex I, I.2.3
Pr	Probability of occurrence of hazardous event, denoted as Pr1, Pr2 or Pr3	Annex E, E.1, E.2.2, Tables: E.1, E.3, E.4, Formula E.1
PSD	Presence-sensing device	3.1.10.7,
psi	Pounds per square inch, unit of pressure and stress	Annex C, Table C.2
PSPD	Pressure-sensitive protective device	3.1.10.9
PTFE	Polytetrafluoroethylene	Annex N
s	Second, unit of time	3.1.8.6, 5.5.6.2, 5.5.6.2, 5.7.2.3.2, 7.5.19, Annex C, Table C.2, Annex M, Annex N, Table M.5, Figure N.6, N.7, N.8
S1	Severity parameter – minor	Annex C, C.2.1.2.1, Annex E, E.1, E.2.1, Tables: C.2, E.1, E.2, E.5
S2	Severity parameter – moderate	Annex C, C.2.1.2.1, Annex E, E.1, E.2.1, Tables: C.2, E.1, E.2, E.5
S3	Severity parameter – serious	Annex C, Annex E C.2.1.2.1, E.1, E.2.1; Tables: C.2, E.1, E.2, E.5
S4	Severity parameter – catastrophic	Annex C, C.2.1.2.1, Annex E, E.1, E.2.1, Tables: C.2, E.1, E.2
Se	Severity, denoted as Se1, Se2, Se3 or Se4	Annex E, Tables: E.1, E.4
S_h	Contribution to the separation distance attributable to the operator's change in location until the robot application has stopped	Annex L, Figure L.1, Formulae: L.1, L.2, L.3
S_p	Separation distance	Annex L, Figure L.1, Formula L.1, Figure L.1
S_r	Contribution to the separation distance attributable to the robot application reaction time	Annex L, Figure L.1, Formulae: L.1, L.4, L.5
S_s	Contribution to the separation distance that occurs while the robot application is stopping until it stops	Annex L, Figure L.1, Formulae: L.1, L.6

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Abbreviated term or symbol	Term	Occurrence
Shore A	Shore A, unit of measurement of the hardness of a material, i.e., resistance to indentation, obtained by use of a shore durometer	Annex N, Table N.1
SIL	Safety Integrity Level, denoted as SIL 1, SIL 2, or SIL 3	4.1, 5.5.2, 5.5.3, Annex C, C.1, Annex D, Annex E, E.1, E.2.2, Tables: C.1, D.1, E.1 (footnote), E.3, E.4
SPE	Sensitive protective equipment	3.1.10.6, 5.8.4, 5.8.6.2, 5.8.6.3, 5.8.8, 5.12.2.3, Annex B, Figure B.5, Annex J, J.2.3, J.2.8, J.2.9, Figure J.3, J.4, J.5
SR	System robustness	Annex C, C.2.1.3.5.4, Table C.5
SRP/CS or SCS	Safety-related part of the control system	5.5.1, 5.5.2, 5.5.3, Annex F, Table F.1, Annex J, Figure J.4
SSM	Speed and Separation Monitoring	4.3.1, 5.14.3, 5.14.4.1, 5.14.5, 5.14.5.1, 5.14.5.2, Annex C, Annex F, Annex L, L.2, L.3, Tables: C.1, F.1, Figure L.1, L.2
t or T	Time	Annex C, Annex L, Table C.3, Figure L.1
T, dt	Time (T) and the differential for the integration variable (dt)	Annex L, Figure L.1, Formulae: L.2, L.3, L.4, L.5, L.6
t_0	Present or current time	Annex L, Figure L.1, Formulae: L.2, L.4, L.5, L.6
T_r	Reaction time of the robot application, excluding the time for the robot application to come to a stop	Annex L, Figure L.1, Formulae: L.2, L.3, L.4, L.5, L.6
T_s	Stopping time of the robot application, from the activation of the stop command until the robot application has stopped	Annex L, Figure L.2, Formulae: L.2, L.3, L.6
T_{trig}	Trigger time	Annex N, N.2.4.6
TCP	Tool centre point	3.1.2.13, 5.2.14, 5.9.6, 7.5.8, Annex L, L.2
TCP/UDP	Transmission control protocol/ user datagram protocol, describing types of ports for transmission or receipt of data	5.2.16
μ	Reduced mass of the two-body system	Annex M, Formulae: M.2, M.3, M.5, M.6
V	Volt, unit of electric potential or electromotive force	Annex A, Table A.1
V	Velocity	Annex L, Figure L.1, Formulae: L.2, L.4, L.5, L.6
v_h	Directed speed of an operator in the safeguarded space in the direction of the moving part of the robot application	Annex L, Figure L.1, Formula L.2
v_r	Directed speed of the robot application in the direction of an operator in the safeguarded space	Annex L, Figure L.1, Formulae: L.4, L.5
v_s	Speed of the robot application during stopping, from the activation of the stop command until the robot application has stopped	Annex L, Figure L.1, Formula L.6
v_{rel}	Relative speed between moving parts of the robot application and human body region	Annex M, Figure M.2, Formula M.2
$v_{rel,max}$	Maximum relative speed between moving parts of the robot application and human body region	Annex M, Figure M.4, Formula M.6
VBPD	Vision-Based Protective Devices	5.8.6.1
ω	Rotational speed	Annex M, Figure M.3
Z_d	Position uncertainty of the operator as measured by the PSD, resulting from the accuracy of the sensing system measurement	Annex L, Figure L.1, Formula L.1

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Abbreviated term or symbol	Term	Occurrence
Z_r	Position uncertainty of the robot application, resulting from the accuracy of the robot application position measurement system	Annex L, Figure L.1, Formula L.1

4 Risk assessment

4.1 General

A risk assessment in accordance with ISO 12100:2010 shall be performed for the robot application(s) and if applicable, the robot cell(s).

NOTE 1 ISO 12100:2010 provides requirements and guidance in performing hazard identification and risk reduction.

NOTE 2 Annex A contains a list of hazards that can be present with robot applications and robot cells, including end-effectors and manual load/ unload stations.

NOTE 3 Annex C contains safety function performance requirements with a choice of using the listed performance or performing a risk assessment using the parameters and thresholds of C.2 for risk estimation.

NOTE 4 Annex E contains examples for determining the PL_r or required SIL when the risk estimation parameters of C.2 are used. See 5.3.

NOTE 5 See IEC 60812:2018 for information about failure mode and effects analysis.

NOTE 6 For practical guidance on conducting risk assessment for machinery in accordance with ISO 12100:2010 including descriptions of various methods and tools, see ISO/TR 14121-2:2012.

The integrator should seek participation of the user when conducting the risk assessment.

4.2 Characteristics of robot applications and robot cells

The characteristics of robot applications and robot cells can be significantly different from those of other machines and equipment. The risk assessment shall include the following aspects, if relevant:

a) robot applications and their workpieces are capable of high energy movements through a large space;

b) the initiation of movement and the path of the robot application are difficult to predict and can vary;

   EXAMPLE Changes and variations can be due to handling of various size parts, changing motion paths based on conditions that are not obvious, and running different program.

c) the operating space of the robot application and its workpiece(s) can overlap

   — a portion of other robot applications' operating space(s) and their workpiece(s);

   — the task zones for other machines and related equipment;

   — task zones of operators.

d) end-effector selection and design can be used to reduce risks due to hazards of the end-effector and of workpiece(s).

   — end-effectors interact with workpieces and other parts of the robot application;

   — cleaning and maintenance can require frequent interactions, e.g. extended operator interaction with an adaptive fixture for variable presentation of workpiece or assembly;

   — troubleshooting is also a consideration;

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NOTE See 5.9 and Annex I.

e) robot applications can vary greatly, as will the tasks associated with these uses, where the tasks can include:

1) commissioning;
2) process control and monitoring;
3) workpiece loading;
4) performing operations on the workpiece(s);
5) teaching, programming and verifying;
6) operator intervention not requiring disassembly;
7) entering and/or leaving the safeguarded space;
8) starting and stopping the robot application;
9) tasks involving more than one operator;
10) tasks involving more than one robot;
11) setting-up (e.g. fixture changes, end-effector exchange, process equipment refresh or adjustment);
12) troubleshooting;
13) correcting malfunction(s) (e.g. equipment jams, dropped parts, event recovery);
14) control of hazardous energy (including fixtures, clamps, turntables, and other equipment);
15) integrating hardware and software with local cell control systems or wider enterprise systems;
16) integrating local 2D/ 3D vision systems;
17) maintenance and repairing;
18) equipment cleaning;
19) application changes;
20) re-deploying of the robot application or robot cell;
21) decommissioning;
22) disposal.

f) operator tasks not associated with the collaborative application could have travel path(s) through a collaborative application's safeguarded space, requiring this additional consideration when determining the collaborative application layout and access requirements.

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4.3 Characteristics of collaborative applications

4.3.1 General

In addition to 4.2, the risk assessment of collaborative applications shall include the following aspects, if relevant:

a) operators can work near the robot application while power to the robot actuators and end-effector(s) are available;

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b) collaborative applications can use one or more of the following safety functions:

— hand-guided controls (HGC) (5.14.4);

— speed and separation monitoring (SSM) (5.14.5);

— power and force limiting (PFL) (5.14.6).

c) there is the potential for intended or reasonably foreseeable unintended contact situations from the moving parts of the robot application to operator(s);

d) collaborative applications can have additional tasks to those listed in 4.2 e); these collaborative tasks can include the following:

1) during production or normal operation, there can be greater frequency and duration of:

— operator presence in the safeguarded space with a moving robot application (e.g. collaborative assembly with external fixtures);

— contact (e.g. hand guiding, physical interaction with tool or workpiece);

— operator interaction with the robot application.

2) transitioning between non-collaborative and collaborative use;

3) automatic or manual restart of motion after the collaborative application has been completed;

4) tasks involving more than one operator.

NOTE See 5.4 for the layout. See Annex B for illustrations of spaces, Annex M for collaborative application biomechanical limits, and Annex N for pressure and force measurement.

4.3.2 Risk assessment for contacts between moving parts of the robot application and operator(s)

Risk assessment shall consider hazardous situations in which possible contact could result in harm to the operator. Risk assessment shall consider means of reducing the possible contact where practicable and where not practicable, the contact situations shall not result in harm to the operator. This shall be achieved by:

— identifying conditions in which such contact would occur;

— evaluating the risk potential for such contacts;

— designing the robot application and safeguarded space so that such contact is infrequent and avoidable;

— applying risk reduction measures to keep the contact situations below pressure and force threshold limit values.

This identification shall consider the following criteria for potential contact events:

a) exposed operator body regions;

b) origin of contact events, i.e. intentional action as part of intended use versus unintentional contact or reasonably foreseeable misuse;

c) probability or frequency of occurrence;

d) type of contact event, i.e. quasi-static or transient (see 5.14.6.2);

e) contact surface areas, speeds, forces, pressures, momentum, mechanical power, transfer energy, and other quantities characterizing the physical contact event.

NOTE For information about ergonomic design principles related to mental workload, see ISO 10075-2:2024.

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5 Safety requirements and risk reduction measures

5.1 General

Robot applications and robot cells shall be designed according to ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document. Robots applied in robot applications shall conform with the requirements of ISO 10218-1:2025.

Figure 1 shows the organization of Clause 5.

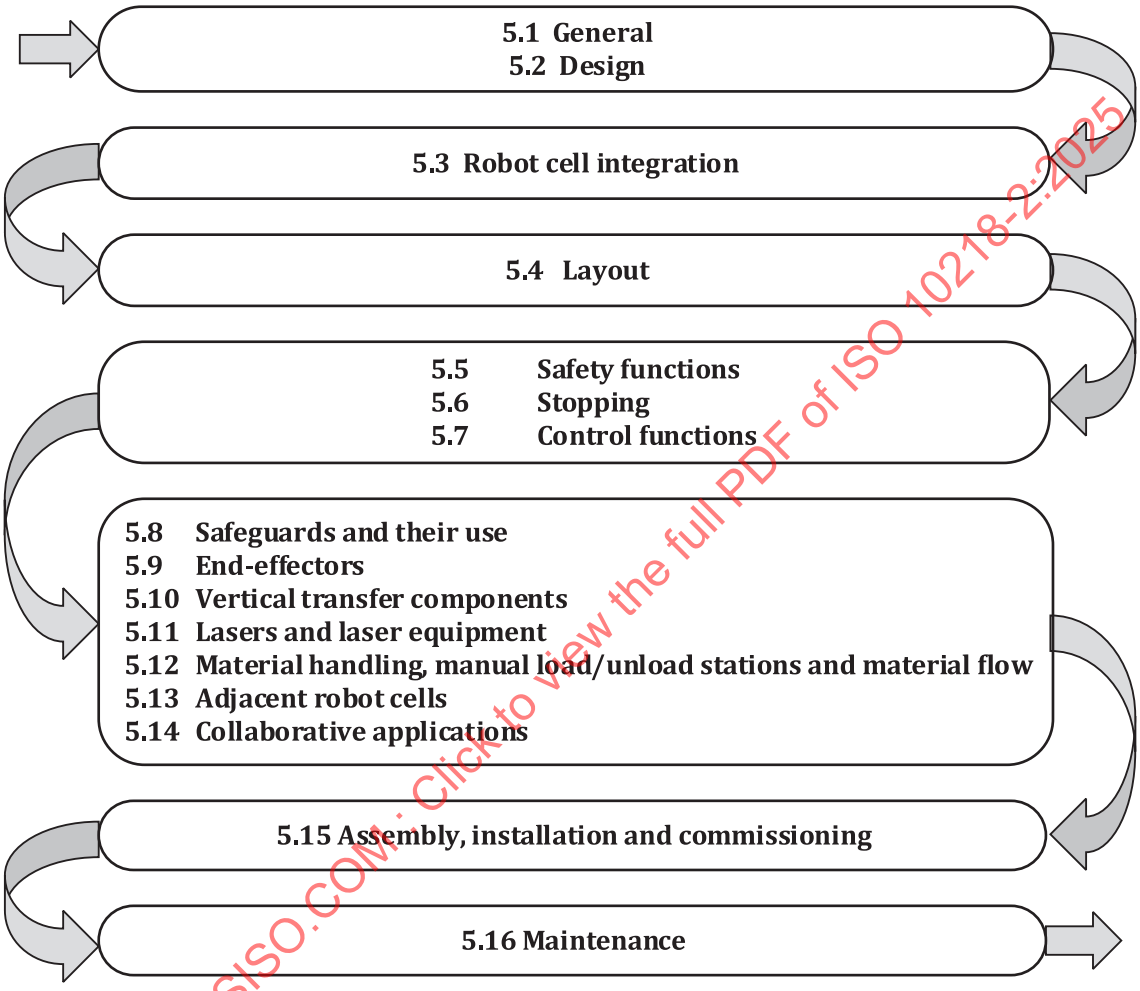


Figure 1 — Clause 5 structure

NOTE Methods of verification and validation of the requirements in this clause are in Clause 6 and Annex H.

5.2 Design

5.2.1 General

The design shall be based on the information for use provided with the robot, end-effector and the associated machinery and equipment. The design shall conform with the requirements as described in 5.2.2 through 5.2.16.

NOTE Suitable housings and covers can be used to mitigate potential hazards.

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5.2.2 Materials, mechanical strength and mechanical design

5.2.2.1 General

Robot applications and robot cells shall be designed and constructed to prevent hazardous situation(s) which result from failure due to fatigue and wear. Design and manufacturing shall take into account the lifecycle of the intended use (e.g. transportation, installation, operating conditions and maintenance in accordance with Clause 7, information for use).

Robot applications and robot cells shall be designed and constructed to take account of the constraints (e.g. protective gloves and control device push button dimensions) to which the operator is subject as a result of the use of personal protective equipment for the intended application.

5.2.2.2 Materials

Materials used shall:

a) be selected to be appropriate for the intended use (e.g. resistance to corrosion, abrasion, impacts, fatigue, deformation, aging);

b) not endanger persons' safety or health;

c) be non-toxic in all reasonably foreseeable conditions of use;

d) not be prone to brittle fracture, excessive deformation, or emission of toxic or flammable fumes;

e) retain their properties in the reasonably foreseeable range of climatic and workplace conditions, including temperature variations or sudden changes.

Where fluids are used, the design and construction shall address risks due to filling, use, recovery or draining.

5.2.2.3 Mechanical strength

The parts of the robot application shall be designed and constructed to withstand the loads expected for the intended application and the expected operating conditions.

The parts of the robot application involved in lifting operations (e.g. lifting workpieces or tools) shall be designed and constructed to:

— withstand an overload in static tests without permanent deformation or patent defect, where strength calculations shall have a minimum static test coefficient of 1,25;

— undergo, without failure, dynamic tests using the maximum payload multiplied by the dynamic test coefficient, where the dynamic test coefficient shall be at least 1,1.

Dynamic tests shall be performed at maximum speeds. If simultaneous movements can be programmed, the tests shall be done using the least favourable conditions.

Where complete ropes are used for lifting functions, the ropes and their endings shall have a minimum working coefficient of 5. Where chains are used for lifting functions, they shall have a minimum working coefficient of 4.

NOTE Complete ropes are finished assemblies which are designed to meet the requirements for use in lifting.

5.2.2.4 Mechanical design

The parts of the robot application shall be designed and constructed such that

— exposed sharp edges and corners unnecessary for the robot application and accessible to operator(s) shall be eliminated;

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— hazardous projections and corners unnecessary for the robot application and accessible to operator(s) shall be eliminated;

— any exposed sharp edges, sharp corners and hazardous projections that are necessary for the robot application shall be reduced as far as reasonably practicable.

Hazardous mechanisms that enable motion shall be installed or mounted such they are normally inaccessible.

Exposure to hazards caused by components such as motor shafts, gears, drive belts, or linkages which are not protected by integral covers (e.g. panel over a gear box) shall be prevented either by fixed guards or movable guards according to ISO 14120:2015. The fixing systems of the fixed guards which are intended to be removed for routine service actions shall remain attached to the robot, machine or equipment or remain attached to the guard. Movable guards shall be interlocked with the hazardous movements in such a way that the hazardous machine functions cease before they can be reached.

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

The design shall ensure that errors when fitting or refitting certain parts which could be a source of risk shall be prevented by the design and construction of such parts. If not practicable, information for use shall be provided at least on the parts themselves and/or their housings.

5.2.3 Provisions for lifting or moving

Instructions and provisions for lifting or moving parts of the robot application shall be provided when intended to be moved after initial installation. The provisions shall be capable of handling the anticipated load.

NOTE 1 For the lifting or moving of robot applications and its components, the information provided by the integrator can be sufficient, which could include a specific robot pose.

NOTE 2 The robot could be transported with parts mounted on the robot, e.g. end-effector, wiring, hoses.

5.2.4 Hazardous substances

Robot applications shall be designed and constructed in such a way that risks of inhalation, ingestion or contact of hazardous materials and substances shall be prevented.

Where the use of hazardous substances cannot be eliminated, the robot application shall be designed such that those substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another effective method.

Where the application does not allow the total enclosure of the substances during normal operation, containment and/or evacuation shall be designed to be effective.

5.2.5 Stability

To prevent tipping and falling-over, components of robot applications shall be:

— affixed to be stable (e.g. to other components, rails, tracks, mobile platforms, the floor or parts of the building structure); or

— stable itself for installation, operation and use.

Where components are used that move on rails, they shall be provided with means to prevent derailment when practicable. If risk of derailment or overturning persists due to a failure of a rail or of a moving component, means shall be provided to prevent the components or workpiece from falling or overturning.

NOTE The component could be the robot or any part of the robot application.

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5.2.6 Temperature and fire risks

The design of the robot application shall be such that the temperatures of accessible surfaces are according to ISO 13732-1:2006 and ISO 13732-3:2005.

NOTE 1 ISO/TS 13732-2:2001 contains methods for the assessment of human responses to contact with surfaces at moderate temperatures.

Where there is a risk of fire or overheating, the design principles of ISO 19353:2019 shall be applied.

NOTE 2 Conforming with ISO 19353:2019 could require safety function(s).

5.2.7 Special equipment

Special equipment and accessories to enable the robot application to be adjusted, maintained and used safely shall be supplied or made available.

NOTE Usual workplace equipment, e.g. ladders, spanners, hexagonal keys, is not considered to be special equipment.

5.2.8 Position holding

Hazardous motion of the robot application shall be prevented by position holding when drive power is lost. Position holding shall conform with ISO 10218-1:2025, 5.1.8.

When the position holding means is provided as part of the robot, it shall be implemented in accordance with the robot's information for use.

Position holding can be achieved using mechanical devices (e.g. brakes, pins, or other technology).

Position holding can be provided by:

a) safety function(s) to prevent hazardous situations whereby operators are crushed or impacted by the robot, end-effector, workpiece(s), other machines and sub-assemblies; and/or

b) a means to maintain posture and/or position of the robot, end-effector and workpiece(s), other machines and sub-assemblies to prevent hazardous situation(s) and damage of the workpiece or robot application.

NOTE 1 When provided by a safety function, the capability of configurable monitored position(s) can be provided. See Annex O, O.7.1.

NOTE 2 See 5.5.4 for failure or fault detection.

NOTE 3 See 5.2.10 about power loss or change.

Position holding means shall be designed and constructed to withstand an overload during static testing according to 5.2.2.3.

5.2.9 Additional axis (axes)

Additional axes that are associated with lifting or holding a suspended mass, (e.g. machinery, sub-assemblies, equipment, the robot, a payload) shall conform with relevant requirements in this document (e.g. 5.2.1, 5.2.2, 5.2.8, 5.5, 5.6, 5.7). When additional axis motion can affect the TCP speed in reduced-speed manual mode, the requirements of reduced-speed (5.5.6.1) shall be applied to the additional axes.

If the robot application has additional axis (axes) being operated in coordination with one another, each axis can move at different speeds. Safeguarding and/or safety functions shall be implemented to protect operators from the risks associated with the speed differences.

For calibration or other isolated movements of an additional axis,

— high-speed manual mode (5.7.2.3.3) may be used with the monitored-speed parameter set for this use;

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— it shall not be possible to actuate other axes when an additional axis operates at greater than reduced-speed.

5.2.10 Power loss or change

Loss or change of electrical, hydraulic, pneumatic or vacuum power shall not result in a hazardous situation.

Re-initiation of power shall not lead to any hazardous movements or a change of the safety-related parameters.

Unexpected start-up shall be prevented in accordance with ISO 14118:2017.

NOTE 1 See IEC 60204-1:2016+AMD1:2021 for electrical power supply requirements, ISO 4413:2010 for hydraulics and ISO 4414:2010 for pneumatics requirements.

NOTE 2 See 5.9 for end-effectors.

5.2.11 Component malfunction

Robot application components shall be designed, constructed, secured, or contained in accordance with 5.2.2, so that risks caused by breaking or loosening, or releasing, including those related to stored energy, are prevented as far as practicable.

NOTE Robot application components can include robot, end-effectors, safeguarding, external controllers, other equipment and machinery, etc.

5.2.12 Hazardous energy

5.2.12.1 General

Release of stored energy shall not cause hazardous situation(s). A means shall be provided to prevent uncontrolled or hazardous release of stored energy. If the hazardous energy is potential, there shall be a means to secure it in a position which can be either the energized or de-energized position.

Safe release or containment shall be provided in accordance with ISO 14118:2017.

A label shall be affixed to identify the stored energy hazard.

NOTE 1 Hazardous energy can take many forms: kinetic, gravity, electrical, pneumatic, hydraulic, thermal, chemical, etc. The sources of these energies can sometimes be readily identified, however often the sources are hidden or not obvious (e.g. accumulators, capacitors, batteries, springs, counterbalances, flywheels, heat as an outcome due to friction or other reactions).

Where additional axes can sink, drop or drift, means shall be applied either to prevent axis motion or to ensure that resulting motions can be initiated and result in a de-energized position in a controlled way. Safety function(s) for position holding (5.2.8) may be provided to prevent uncontrolled or hazardous release of stored energy.

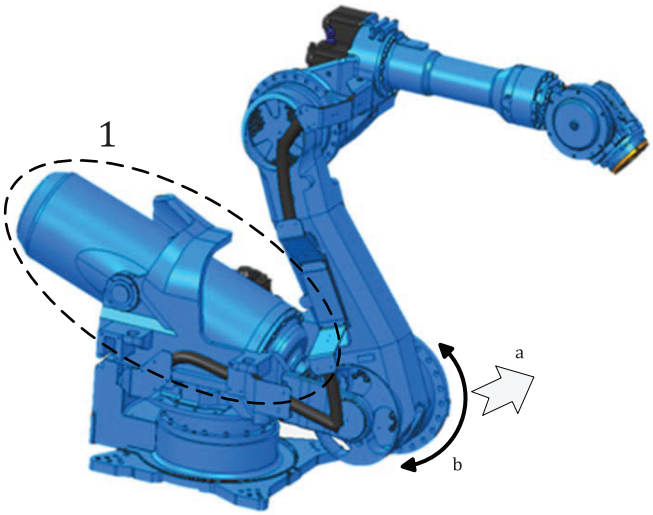
NOTE 2 Axes that do not maintain position (e.g. axis or axes that hang, drop, sink, drift) can create a significant risk depending on the task and frequency or duration of exposure (e.g. standing below the axis [axes] during setting).

Figure 2 shows an example of stored energy in a spring balancer.

EXAMPLE A hazardous situation can occur when a motor is removed, even though the energy to the robot is isolated as shown in Figure 2. Upon release, the unexpected motion due to the energy in the spring balancer can cause crushing, entrapment and more.

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Key

1 spring balancer

a Motor removal (direction of motion removal).

b Motion direction.

Figure 2 — Example of stored energy in a spring balancer

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5.2.12.2 Isolation of sources

Means of isolating the robot, end-effector, and robot application from any hazardous energy source shall be provided. This means shall be provided with capability of locking or otherwise securing only in the de-energized position.

The robot application should have a single supply disconnecting device for each type of energy source (e.g. electrical, pneumatic, hydraulic). For multiple robot applications and robot cells, multiple disconnecting devices for each type of energy can be necessary.

Each isolation device shall be readily identifiable as to what it isolates (e.g. by durable marking where necessary). The span-of-control for each of these devices shall be clearly marked near the disconnecting device (e.g. text or symbol).

For electrical supply disconnecting devices, IEC 60204-1:2016+AMD1:2021, 5.3.1 shall be applied.

For energy separation and dissipation requirements, ISO 14118:2017 shall be applied.

5.2.13 Electrical, pneumatic and hydraulic parts

Electrical parts shall be designed and implemented in accordance with the relevant requirements of IEC 60204-1:2016+AMD1:2021.

Pneumatic parts of the robot application shall be designed and implemented according to the relevant requirements of ISO 4414:2010.

Hydraulic parts of the robot application shall be designed and implemented according to the relevant requirements of ISO 4413:2010.

NOTE For requirements related to specific sub-assemblies, and components and machines, see relevant IEC or ISO standards (e.g. IEC 60269-1:2014, IEC 60745-1:2006, IEC 60947-1:2020, ISO 13850:2015).

Electric, pneumatic and hydraulic connectors shall be selected to prevent erroneous connections when this could lead to a hazardous situation. Where this is not practicable, connectors shall be labelled to lessen the likelihood of erroneous connection(s).

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5.2.14 Tool centre point (TCP) setting

When the capability to enter tool centre point (TCP) settings has been provided in the robot (ISO 10218-1:2025, 5.1.14) and failure to enter these settings can create a hazard, the TCP setting shall be entered in accordance with the robot information for use.

NOTE For additional axis requirements, see 5.2.9.

5.2.15 Payload setting

Where the payload setting is provided in the robot (ISO 10218-1:2025, 5.1.15) and failure to enter these settings can create a hazard, the payload setting shall be entered in accordance with the robot information for use.

NOTE The payload setting can be determined by the robot application.

5.2.16 Cybersecurity

A cybersecurity threat assessment shall be conducted. If the cybersecurity threat assessment identifies that a threat could result in safety risk(s), cybersecurity measures shall be provided to prevent unauthorized access to the control system(s), its hardware, software, configuration data and the application program(s).

NOTE 1 The means to prevent unauthorized access can include providing the following:

— ability to disable access to communications ports, e.g. Transmission Control Protocol/ User Datagram Protocol (TCP/UDP) port;

— ability to change the TCP/UDP port number, e.g. logical connection;

— authenticated protection of the safety configuration;

— ability to change the default configurations (e.g. usernames, user passwords, IP addresses and safety authentication).

NOTE 2 For guidance about the IT-security (cybersecurity) aspects and ISO 12100:2010, see ISO/TR 22100-4:2018.

NOTE 3 For information about security aspects related to functional safety, see IEC TS 63074:2023.

NOTE 4 For information about industrial communication networks and system security, see IEC 62443-3-3:2013.

5.3 Robot cell integration

5.3.1 General

Other machinery and equipment can be associated with the robot application or robot cell. If the associated machinery and equipment have relevant type-C standards, these standards shall be applied.

When machines are integrated and not directly controlled by the robot application or robot cell controller, ISO 11161 can be applicable.

Any safety-related control interfaces between the robot application(s), robot cell(s) and other machines and, if applicable, an IMS (Integrated Manufacturing System) shall conform with the requirements of 5.5 and Annex C.

Safeguarding shall protect operators against access to the following hazards:

— from other machines;

— within each hazard zone of a robot application and robot cell; and

— at the interfaces to adjacent hazard zones (e.g. conveyors).

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5.3.2 Span-of-control

In the case of multiple robot applications, multiple robot cells or other machinery, different span-of-control may be applied. In such cases, the span-of-control shall be set according to the requirements of the task(s) to be performed or the characteristics of the system (e.g. process flow, equipment structure, entry locations through perimeter safeguarding, location of other protective devices, hazards inside the safeguarded space).

NOTE See ISO 11161 for information about span-of-control.

5.3.3 Span-of-control of emergency stop function

Actuation of an emergency stop function shall stop:

— all hazardous motion of the robot, end-effector, and workpiece; and

— other hazardous movements and hazardous functions:

  — in the robot application or robot cell; and

  — at the interface(s) between robots, end-effectors, robot applications and robot cells.

The span-of-control shall be in accordance with ISO 13850:2015, 4.1.2 and be either perspicuous or clearly marked (e.g. by text or symbol) near the emergency stop device. The emergency stop functions for the robot and its end-effector shall have the same span-of-control. All emergency stop devices for the same hazard zone shall have the same span-of-control. In the event of additional risks due to hazards in the remainder of the robot application, the risk assessment may be used to determine whether these risks share the same span-of-control.

NOTE See ISO 13850:2015 for more information about the emergency stop span-of-control.

5.3.4 Operational modes with multi-robot applications or robot cells

In a robot cell with more than one robot system or robot application, mode(s) may be selected:

— individually on each robot control; or

— for each robot application; or

— be common for all associated robot applications in the robot cell.

If a mode is selected individually for each robot, it is not necessary that all robots be switched to manual mode. Robot applications that are not operated manually shall remain in a safe state, independent of the operational mode selected, and shall not create a hazard.

5.3.5 Local control, remote control and single-point-of-control

The following shall be fulfilled:

— determining what is considered remote control shall be according to 5.7.6.1;

— local control shall be according to 5.7.6.2;

— remote control shall be according to 5.7.6.3;

— single-point-of-control shall be according to 5.7.5.

When local control (5.7.6.2) is selected, other machines and their control systems shall be notified of this condition. Local control shall not be overridden by remote controls. The local control shall be located to be adjacent to and have a direct view of the robot cell.

The emergency and protective stop functions shall remain operational during both local control and remote control, in accordance with 5.6.1.

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5.3.6 Automatic workpiece feeding

Where workpieces are automatically fed, hazards caused by breakage shall be prevented or the risks shall be minimized by the design and integration.

5.4 Layout

5.4.1 General

The design shall be such that the operator can safely perform all intended and reasonably foreseeable tasks. The location of the robot application(s), equipment and machinery within the robot cell should not introduce additional hazards. If additional hazards are introduced, protective measures shall be applied to reduce the risks associated with these hazards, in accordance with Clauses 4 and 5.

Robot applications and cells shall be designed and constructed so that risks due to access of controls and equipment (e.g. weld controller, pneumatic valves) during automatic operation have been assessed and reduced.

The layout and anticipated tasks shall be reviewed to eliminate trapping and crushing possibilities within the robot application restricted space.

EXAMPLE The robot application can include fixtures, manual load/unload station (5.12.2), material handling equipment (5.10), end-effector changing systems (5.9) and process-related equipment.

The layout shall allow operator tasks to be performed from outside the safeguarded space. Where it is necessary to perform tasks within the safeguarded space(s), there shall be safe and adequate access to the task locations. Access paths and means shall not expose operators to hazards, including slipping, tripping, and falling hazards.

The design for access shall consider, for example:

— cable channels, places where operators could stumble;

— frequency of the required access for manual loading/unloading;

— physical characteristics of the load;

— abidance and observation zones;

— service positions (e.g. tip change);

— easily accessible maintenance locations.

Components which have to be changed frequently shall be capable of being removed and replaced easily and safely.

Permanent means of access shall be provided, considering the frequency and the ergonomic aspects of the task. Platforms, walkways, stairs, stepladders, and fixed ladders shall be in accordance with the relevant parts of the ISO 14122:2016 series.

Workstations shall be designed according to ISO 14738:2008. Access openings shall be designed according to ISO 15534-2:2000. Opening dimensions for the purpose of providing whole body access shall conform with ISO 15534-1:2000.

NOTE 1 See ISO/TR 22100-3:2016 for guidance on ergonomics standards.

NOTE 2 For whole body access requirements, see ISO 13857:2019, 4.4, where the whole body access is into hazardous areas or safeguarded spaces. See 5.5.7 and 5.8.

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5.4.2 Use and limits

The following shall be considered during the layout design process.

— use limits;

— operator task limits;

— space limits;

— time limits;

— end-effector limits;

— workpiece limits.

5.4.3 Design

Design considerations shall include:

a) the need for manual intervention(s);

b) allowing tasks requiring manual intervention to be performed from outside the safeguarded space;

EXAMPLE Loading and unloading the workpieces and the end-effector exchange system can be located outside the safeguarded space for ease of access.

c) ergonomics and human interface with equipment:

1) allowing for the variability of the operator's physical dimensions, strength and stamina;

2) providing enough space for movements of the parts of the operator's body;

3) visibility of the robot application and activities associated with the equipment;

4) clear association of controls with robot application(s) and robot cell(s);

5) local or user control design specifications;

6) position of workpiece relative to the operator;

7) consideration of avoiding a machine determined work rate;

8) avoiding tasks that requires lengthy concentration;

9) foreseeable misuse.

d) requirements for and location of emergency stop devices and possible spans-of-control (e.g. robot application or robot cell stops);

e) requirements for and location of additional enabling devices;

f) the intended use of all components;

g) specifications:

1) robot cell safety functions, including speed monitoring and limiting devices;

2) end-effector safety functions, if any;

3) robot(s) mass, payload, velocity, shape and dimensions;

4) mass, shape and dimensions of the end-effector and workpiece(s);

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5.4.4 Design for collaborative applications

Since collaborative applications can present unique risks, the following factors shall be addressed:

a) the spatial (three dimensional) limits of the safeguarded spaces;

NOTE Established limits can be static or dynamic.

b) access and clearance, and contacts:

1) influences on the safeguards (e.g. material storage, workflow requirements, obstacles);

2) the intended and reasonably foreseeable contact(s) from portions of the robot application to an operator, including pressure, force, and body location of contact;

3) object features (e.g. sharp edges, hot surfaces, etc.) around or in the space where trapping between the robot application and object could occur;

4) end-effectors, workpieces and protrusions shall not have exposed sharp edges where hazardous contact between robot application and person could occur.

c) ergonomics and human interface with equipment:

1) possible stress, fatigue, or lack of concentration arising from the collaborative applications;

2) ease of error or misuse (intentional or unintentional) by operator;

3) possible reflex behaviour of operator to movement of the robot, end-effector, workpiece and related equipment;

4) inability to predict potential motion of the robot application;

5) required training level and skills of the operator;

6) potential consequences of single or repetitive contacts from the robot application to operators.

d) transitions (time limits):

1) starting and ending of collaborative tasks;

2) transitions from collaborative tasks to other tasks.

5.4.5 Prevention of trapping within the safeguarded space

The robot application shall be designed and constructed such that it prevents a person from being trapped within the robot application or robot cell.

The safeguarded space shall be designed, constructed, or fitted with a means of preventing an operator from being trapped within the safeguarded space. For example, this may be fulfilled by providing for manual opening of movable guards from inside the safeguarded space, regardless of the state of the energy supply.

NOTE For information about escape release, see ISO 14119:2024, 6.9.1.

If this is not practicable, all the following shall be provided:

— a means by which to stop the robot application;

— a means to prevent the start/restart of the robot application (5.5.7 and 5.7.3);

— a means to summon help;

— a means to release a trapped operator.

When means to stop and means to prevent the start are provided, these means shall be readily accessible and located away from hazardous zone(s).

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5.4.6 Establishing restricted spaces

The restricted space shall be established by limiting motion of the robot, end-effector and workpiece in accordance with 5.4.7.

When the maximum space is required for the robot application, the maximum space shall be considered to be the restricted space.

5.4.7 Limiting motion

5.4.7.1 General

Robot applications shall be designed and integrated to reduce the potential exposure of operator(s) to hazards by implementing limiting devices. Limiting devices are used to reduce the space that a robot application uses, thereby establishing a restricted space (5.4.6). The restricted space can be made smaller than the maximum space by use of limiting devices. Limiting devices can be integral to the robot or by external means.

NOTE 1 See ISO 10218-1:2025, 5.7 for motion limiting requirements of robots.

NOTE 2 See space illustrations in Annex B.

Limiting the motion of the robot application may be fulfilled by a combination of the following:

a) means integral to the robot (e.g. safety functions, software-based limiting safety function(s));

b) mechanical limiting devices provided with the robot in accordance with ISO 10218-1:2025, 5.7;

c) mechanical limiting devices provided with the integration;

d) integrating external limiting devices;

e) installing limiting devices for machines and components of the robot application and robot cell.

Limiting devices shall

— prevent motion beyond the limiting device setting by either mechanical limiting devices (5.4.7.2) or safety functions that prevent reaching the limit (5.4.7.3 and Annex C); or

— initiate a protective stop by non-mechanical limiting devices (5.4.7.3) which can include software-based limiting safety functions.

NOTE 3 For robot applications using robots that compensate speed based on actual payload, it is possible for the speed to change when the robot carries less than the expected payload.

NOTE 4 The restricted space is defined where the motion stops, not by where the stop is initiated. The restricted space can be defined by the location of mechanical limiting devices (e.g. hard stops). Locating non-mechanical limiting devices, including software-based limiting (5.4.7.3), can require that activation time and stopping distance be considered.

Devices designed to protect the machine (e.g. collision sensors) may be used as limiting devices if they are specifically designed, tested, integrated and determined to be suitable as a safety function for limiting motion according to ISO 10218-1:2025, 5.7.

5.4.7.2 Mechanical limiting devices

If mechanical limiting devices are used, they shall conform with the requirements for limiting devices in ISO 10218-1:2025, 5.7.3 or 5.7.4 and this subclause. If mechanical limiting devices are selected as the means for limiting motion, the mechanical limiting devices shall be installed and adjusted for the robot application.

In cases where the perimeter guard is designed to be the limiting device, the results of the risk assessment and ISO 14120:2015 shall be used to determine the requirements for the design, strength, and deflection for that guard.

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The perimeter guard shall not be used as a limiting device when robot applications can cause hazardous deformations of the guard.

5.4.7.3 Non-mechanical limiting devices

If non-mechanical limiting devices are used, non-mechanical limiting devices shall conform with this subclause and ISO 10218-1:2025, 5.7.1 and either 5.7.3 or 5.7.4. Functional safety performance shall conform with 5.5 and Annex C.

NOTE 1 Software-based limiting safety function(s) are a type of non-mechanical limiting device implemented using safety functions within the robot. See ISO 10218-1:2025, 5.7.4.

If the robot has software-based limiting safety function(s), the safety function(s) shall be configured for the robot application using the robot manufacturer's instructions.

When non-mechanical limiting devices are used, the robot application restricted space shall be determined where the moving parts of the robot application stops. If the speed of the robot TCP is limited by monitored-speed safety function, the restricted space may be based on the parameter setting of the monitored-speed safety function. Otherwise, the restricted space shall be based on the maximum speed of the robot application.

NOTE 2 For software-based limiting requirements of the robot, see ISO 10218-1:2025, 5.7.4.

NOTE 3 For speed monitoring safety function(s) requirements of the robot, see ISO 10218-1:2025, 5.5.3.

When the limiting device functions by initiating a protective stop when the limit is reached or exceeded, the stopping distance/ angle and stopping time (starting at the position and time of triggering the protective stop) shall be used to determine the restricted space of the robot application.

If the software-based limiting safety function(s) causes a stop such that the limit will not be exceeded, then the restricted space may be at the limit setting.

NOTE 4 See ISO 10218-1:2025, Annex H stopping time and distance measurement.

5.4.7.4 Dynamic limiting

Dynamic limiting shall automatically modify the axis limiting device setting(s) to result in the intended restricted space for that portion of the robot application's automatic operation.

Dynamic limiting safety functions(s) are optional. When provided, dynamic limiting shall conform with 5.5 and may be fulfilled by parametrization according to 5.5.5. When dynamic limiting is provided:

— the axis limiting function(s) shall conform with 5.4.7.3; and

— axis limiting of the robot shall conform with ISO 10218-1:2025, 5.7.4.

NOTE Dynamic limiting can be useful in designing two alternately selectable restricted spaces to increase work cell productivity by having one robot service two task zones (e.g. two manual load/unload stations).

5.5 Safety functions

5.5.1 General

Control systems shall be designed so reasonably foreseeable human error during operation does not lead to hazardous situations.

Robots shall be selected with suitable safety functions for the requirements of the robot application. The safety functions of the selected robots shall be in accordance with ISO 10218-1:2025, 5.3.

Robot applications can include a broad range of applications. Therefore, it is not possible to provide a list of all significant hazards, hazardous situations or events, which could be related. Moreover, similar applications can have different levels of risk resulting from different designs which correspond to the

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intended application (e.g. paint spraying on large or small parts, handling of a small harmful payload like a hot metal bolt or a large harmless payload like a box of paper tissues)

As a result, this document cannot prescribe the performance of the safety-related control functions for all applications. The following requirements shall be fulfilled:

— safety-related control systems (electric, hydraulic, pneumatic, mechanical and software) shall conform with 5.5 and Annex C; and

— safety-related control system performance information of all safety functions shall be provided according to 7.5.16.

NOTE 1 Safety-related control systems can also be called SRP/CS (safety-related parts of control systems) or SCS (safety-related control system).

Safety functions may be provided that are not described within this document. If provided, the safety function(s) shall be described according to 7.5.16.

NOTE 2 See Annex D for an example of how to present functional safety information.

5.5.2 Functional safety standards

Safety-related control system (SRP/CS or SCS) shall be designed in accordance with either:

— ISO 13849-1:2023 or

— IEC 62061:2021.

ISO 13849-1: 2023 and IEC 62061:2021 standards address functional safety using similar but different methods. Requirements in those standards shall be used for the respective safety functions for which they are intended. Either ISO 13849-1:2023 or IEC 62061:2021 shall be used.

NOTE The performance of each specific safety function is generally stated in terms of the probability of dangerous failure per hour (PFH).

5.5.3 Performance

The integrator shall determine the performance of each required safety function according to one of the below:

— functional safety PL_r or required SIL listed in Annex C, Table C.1;

or

— the results of a comprehensive risk assessment where the risk estimation meets the requirements of ISO 12100:2010 and either ISO 13849-1:2023 or IEC 62061:2021.

NOTE 1 Guidance for risk estimation parameters is provided in Annex C, C.2.

The robot application shall have the required SRP/CS for each safety function in accordance with the determined performance requirements.

Where PL d is determined to be required, the safety function shall achieve PL d using either a Category 3 architecture or the PFH shall be less than $4{,}43 \times 10^{-7}$/h.

Where SIL2 is determined to be required, either the hardware fault tolerance (HFT) shall be at least 1 or the PFH shall be less than $4{,}43 \times 10^{-7}$/h.

NOTE 2 Achieving a PFH value less than $4{,}43 \times 10^{-7}$/h using a Category 2 architecture requires a DCavg > 90 % and a $MTTF_D$ > 62 years. This can be achieved by sub-systems based on electronics and non-mechanical solutions. See ISO 13849-1:2023, Annex K.

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5.5.4 Failure or fault detection

Any detected fault of the safety-related control system shall result in a reaction that is appropriate for the intended performance of the safety function. Depending on the safety function and the fault, the appropriate reaction can include finishing the cycle or initiating a stop which shall be a stop category 0 or 1 according to IEC 60204-1:2016+AMD1:2021.

NOTE Triggering of a safety function indicates that the safety function works as intended. This is not a fault or failure of the safety function. The triggering of the safety function results in the defined behaviour of the safety function according to Annex C.

5.5.5 Parameterization of safety functions

Parameter settings that are a part of a safety function shall be according to ISO 13849-1:2023 or IEC 62061:2021. Safety functions and their parameters shall be secured such that they are only changeable by authorized personnel. This parameter security shall be separate from that which allows access for programming non-safety functions and configuring parameters.

NOTE 1 See ISO 13849-1:2023, 5.2.2 and 6.3 or IEC 62061:2021, 6.7.

Once the safety function(s) is activated, they shall always be active upon power-up and an identifier (e.g. checksum) shall be generated so that changes to these settings can be identified. This identifier shall be capable of being output as a non-safety function. Change(s) to safety function parameters shall require re-initialization after manual change(s) and shall not be capable of being reconfigured during automatic execution of the task program.

Software on-line tools that directly influence the safety-related system, as defined in IEC 61508-4: 2010, 3.2.10, shall not be used.

NOTE 2 For guidance about on-line and off-line tools, see IEC 61508-3:2010, 7.4.4.1, IEC 61508-4:2010, 3.2.10 and 3.2.11.

NOTE 3 Correct operation of a safety function is based on proper and reliable setting of a safety-related parameter(s) used in the safety function(s), especially for safety-related application software.

Safety function parameters shall be verified and validated (6.3.2) before starting use of the robot application. This includes both for initial parameters and any changes to these parameters.

Information on the active settings and configuration of the safety functions shall be capable of being viewed and documented, for example by showing the identifier's result on the user interface. Additional data may be provided (e.g. configuration information, authorized personnel, configuration date).

5.5.6 Speed limit(s) monitoring

5.5.6.1 Reduced-speed

This is a safety function where the speed of accessible moving parts shall be no greater than 250 mm/s or the set maximum limit that is less than 250 mm/s. Reduced-speed shall be used with reduced-speed manual mode (5.7.2.3.2). Reduced-speed may be used for limiting the speed of a PFL collaborative application in accordance with 5.14.6.3 d).

NOTE 1 Reduced-speed can be decreased to any setting below 250 mm/s. The setting is determined for each application.

If there is an additional axis such that the robot and additional axis (axes) are operating in a coordinated manner, the speed of the TCP and any exposed part of the manipulator shall not exceed 250 mm/s and could require the capability of a reduced-speed limit that is less than 250 mm/s.

NOTE 2 This can be achieved by monitoring the TCP and the speed of the joints.

NOTE 3 See 5.2.9 for additional axis requirements.

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If a reduced-speed setting less than 250 mm/s is required for the application, the robot application shall be configured with the reduced-speed parameter.

NOTE 4 See 5.9 for end-effector requirements.

5.5.6.2 Monitored-speed

A monitored-speed safety function is a speed limiting safety function that may be set to be greater than 250 mm/s or as low as zero (0) speed.

Zero speed setting can be required for operational reasons and may not always be the result of a protective stop.

If a monitored-speed safety function is provided with the robot, the robot application shall be configured and implemented with the monitored-speed value that will achieve the results required as determined by risk assessment.

NOTE See 5.9 for end-effector requirements.

5.5.7 Start / restart interlock and reset

5.5.7.1 Start/ restart interlock

The control system shall have a start/restart interlock function to prevent the automatic start/ restart. Automatic restart shall conform with ISO 13849-1:2023, 5.2.2.4. The start/restart interlock safety function shall conform with 5.5 and Annex C, Table C.1.

Automatic start/restart shall be prevented:

a) after a change in the mode of operation:
   - from automatic mode to manual mode;
   - from reduced-speed manual mode to high-speed manual mode;
   - from high-speed manual mode to reduced-speed manual mode; and
   - from modes described in 5.7.2 to other modes and vice versa, when the automatic start/restart can lead to a hazard;

b) in manual mode, after a protective stop is initiated by any enabled protective device;

c) after actuation of a safeguarding function when that safeguard allows undetected presence in the safeguarded space(s).

NOTE 1 Undetected presence in the safeguarded space is also called “whole body access”. Whole body access can happen after actuation of a safeguard that allows undetected presence within the safeguarded space(s). See 5.8.10.

NOTE 2 The restart interlock function can be combined with a start interlock function.

NOTE 3 See Annex P and Figure P.1.

5.5.7.2 Reset

The reset safety function and the reset actuator location shall conform with ISO 13849-1:2023, 5.2.2.3. The reset safety function shall be in accordance with 5.5 and Annex C, Tables C.1, with a minimum functional safety performance of PL b.

Resetting shall be by a deliberate manual action on a specific control device in a control station (e.g. an electro-mechanical pushbutton in a control panel or a virtual pushbutton) according to 5.7.8. If HGC are deactivated and then activated while being within the same mode, the start/restart interlock may be reset by the release and re-actuation of the hold-to-run device on the HGC.

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Unintended reset shall be prevented by either only accepting the release of the actuator from its energized (on) position or another suitable method (e.g. two activation zones on a touch sensitive screen).

Where whole body access is possible, supplementary protective measures shall be provided in accordance with 5.8.10 to prevent resetting the start/restart interlock.

NOTE See Annex P and Figure P.1.

5.5.8 Monitored-standstill

When a monitored-standstill safety function is needed to prevent unintended motion, the following shall be fulfilled:

a) the standstill position shall be monitored and maintained according to 5.5.3;

b) any unintended motion from the standstill position shall result in a stop category 0 or 1 in accordance with IEC 60204-1:2016+AMD1:2021;

c) a detected failure shall conform with 5.5.4.

This safety function may be initiated externally (e.g. from protective devices). A safety function output may be provided for when monitored-standstill is active.

5.5.9 Communications

When data communications are used in the implementation of a safety function, the requirements of IEC 61508-2:2010, 7.4.11 shall be applied.

The three permissible transmission categories are described in Table 1.

Table 1 — Categories of communications transmission systems

Transmission Category	Main characteristics
1	Designed for known and fixed maximum number of participants. All properties of the transmission system are known and invariable during the lifetime of the system. Negligible opportunity for unauthorised access.
2	Properties are unknown, partially unknown or variable during the lifetime of the system. Limited scope for extension of user group. Known user group or groups. Negligible opportunity for unauthorized access (networks are trusted). Occasional use of non-trusted networks.
3	Properties are unknown, partially unknown or variable during the lifetime of the system. Unknown multiple user groups. Significant opportunity for unauthorized access.
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NOTE 1 A transmission category 1 network typically has a fixed maximum number of participants, while a transmission category 2 network is a less controlled network but has negligible opportunity for unauthorized access. A transmission category 3 network has unknown properties and a high risk of unauthorized access. See Table 1.

NOTE 2 For a full description of communications categories, see IEC 62280:2014 or EN 50159:2010.

When a robot application has an internal network, the network shall be considered as a transmission category 1 network according to Table 1. When a robot application has an external network, the network

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shall be considered as a transmission category 2 or transmission category 3 network according to Table 1, then Table 2 provides countermeasure requirements.

Table 2 — Robot application external network – countermeasure requirements

Transmission Category	Repetition	Deletion	Insertion	Resequence	Corruption	Delay	Masquerade
1	+	+	+	+	++	+	-
2	++	++	++	+	++	++	-
3	++	++	++	++	++	++	++

NOTE The term: "masquerade" means that the true source of a message is not correctly identified. For example, a message from a non-safety element is incorrectly identified as a message from a safety element. See IEC 61508-2:2010, 7.4.11.1 [21].

Key

- - Threat can be neglected.
- + Threat exists, but rare; weak countermeasures sufficient.
- ++ Threat exists; strong countermeasures required.

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5.5.10 Electromagnetic requirements

Safety-related control systems shall fulfil the requirements of IEC 61000-6-7:2014.

NOTE This requirement is relevant to functional safety. Other EMC standards can be required for reasons not related to functional safety.

5.6 Stopping

5.6.1 General

Every robot application or robot cell shall have a protective stop function, a normal stop and an independent emergency stop function.

The control system shall be designed such that stop functions have precedence over any other control functions. When a stop function has been initiated, no other control functions shall enable robot application functions until the stop condition has been achieved.

NOTE Annex F shows a comparison of the stop functions.

5.6.2 Emergency stop

5.6.2.1 General

Each control station, including pendants, capable of initiating motion or other hazardous functions shall have a manually initiated emergency stop function that complies with the requirements of IEC 60204-1:2016+AMD1:2021 and ISO 13850:2015. Selection of a stop category 0, or 1 in accordance with IEC 60204-1:2016+AMD1:2021 shall be determined from the risk assessment.

Robot applications shall have a single emergency stop function with a span-of-control affecting all relevant parts of the robot application, including fixtures.

Emergency stops shall remain functional even if the control station is not powered.

NOTE For requirements of cableless or detachable pendants (including teach pendants), see 5.7.8.4.

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Emergency stop function shall have the ability for the connection of additional emergency stop devices. The emergency stop function shall conform with 5.5 and Annex C, Table C.1.

5.6.2.2 Control stations

Each control station, including pendants, capable of initiating robot motion or other hazardous situations shall have a manually initiated emergency stop function that:

a) complies with the requirements of 5.6.2;

b) takes precedence over all other functions;

c) causes all hazardous machine functions within the span-of-control (5.3.3) to stop;

d) removes drive power; and

e) remains active until the emergency stop device is disengaged in accordance with ISO 13850:2015, 4.1.4.

The emergency stop function shall only be reset by a deliberate manual action that does not cause a restart after resetting but shall only permit a restart to occur.

5.6.2.3 Emergency stop input

Any safety function input for emergency stop shall remain operative when the power is removed and recovered.

NOTE See 5.8.10 for prevention of unexpected restart and 5.7.3 for prevention of unexpected start-up.

5.6.2.4 Emergency stop output

When an emergency stop output is provided, the output shall continue to function when the power is removed. When a safety function output for an emergency stop is provided, the function shall remain operative when the drive power is removed and recovered.

NOTE See ISO 10218-1:2025, 5.4.2.

5.6.3 Protective stop

The robot application shall have one or more protective stop functions that have the capability to be initiated by an internal safety function or external protective devices. The following shall be fulfilled:

a) the protective stop function shall conform with 5.5;

b) selection of stop category 0, 1 or 2, in accordance with IEC 60204-1:2016+AMD1:2021, shall be determined by the risk assessment;

c) a monitored standstill safety function according to 5.5.8 shall be required when a stop category 2 according to IEC 60204-1:2016+AMD1:2021 is used for the protective stop.

5.6.4 Normal stop

The control station(s) for the application shall be fitted with a normal stop control device to stop some or all the functions, according to the span-of-control. This stop function, when activated, shall result in a category 0 or category 1 stop according to IEC 60204-1:2016+AMD1:2021. Once the hazardous functions have stopped, the energy supply to the hazardous function actuators shall be removed.

The protective stop function may be used as the normal stop function when it complies with stop category 0 or 1 according to IEC 60204-1:2016+AMD1:2021.

The normal stop safety function shall be in accordance with 5.5 and shall have a minimum functional safety performance of PL b (Annex C, Table C.1).

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Emergency stop devices shall not be used as a normal stop device.

5.6.5 Associated equipment stopping

The robot application shall be integrated and installed so stopping, e.g. emergency or protective stop, of associated equipment shall not result in a hazard or hazardous situation(s).

5.7 Control functions

5.7.1 General

Control functions shall meet the requirements of IEC 60204-1:2016+AMD1:2021. The control functions shall be designed to be consistent with the requirements of ISO 10218-1:2025. Control functions that initiate power or motion shall be designed and implemented to meet the requirements in 5.7.2 to 5.7.9.

5.7.2 Modes

5.7.2.1 General

The following requirements apply to a robot application or a robot cell and do not apply to equipment within the robot cell that is not required for the robot application.

5.7.2.2 Automatic

The robot application and robot cell shall have an automatic mode. In automatic mode, the intended functions shall be performed and the associated safety functions shall be active.

Changing from automatic mode to any other mode shall result in a protective stop. Automatic operation shall not start until a separate confirmation from outside the safeguarded space is provided by the operator. In the case of using perimeter safeguarding, automatic operation shall require a separate confirmation from outside the perimeter safeguarding.

5.7.2.3 Manual

5.7.2.3.1 General

A manual mode shall be provided for jogging, teaching, programming, program verification and manual intervention tasks.

When a robot application is operated in manual mode, the following shall be fulfilled:

a) all other equipment that is not required for the task shall be placed in, and maintained in, a safe state;

b) if it is necessary for other machines, equipment or processes to operate while in manual mode, they shall operate under reduced risk conditions (e.g. reduced-speed, reduced torque, reduced force, limited movement, by jogging which can be in conjunction with the same or another enabling device specific to that use);

c) the robot application shall be under local control according to 5.7.6.2 with single-point-of-control according to 5.7.5;

d) automatic operation shall be prevented;

e) movements shall only be possible by use of a control station in accordance with 5.7.8, where that control station is the single-point-of control (5.7.5).

NOTE See ISO 10218-1:2025, 5.2.7.2.1 for manual mode when movement of the robot is caused by a human using HGC as compared to movements caused by the robot control.

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5.7.2.3.2 Reduced-speed

A reduced-speed manual mode shall be provided for jogging, teaching, programming, program verification and manual intervention tasks. Where these tasks require control of the functions of the robot application or robot cell while a person or person(s) are in the safeguarded space, manual mode shall be provided by a teach pendant in accordance with 5.7.8.3.

For Class I robots that fulfil the requirements of ISO 10218-1:2025, 5.1.17, the requirement for reduced-speed manual mode may be excluded when jogging, teaching, programming and program verification shall not lead to a hazardous situation.

Movements shall only be possible with reduced-speed according to 5.5.6.1 during the actuation of the enabling device on the control station that enables movements of the robot application/robot cell. A separate deliberate manual action shall be required to initiate motion(s).

If a speed setting of less than 250 mm/s is needed in reduced-speed manual mode for the robot application, the following shall be fulfilled:

— the robot(s) shall be configured to the required reduced-speed limit for the robot application;

— if the end-effector and/or other machinery/ equipment in the robot application need to be operated at a configurable reduced-speed setting, this safety function (and the required speed value) shall be implemented for the end-effector and/or other machinery/ equipment as needed.

NOTE See 5.3 and 5.9.

5.7.2.3.3 High-speed

When provided, high-speed manual mode shall be a selection within manual mode which shall have a monitored-speed safety function according to 5.5.6.2. High-speed manual mode is optional. In high-speed manual mode, the speed of the selected TCP and other parts of the robot application (e.g. end-effector, robot joints, workpieces) may exceed 250 mm/s.

When provided, high-speed manual mode shall be integrated such that it can only be used for the purpose of program verification and not production.

If high-speed manual mode is provided and enabled, the robot shall conform with the requirements of ISO 10218-1:2025, 5.2.7.2.3 and high-speed manual mode for the application shall fulfil the following:

a) have a teach pendant that

   — fulfils the requirements of ISO 10218-1:2025, 5.2.8.4 and if applicable 5.2.8.5 for the robot;

   — has an enabling device according to ISO 10218-1:2025, 5.5.4 for the robot;

   — the enabling device function, according to 5.7.7, associated with the teach pendant (5.7.8.3) shall be integrated with the relevant components (e.g. end-effector), equipment and/or machines within the safeguarded space;

   NOTE See 5.6.5 and 5.14.

b) other machines, equipment and processes shall be at a safe state or operating under reduced risk conditions (e.g. reduced-speed, reduced torque, reduced force, limited movement), by jogging which can be in conjunction with an enabling device;

c) safeguarding shall be the same as when the application is in automatic mode such that one or more of the following shall be fulfilled:

   — access to hazards shall be prevented;

   — access shall be detected, thereby resulting in a safe state and/or protective stop of all hazardous situations.

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d) when perimeter safeguarding establishes the safeguarded space, entering the safeguarded space in high-speed manual mode shall cause a protective stop of all equipment that could present a hazard.

5.7.2.4 Operating mode(s) and active protective devices and safety functions

If the robot application needs to be able to operate with a guard displaced or removed and/or a protective device disabled, an appropriate operating mode shall be provided. This mode shall automatically result in the following:

a) disable all other control or operating modes;

b) permit operation of hazardous functions only by control devices requiring sustained action;

c) permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences;

d) prevent any operation of hazardous functions by voluntary or involuntary action of the application sensors.

If the above four conditions cannot be fulfilled simultaneously, the control or operating mode selector shall automatically activate alternative safeguarding in accordance with 5.8, which shall be implemented to ensure safe intervention(s).

5.7.2.5 Selection, activation and change of the operating mode

Selection of the operating mode shall require a deliberate manual action, e.g., use of a key switch, selection on a touch screen.

The means of mode selection is not required to conform to any functional safety requirements; it is out of the scope of the safety-related parts of the control system. See Figure 3.

NOTE 1 Figure 3 shows information flow and does not represent physical devices or architecture.

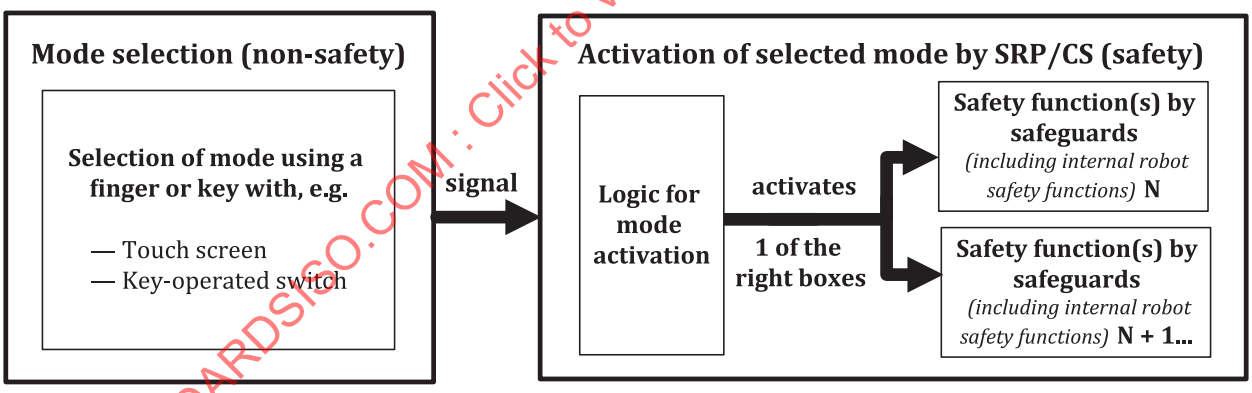


Figure 3 — Separation of mode selection and mode activation

The active mode shall be:

— clearly identifiable; and

— unambiguously indicated.

Unauthorized and/or inadvertent activation of mode shall be prevented by suitable means. The suitable means may include restricting access with a secured access means (e.g. key switch, access control systems or access codes) that limits the use of some modes or functions of the robot application.

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If the activation of a mode results in a change in the safeguarding or active safety functions, the following shall be fulfilled:

a) the activation, but not starting operation, of the selected mode shall be considered a safety function;

b) mode selection shall require a deliberate manual action;

c) activating a different mode shall result in a protective stop (5.6.3);

d) initiation of motion shall be according to the requirements of 5.5.7;

e) each mode shall have the required risk reduction measures active for that mode;

f) activation of the selected operating mode shall not initiate robot motion or other hazardous functions according to IEC 60204-1:2016+AMD1:2021;

g) only one operating mode shall be active at a time;

h) activation of safety functions shall result from the output of the logic for mode activation.

NOTE 2 See Figure 3.

NOTE 3 Many robots implement manual mode so that the robot inputs for the "perimeter safeguard" are not active in manual mode (to allow entry), while "perimeter safeguard" would be active in automatic.

Optional output(s) may be provided to indicate the active mode. When provided for safety-related purposes, the safety function output(s) shall conform to 5.5.

NOTE 4 Symbols for mode labelling are shown in Annex G.

When activation or selection of mode are safety functions, then the safety function(s) shall conform with ISO 13849-1:2023, 5.2.2.9.

5.7.3 Protection from unexpected start-up

Controls shall be implemented and/or located for prevention of unexpected start-up and shall conform with ISO 14118:2017.

NOTE See also 5.2.10 and 5.2.12.

5.7.4 Status indication and warning devices

The status of the controls shall be clearly indicated (e.g. power on, fault detected, automatic operation in process, local control, remote control). Indicators shall be suitable for the installed location and shall be in accordance with IEC 60204-1:2016+AMD1:2021. When provided, warning devices (e.g. audible and visual) shall be in accordance with ISO 12100:2010, IEC 60204-1:2016+AMD1:2021 and IEC 60073:2002.

NOTE IEC 60073:2002 contains the basic and safety principles for man-machine interface, marking and identification – coding principles for indication devices and actuators. IEC 61310:2007 series is specific to safety of machinery with requirements for indication, marking and actuation. The IEC 61310:2007 series is normatively referenced in IEC 60204-1:2016+AMD1:2021.

5.7.5 Single-point-of-control

Single-point-of-control shall be provided when the robot application or robot cell is under local control (5.7.6.2). Only one source of control shall be accepted at one time.

NOTE Single-point-of-control is a "single source of control".

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5.7.6 Local and remote control

5.7.6.1 General

Remote control capability may be provided. If the only means of control is by network or a connection to a computer, this shall be considered remote control. A robot application may be network enabled (e.g. LAN, modem, and internet) which allows remote access for diagnostics, technical consultation and testing.

NOTE See 5.3.

5.7.6.2 Local control

When a local control function is provided, it shall conform with ISO 13849-1:2023, 5.2.2.5. When in local control, the control station shall be the single-point-of-control according to 5.7.5. When manual intervention is required, local control shall be affected by a single teach pendant or similar control station meeting the requirements of ISO 10218-1:2025, 5.2.9 for the robot and according to 5.7.8 for the robot application.

If local control is provided by a teach pendant, the teach pendant shall have:

— direct control of the robot in accordance with ISO 10218-1:2025, 5.2.8.2; and

— priority over and override all other sources of control to the robot application.

If there is no teach pendant, local control for the robot application and any associated machines and sub-assemblies shall:

a) be located in close proximity to what is being controlled; and

b) have priority over and override all other sources of control; and

c) have an indication when remote control is active.

If local control for other machines or sub-assemblies is provided by a control station or pendant that is positioned near the machine or sub-assemblies, this control station or pendant shall have local control priority over all other sources of control to the machine or sub-assemblies and shall override these other sources of control.

Local controls (control stations, pendants and teach pendants) shall have an indication when remote control is active.

Means of selecting and deselecting local control shall be near the robot application, robot cell, or machine or sub-assembly being placed under local control.

If local control can be deselected from within the safeguarded space, a separate confirmation from outside the safeguarded space shall be required prior to any hazardous conditions being present. Means of deselecting local control from within the safeguarded space shall not initiate hazardous conditions.

5.7.6.3 Remote control

If remote access to the control system is provided, it shall conform with ISO 13849-1:2023, 5.2.4.

NOTE 1 For remote control, remote access is required.

If a robot application can be remotely controlled by an operator who is physically away from the robot cell (e.g. in a distant office), the following shall be fulfilled:

a) activation of the remote control function shall require a manual command from the local control (5.7.6.2);

b) any operation start, in any mode, shall require one of the following:

— a separate confirmation from the local control (5.7.6.2); or

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— a separate confirmation from the remote control where the remote control provides means (e.g. video) for an unobstructed view to the entire robot cell;

c) when in manual mode, the requirements of 5.7.2.3 shall be applied;

d) all functions that can cause a hazard (e.g. motion of robot application or robot cell, forcing outputs that control hazardous equipment, changing values that can cause a hazardous situation), reset of safety functions shall be possible only from the selected single-point-of-control according to 5.7.5;

e) remote control shall not override the local control and shall not cause any local hazardous situation(s);

f) any machines, equipment, processes and sub-assemblies that could create a hazard and that are not needed for remote control shall be in a safe state;

g) safeguarding operators while in remote control shall be in accordance with 5.8 such that the following are fulfilled:

— access to hazards shall be prevented; and/or

— access shall be detected, thereby resulting in a safe state and/or protective stop of all hazardous situations such that the safe state and/or protective stop is achieved before the hazard(s) is reached;

NOTE 2 Safeguarding for remote control can be different than that which is active for manual and automatic modes.

h) remote change(s) to safety-related parameters shall require the following before the change(s) may take effect:

— a local action to confirm the acceptability of the change(s); and

— verification that the change(s) did not create any hazardous situations;

NOTE 3 See 5.5.5.

i) remote controls should have an indication that the robot application is under local control (5.7.6.2).

Activation of a mode change by remote control shall require local deliberate manual confirmation.

NOTE 4 For cybersecurity issues of unauthorized remote-control access, see 5.2.16.

5.7.7 Enabling devices

Enabling devices on the teach pendant and additional enabling devices shall conform with ISO 10218-1:2025, 5.5.4 and IEC 60204-1:2016+AMD1:2021, 10.9, and IEC 60947-5-8:2020.

When more than one operator is required to be protected within the safeguarded space by an enabling device, such an enabling device shall be provided to each operator. All enabling devices associated with a robot application shall have the same span-of-control.

Where personnel could be exposed to hazardous situation(s) during manual mode, relevant control systems shall be interlocked such that enabling devices control all hazards within their span-of-control.

NOTE 1 Hazardous situations during manual mode can include the following:

— standing in the restricted space of an adjoining robot application having over-lapping restricted spaces;

— concentrating on the workpiece rather than the movement of the manipulator or nearby equipment;

— applications intended to be PFL but risks have not yet been validated;

— etc.

NOTE 2 An enabling device's span-of-control can depend on the following:

— cell layout (which could include overlapping robot applications and/or other equipment within the cell);

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— the space available;

— the anticipated tasks and the work locations for these tasks.

When the 3P enabling device is continuously held in a centre-enabled position, the enabling device shall permit robot application motion and the operation of other processes whose hazards are controlled by the robot application and the integration of the enabling device function.

Interlocked hazardous machine functions shall require a separate act to restart after a protective stop is initiated by the enabling device.

5.7.8 Control stations

5.7.8.1 General

The robot application shall have the means to control, program/teach, configure and troubleshoot (e.g. teach pendant or other control stations). At least one of the following means shall be provided:

— control panel or teach pendant;

— remote control capability and the corresponding connectivity (cabled or wireless).

Each control station or teach pendant that has the capability of initiating motion or hazardous functions shall have an emergency stop device in accordance with ISO 13850:2015, 4.3.5, for the initiation of an emergency stop function in accordance with 5.6.2.

If entering the safeguarded space in manual mode leads to a hazardous situation, all pendants shall have an integrated 3P enabling device.

NOTE According to ISO 10218-1:2025, 5.5.4.1, a 3P enabling device is not required to be integrated into the pendant of Class I robots that meet ISO 10218-1:2025, 5.1.17. If a Class I robot pendant does not have an integrated 3P enabling device, then a safety function input is provided for a 3P enabling device.

Teach pendants and control panels shall be in accordance with the requirements of the IEC 61310:2007 series.

A visual signal at the control station shall indicate the active status of a control station (e.g. an indicator light on a control panel or a warning at a teach pendant display).

For robot applications with remote control capability, control stations (including teach pendants) shall indicate when remote control is active.

5.7.8.2 Location

Control stations, pendants, teach pendants, electrical cabinets and equipment shall fulfil the following:

a) be located for access by operators while the operators are safeguarded;

b) portable control stations (e.g. pendants and movable control station) shall be located or positioned to allow an operator to have an unobstructed view of the application;

c) electrical cabinets and fixed control stations shall be located or positioned (for access) outside of the perimeter safeguard (5.8.3) when perimeter safeguarding is provided;

d) portable control stations (e.g. pendants and movable control station) when not used shall be located or positioned outside of the perimeter safeguard (5.8.3) when a perimeter safeguard is provided;

e) those having the capability of mode selection, local/ remote control selection or use within the safeguarded space(s) shall be placed near the access means for improved ease of use by the operators.

When electrical equipment, containing elements that require access (e.g. for routine service), are mounted above the level of normal reach (e.g. on the roof of machine), a means for access shall be provided (e.g. a work platform) according to the ISO 14122:2016 series. The results of a risk assessment shall be used to determine

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the means for providing access to the relevant devices between a height of 400 mm and 2 000 mm from the access level.

NOTE See also IEC 60204-1:2016+AMD1:2021.

Electric enclosures shall be mounted so that their doors can be fully opened and escape routes are always available even when doors are opened. This is fulfilled when:

— doors can be easily pushed to a closed position, taking escape direction into account;

— the remaining clearance is not less than 500 mm when the door is fully open (see IEC 60364-7-729:2007).

Selection and design of platforms, walkways, stairs, stepladders and fixed ladders shall be in accordance with the relevant parts of the ISO 14122:2016 series.

5.7.8.3 Pendants and teach pendants

Pendants and teach pendants shall fulfil the following:

a) Those that can cause motion or hazardous movements shall have the following functions:

   1) emergency stop in accordance with 5.6.2;

   2) enabling device in accordance with 5.7.7; and

   3) single-point-of-control, in accordance with 5.7.5, when in manual mode (5.7.2.3).

b) if equipped with a cable,

   1) the cable shall be:

      — of sufficient length to allow operators to perform expected tasks in a safe manner (e.g. not having to go over the equipment to get to a task zone due to insufficient cable length);

      — capable of withstanding the anticipated environmental conditions of the location in which it is to be used.

   2) the cable shall be provided with the means:

      — for proper placement to minimize the possibility of damage which could result in a hazard;

      — of cable stowage to reduce entanglement and tripping hazards.

c) Cableless or detachable pendants and teach pendants shall conform with 5.7.8.4.

Pendants and teach pendants may consist of multiple parts, that can be connected by a cable (5.7.8.3) or be cableless or detachable (5.7.8.4).

Teach pendants shall conform with the requirements in ISO 10218-1:2025, 5.2.8.4.

5.7.8.4 Cableless or detachable pendants

In addition to 5.7.8.3, cableless or detachable pendants shall fulfil the following:

a) the possibility of unintentionally controlling a robot application shall be avoided by:

   1) unambiguous means that identify the robot application being operated;

   2) connection means to ensure integrity of communication (e.g. login, encryption, firewalls);

   3) unambiguous means to indicate connection continuity (e.g. screen display);

b) a single cableless teach pendant shall not be simultaneously connected to more than one robot or robot application;

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c) loss of safety-related communication (e.g. out of range, loss of battery power) on any active pendant (i.e. teach pendant paired to a robot) shall result in a protective stop for all controlled equipment; restoration of safety-related communications (5.5.9) shall not allow a restart without a separate deliberate action (5.5.7.1);

NOTE 1 See ISO 10218-1:2025. IEC 60204-1:2016+AMD1:2021 and IEC 62745:2017.

d) an unambiguous means shall be provided to disconnect controllers from the pendant (e.g. a positive action by the operator to de-couple a teach pendant from a robot control), and when devices are logged out, it shall be clearly recognizable that the relevant safety functions are not active anymore;

e) confusion between active and inactive emergency stop devices shall be avoided by providing appropriate storage or design.

NOTE 2 See ISO 13850:2015.

NOTE 3 Cableless (e.g. wireless) pendants that can cause motion or any hazardous functions could provide remote control to which the requirements of 5.7.6.3 apply.

5.7.9 Simultaneous motion

A single teach pendant may control simultaneous motion of a robot application with multiple robots. Each robot (and if necessary, end-effectors, additional axes and other parts of the robot application) shall be selected before being activated. To be selected, all robots shall be in the same operational mode (e.g. reduced-speed manual mode). An indication of what will be activated (selected to be moved) shall be provided in accordance with ISO 10218-1:2025. Only what is selected shall be activated. Any robot not selected shall not move and shall not present hazards by means in accordance with 5.2.8.

5.8 Safeguards and their use

5.8.1 General

Guards and protective devices shall be used to reduce risks by:

a) preventing access to the hazard(s);

b) causing hazard(s) to cease before access;

c) preventing unintended operation;

d) containing ejected parts and tooling;

e) limiting other process hazards, e.g. laser, fluids, airborne materials.

The location of equipment and machinery should not introduce additional hazards.

When protective devices initiate a protective stop, the stop shall remain active while an operator or part of an operator is within the safeguarded space. If whole body access exists or if it is possible for parts of an operator to be undetected within a safeguarded space and also hidden from view at the reset control, the requirements of 5.5.7 and 5.8.10 shall be fulfilled.

NOTE 1 If sensitive protective equipment is used, it is advisable to verify that operators cannot circumvent the detection zone, (e.g. by climbing onto parts of the machinery). See 5.8.6.3.

Risks of whole body trapping or body parts being crushed between moving portions of the robot application with, for example, parts of buildings, structures, utilities, other machines, and equipment, shall be reduced to acceptable levels. Clearance in accordance with ISO 13854:2017 should be provided. Safeguarding shall be provided when clearance is not in accordance with ISO 13854:2017.

NOTE 2 See Annex Q for a relationship of standards and safeguards.

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5.8.2 Establishing a safeguarded space

The safeguarded space(s) shall be defined during the design of the robot application. Safeguarded spaces may change dynamically as needed for the application, e.g. different modes, equipment position or location changes. Changing shall be part of the functional safety of the limiting device implementation.

Robot applications can have a potentially large operating space, e.g. handling a large workpiece, using all the movement and reach capabilities of the robot including the space for the end-effector and workpiece(s). The safeguarded space(s) should be reduced. This is accomplished using limiting devices to restrict the movements. Software-based limiting according to ISO 10218-1:2025, 5.7.4, may be used to modify and /or reduce the size of the restricted space(s).

The restricted space(s) shall be within the safeguarded space.

NOTE 1 See 5.4.7.

NOTE 2 See Annex B for illustrations of spaces.

5.8.3 Perimeter safeguarding

When required, perimeter safeguarding shall be implemented using guards in accordance with 5.8.5 and/or sensitive protective equipment in accordance with 5.8.6.

Where crushing or trapping is prevented by the maintaining of minimum gaps, the gaps shall meet the requirements in ISO 13854:2017.

Unless allowed by 5.12.2, the height of the perimeter guard shall be at least 1 400 mm from adjacent walking surfaces. The perimeter guards shall not be installed closer to the hazard than the restricted space (5.4.6), unless guards are designed to be the limiting device in accordance with 5.4.7.

NOTE For requirements about adjacent robot cells, see 5.13.

5.8.4 Overriding of protective devices

There are circumstances that could require overriding a protective device (e.g. for purposes of material entry / exit, threading or feeding set-up). Providing this capability shall be according to 5.7.2.4. For SPE, providing the override shall be according to 5.8.8. When provided, the overriding means shall provide the same level of risk reduction as the protective device.

5.8.5 Guards

5.8.5.1 General

Guards shall conform with ISO 14120:2015.

Non-interlocked guards shall only be removable using a tool and shall not be easily circumvented without a tool. Their fixing systems shall remain attached to the guards or to the machinery when the guards are removed. The requirement does not necessarily apply to fixed guards that are only subject to be removed, for example, when the machinery is completely overhauled, is subject to major repairs or is dismantled for transfer to another site.

Guards shall be located in accordance with 5.8.5.2. Guards shall not allow an operator to reach over, under, around or through (an opening or gap) the guard and access a hazard zone.

5.8.5.2 Minimum distances

Fixed and moveable guards shall meet the requirements of ISO 14120:2015 and their minimum distance from any hazard shall be determined according to the relevant requirements of ISO 13855:2010 and ISO 13857:2019, except as permitted in 5.12.2. The minimum distances associated with openings in guards shall meet the relevant requirements of ISO 13857:2019.

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5.8.5.3 Interlocked movable guards

Interlocking devices associated with moveable guards shall meet the requirements of ISO 14119:2024.

Movable guards should open laterally or away from the hazard, and not into safeguarded space(s). Interlocked moveable guards shall be positioned relative to the hazard zone in accordance with ISO 13855:2010.

Movable guards used to initiate starting on closure (control guards) shall meet the requirements of ISO 14120:2015.

The interlocking function shall meet at least the requirements of 5.5. The reset shall be in accordance with 5.5.7.2

5.8.5.4 Interlocked movable guard with guard locking

When it is possible for the operator to open an interlocked movable guard and reach the hazard zone before the hazard is brought to a safe state, guard locking shall be provided in addition to the interlock function of the interlocking device.

This guard locking shall conform with the following:

a) permit the actuation of hazardous machine function only when the guard is closed and locked (e.g. a door in a fence);

b) keep the guard in the closed and locked position if the risk of harm due to hazardous functions of the machine exists;

c) the additional requirements of guard locking devices according to ISO 14119:2024, 6.6.

NOTE See ISO 14119:2024, 5.3.1 for conditional unlocking.

When process parameters, such as speed, are being used as a condition for locking or unlocking, then this forms part of the safety function and shall meet the same functional performance requirements as the interlocking function.

5.8.6 Sensitive protective equipment

5.8.6.1 General

Sensitive protective equipment is typically selected when an application requires frequent access, personnel interaction with the machine, good visibility of the machine or process, or when it is not ergonomic to provide moveable guards. However, some characteristics of applications can preclude the use of sensitive protective equipment as the only protective device. Examples of these characteristics are:

a) possibility that the machinery will eject materials, swarf or component parts;

b) risk of injury from thermal or other radiation;

NOTE 1 Hazards due to ionizing and non-ionizing radiation are excluded from the scope of this document.

c) hazardous noise levels;

NOTE 2 Hazards due to noise are excluded from the scope of this document.

d) an environment likely to adversely affect the function of the sensitive protective equipment;

e) a material being processed which can influence the effectiveness of the sensitive protective equipment.

Where such situations exist, additional or other safety measures can be required.

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Sensitive protective equipment shall conform with the relevant standards for the protective device:

— parts of the IEC 61496 series are relevant to various electro-sensitive protective equipment (ESPE), e.g. active opto-electronic protective devices (AOPD), active opto-electronic protective devices responsive to diffuse reflection (AOPDDR), vision-based protective devices (VBPD) and radar protective devices (RPD);

— parts of ISO 13856-1:2013, ISO 13856-2:2013 and ISO 13856-3:2013 are relevant to various pressure-sensitive protective devices (e.g. mats, edges and bumpers);

NOTE 3 IEC TS 62998-1:2019 addresses the sensing function and the dependability of the detection capability of electro-sensitive protective equipment that is not covered in the IEC 61496 series.

NOTE 4 IEC TR 62998-2:2020 provides application examples.

Requirements for the application of these protective devices shall be according to IEC 62046:2018.

Where an operator, or part of an operator in the safeguarded space, can remain undetected by the SPE, additional measures shall be provided in accordance with 5.8.1 to prevent hazardous situations arising.

When detecting an operator inside a manual load/ unload station, the requirements of 5.12.2 shall be applied.

NOTE 5 See 5.5.7 for start, restart and reset requirements. See 5.8.10 for the requirements to protect from unexpected restart.

NOTE 6 If sensitive protective equipment is used, it is advisable to verify that operators cannot circumvent the detection zone (e.g. by climbing onto parts of the machinery).

5.8.6.2 SPE used to initiate a protective stop

Where the sensitive protective equipment is used to initiate a protective stop, it shall be positioned at a distance from each hazard such that the following is fulfilled:

— sufficient to ensure the hazard is removed; or

— a safe state is achieved before any part of an approaching operator can reach the hazard.

NOTE 1 Hazards can exist at different locations within safeguarded space(s). The distance needs to ensure that each hazard is controlled.

Sensitive protective equipment shall be securely installed and located such that an operator cannot circumvent (i.e. cannot reach over, under, around or through) the detection zone and reach a hazard. The following functionality shall be provided:

a) a protective stop shall be initiated if the sensitive protective equipment is actuated while the hazardous conditions are operating;

b) following an actuation, the hazardous conditions being safeguarded by the sensitive protective equipment shall be prevented from any hazardous motion or situation until the sensitive protective equipment is reset;

c) when the sensitive protective equipment is reset, the hazardous conditions being safeguarded by the sensitive protective equipment can operate.

The formulae in ISO 13855:2010 shall be used to determine the minimum distance from the hazard zone to the sensitive protective equipment for all directions of approach.

NOTE 2 For the separation distance for speed and separation monitoring, see 5.14.5.3.

5.8.6.3 SPE used for presence sensing

The detection zone of presence-sensing devices shall be positioned and configured so that an operator or part of an operator will be detected throughout the detection zone and a protective stop maintained.

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Where necessary, supplementary measures shall be provided to ensure that the detection zone cannot be circumvented.

NOTE 1 Circumvention by operators includes:

— remaining between the detection zone and the hazard zone;

— reaching over, around or under the detection zone into the hazard zone;

— walking on supporting structures or on top of horizontal ESPEs.

Examples of how to prevent operators from being between the detection zone and the hazard zone include the following:

— use of sloping surfaces to discourage standing in unmonitored detection zones (e.g. on machine frame/feet, on the sensitive protective equipment); and

— making the inside surfaces of guards free of protrusions that can be climbed on.

NOTE 2 See Annex J for further information.

Where the sensitive protective equipment is only used for a presence-sensing function (i.e. it continually senses the presence of an operator or part of an operator in its detection zone) it shall be used in conjunction with other protective devices (e.g. interlocked guards) to ensure that the machine(s) is/are in a non-hazardous state before hazards can be reached.

5.8.6.4 Blanking

Use of blanking shall be according to IEC 62046:2018.

5.8.7 Muting

When muting is applied, it shall be according to IEC 62046:2018.

5.8.8 Overriding of SPE

There are circumstances that could require overriding a SPE (e.g. for purposes of material entry/exit, threading or feeding set-up). Providing this capability shall be according to 5.7.2.4 and IEC 62046:2018. When provided, the overriding means shall provide the same level of risk reduction as the SPE. See 5.8.4.

5.8.9 Minimum distances

5.8.9.1 For use as a trip function (initiate a stop)

The minimum distance for protective devices providing a trip function (for example, interlocking devices, sensitive protective equipment which initiate a protective stop when actuated) shall be in accordance with ISO 13855:2010.

For maintenance tasks being performed within a robot cell, when electro-sensitive protective equipment (ESPE) with vertical detection zones are used to detect inadvertent access to adjacent robot cells (5.13), the approach speed and intrusion distance used for the calculation of the separation distance may, based on the risk assessment, deviate from those of ISO 13855:2010.

5.8.9.2 For presence-sensing (continuous detection)

When protective devices solely provide a presence-sensing function (5.8.6.3) to prevent starting or restart (for example, when they continually sense an operator or part of an operator in their detection zone and

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maintain a protective stop), minimum distance does not apply according to ISO 13855:2010. Detection capability requirements stated in the related formula of ISO 13855:2010 shall be applied.

NOTE When protective devices solely detect presence for start or restart hazards, other protective devices are often used to prevent access or cause the hazard(s) to cease (trip function) or be safely controlled before access.

5.8.9.3 For protection due to a lack of clearance

When protective devices provide a trip function (5.8.6.2) to provide protection against lack of clearance, the minimum distance shall be calculated using ISO 13855:2010 with the robot application speed as the approach speed (i.e. K = the robot application speed).

In manual mode, when protective devices provide a presence-sensing function (5.8.6.3) to prevent unexpected start due to a lack of clearance, the minimum distance according to ISO 13855:2010 is permitted to not be applied. Detection capability requirements stated in the related formula of ISO 13855:2010 shall be applied.

5.8.10 Safeguarding to protect from unexpected restart

From each control station, the visibility to all the locations within the safeguarded space(s) where operators can be, shall be ensured. Where this is not practicable, presence sensing shall be provided to detect any person throughout the safeguarded space. Where this is not practicable, sequenced time-limited reset devices located inside the safeguarded space shall be provided. The final reset device shall be located outside the safeguarded space and shall not be within reach by any person within the safeguarded space.

If presence sensing and sequenced time-limited reset devices are not practicable, one of the following alternatives shall be applied to prevent a restart:

a) multiple means for the isolation and lockout of the hazardous equipment located within the safeguarded space;

b) measures to lock an interlocked guard in the open position;

c) measures to lock an obstruction within the detection zone of an AOPD used to detect entry into the hazard zone;

d) trapped key interlock systems.

If a start/restart interlock in conjunction with presence sensing is provided, then, depending on the risk assessment, the presence-sensing device shall meet at a minimum the requirements of Type 2 from IEC 61496-1:2020.

Protection from unexpected start-up shall be according to 5.5.7. Safety-related manual control devices shall be located at a sufficient distance to prevent actuation from inside the safeguarded space according to ISO 13857:2019.

NOTE See 5.5.7.

5.9 End-effectors

5.9.1 General

End-effectors shall be designed, selected and integrated to fulfil the following:

a) conform with 5.1 and 5.2, as applicable;

b) have a means for manual movement or release, for use without power, to free entrapped fingers or other body parts;

NOTE 1 Power includes electrical, pneumatic, hydraulic, kinetic, stored energies and more.

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c) safety functions to interlock or monitor functions such as gripper closing and opening with information on the positioning of the end-effector shall prevent inadvertent release of the load in a hazardous position;

d) when operators can be within proximity of the end-effector during the gripping of workpieces, the following shall be provided:

   1) minimization of gripping forces needed to achieve adequate grasping of an object instead of maximum force available;

   2) contact between gripper/grasped workpieces and an operator shall be according to 5.14.6;

   3) application design measures in which crush hazards are eliminated (e.g. force limiting safety function setting while the robot is positioning the end-effector (gripper), inhibiting gripper closure if the gripper is not in the grip location, sufficient clearance for an operator's fingers not to be crushed when the gripper closes);

e) when operators are exposed to risks of an end-effector or a tool attached to an end-effector, risks shall be reduced (e.g. protective devices, end-effector or speed limitation);

f) safety functions used to control risks shall conform with 5.5 and Annex C;

g) the static and dynamic forces created by the load and the end-effectors together shall be within the load capacity and dynamic (motion control system) response of the robot;

h) align with the mechanical interface (couple);

i) detachable tools are securely attached while in use;

j) release of detachable tools only occurs in designated locations or under specific, controlled conditions, if the release could result in a hazardous situation;

k) the end-effector withstands the anticipated forces for its expected life, in accordance with 5.2.2.

When practicable, power can be supplied to end-effectors for troubleshooting without applying drive power to the robot actuator(s).

End-effectors shall be selected or designed such that loss or restoration of energy supply (5.2.10) does not cause a hazardous situation (e.g. release of the load or workpiece, throwing the workpiece). If this is not practicable, other safety measures shall be provided.

NOTE 2 See Annex I for additional information about end-effectors.

5.9.2 Risk reduction measures

Additional risk reduction measures shall include the following, as applicable:

a) contain the hazards (e.g. guarding, shields);

b) locate hazards so they are not accessible by the operator;

c) use a disable function that depends on the orientation of the end-effector;

d) reduce collaborative task zones when hazards exist (e.g. orientation monitoring safety functions provided with the robot or end-effector);

e) identify hazard zones where unexpected hazardous processes can occur;

f) use of warnings before and during the hazardous process, which includes residual time after the process has ended (e.g. illuminated signs, symbols audio signals);

g) use of sequencing based on conditions (e.g. temperature range, retracted blade) instead of timers;

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h) use of inspection tools such as ultrasonic inspection and camera systems so as to reduce interventions by operators;

i) warnings of hot surfaces (e.g. warning symbols, illuminated signs).

5.9.3 Shape and surfaces

End-effector and fixture designs shall reduce sharp edges to reduce human contact forces or pressures (e.g. using smooth and compliant surfaces). End-effector mass should be as low as practicable to minimize the forces or pressures associated with a collaborative application transient contact (e.g. minimizing momentum and kinetic energy). Padding and cushioning materials, as well as deformable components, can reduce impact energy transfer.

Motion shall be prevented, or operators safeguarded where edges can result in unacceptable contact force(s) or pressure(s). Some protective measures include increasing edge radius, increasing contact surface area, modifying edge profiles (e.g. chamfer), or using different surface materials.

The end-effector should be designed to provide protection from hazards associated with the workpiece(s).

5.9.4 Protective devices and/or safety functions

When operators are exposed to risks of an end-effector or a tool attached to an end-effector, risks shall be reduced (e.g. protective devices, end-effector or speed limitation) using one or more of the following:

a) force sensing in accordance with 5.14.6, (e.g. enhanced force sensing that is more sensitive than force sensing of the robot): measurement of applied forces on the surface(s) of the end-effector and corresponding monitoring of the end-effector and/or robot;

b) end-effector orientation: if certain orientations of the end-effector result in crush points and/or sharp edges being present (e.g. a screw pointing towards a hole into which it is screwed), then

   — robot movement in that direction should be minimized;

   — movement speed should be decreased to reduce risks; and

   — software-based limiting safety functions should be used to limit robot motion and end-effector orientation and poses;

   NOTE 1 ISO 13854:2017 contains information about the minimum gaps to avoid crushing of parts of the human body.

c) grip force: where the maximum grip force of the end-effector exceeds the acceptable limits, the grip force applied by the end-effector shall be reduced and monitored not to exceed acceptable levels in accordance with 5.14.6;

d) speed monitoring:

   — the robot speed for which the gripper is intended to be used shall be considered in the design of the end-effector so that the end-effector and any workpiece(s) are retained;

   — if the end-effector movement is controlled separately from the robot, the stop monitoring shall be considered in addition to the robot application stopping (time, distance, angle).

e) presence sensing:

   — a sensor (e.g. proximity, motion, image) can be used to detect a workpiece that has the potential to initiate a sequence that could cause an injury to the operator;

   — to reduce risks associated with contact by the moving end-effector to operators during a collaborative application, the end-effector actuation shall be prevented when the operator is contacted or is within a detection zone around the end-effector;

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— presence sensing protective devices used for the protection of persons shall conform with the relevant parts of the IEC 61496 series.

NOTE 2 In the case of safety-related sensors for safety functions, IEC TS 62998-1:2019 provides guidance.

NOTE 3 IEC TR 62998-2:2020 provides examples of applications.

f) compliant link (e.g. a pliable link between the mechanical interface and the end-effector):

— compliant linkages and mechanisms within the end-effector can absorb energy of contact. The transferred force, motion, or energy achieved through compliant links are dissipated in a manner that reduces the risk and does not introduce new risks;

— the force or torque which an end-effector can apply can be limited, e.g. by mechanical couplings that yield when a certain force or torque level is reached;

g) safety functions:

— used to initiate a protective stop;

— for power and force limiting (PFL) collaborative applications, the force parameter for initiating a protective stop shall be in accordance with 5.14.6.

NOTE 4 Protective devices and safety functions built into, or associated directly with, the end-effector can be used in some robot applications to reduce risk.

NOTE 5 Collision protection devices, energy absorbing materials, springs can be used.

NOTE 6 Safety-related functions of the end-effector can be provided by the robot, end-effector or both.

5.9.5 End-effectors and robot application design

To reduce risks due to end-effectors and workpieces, the following shall be provided:

a) clearances between end-effector/fixture/workpiece and any obstructions (e.g. support posts, building columns) in accordance with ISO 13857:2019 and ISO 13854:2017 or protection from hazardous situations due to a lack of clearance with between end-effector/ fixture/ workpiece and any obstructions (e.g. support posts, building columns) in accordance with

— IEC 62046:2018 for the selection and positioning of protective equipment; and

— ISO 13855:2010 for separation distances;

b) protection from hazardous situations due to stationary obstacles (e.g. support posts, or other robot application objects) and moving objects (e.g. carts, mobile platforms, automated guided vehicles) in accordance with

— IEC 62046:2018 for the selection and positioning of protective equipment; and

— ISO 13855:2010 for separation distances.

c) space to access entry/exit locations and paths shall be provided to perform expected tasks in accordance with ISO 14122:2016 series, ISO 15534-1:2000 and ISO 15534-2:2000.

5.9.6 End-effectors exchange systems

End-effector exchange systems shall be selected or designed such that loss or restoration of energy supply does not lead to a hazard. If this is not practicable, other safety measures shall be provided to mitigate against any hazards.

If an end-effector exchange system is used, then the end-effector exchange system design shall not lead to a hazardous situation. Release or disconnection of the end-effector(s), using the end-effector exchange function, shall be prevented at positions where release would lead to a hazard.

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The end-effector exchange system shall withstand the expected static and dynamic requirements (e.g. emergency-stop-situation, loss of energy).

In the end-effector exchange system, it may be necessary to have different tool settings, including TCP values, for the different end-effectors used. The integrator shall ensure that they enter the tool value for each individual end-effector.

In addition, the integrator shall design the system so that it selects the proper TCP for the end-effectors that are being changed.

If motion can be initiated without the end-effector attached, then protective measures shall be applied to reduce the associated risks.

Where several robots use the same type of end-effector exchange system, only intentional combinations of robots and end-effectors shall be permitted.

The possibility of incorrect end-effector selection (e.g. detect the correct end-effector, monitor the end-effector stand/end-effector exchange system) shall be considered and, where practicable, the robot application shall detect such a scenario and shall prevent continued operation until the correct selection occurs.

Unintended release of the end-effector shall be prevented. Release of the end-effector shall only be in a specific and safe configuration. (e.g. release only occurs in a docking station).

NOTE ISO 11593 provides vocabulary for automatic end-effector exchange systems.

5.10 Vertical transfer components

5.10.1 Mechanical design

The movement of the carrier of vertical transfer components serving fixed landings shall be rigidly guided to and at the landings.

NOTE 1 Vertical transfer components and equipment does not include lifts for people.

Where operators have access to the carrier, the vertical transfer shall be designed and constructed in such a way as to ensure that the carrier remains stationary during access.

The vertical transfer shall be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

The vertical transfer shall be designed and constructed to prevent the risk of load falling off the carrier.

Rope carriers, tractors or tractor carriers shall be held by counterweights or be fitted with a device for permanent control of tension.

NOTE 2 For guidance see EN 619:2022, Annex E.

5.10.2 Prevention of falling hazards

Where the robot application contains lifting (vertical transfer) components and there is a risk due to persons falling when the carrier is not present at the landings, guards shall be fitted in order to prevent this risk. Such guards shall not open in the direction of the hazard zone and shall be fitted with an interlocking device with guard locking that prevents:

— movements of the carrier until the guards are closed and locked,

— opening of a guard until the carrier has stopped at the corresponding landing.

5.10.3 Prevention of crushing hazards

Risk of crushing between the moving parts and the landings shall be prevented by safeguarding according to 5.8.

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Sufficient free space shall be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier under all the following conditions:

— it is necessary to access the movement zone; and

— there is a risk that persons situated under or above the carrier can be crushed between the carrier and any fixed parts.

5.10.4 Control of movements

The carrier shall automatically stop at the intended positions. Where this is not practicable, movements shall only be possible with the actuation of a hold-to-run control device.

5.11 Lasers and laser equipment

Where laser equipment is used, it shall be designed and integrated to prevent any hazardous exposure to laser radiation. The requirements of IEC 60825-1:2014 shall be applied.

Optical equipment for the observation or adjustment of laser equipment shall be such that no hazardous situations arise from their use.

5.12 Material handling, manual load/unload stations and material flow

5.12.1 Material handling

Operators shall be safeguarded from the hazards associated with material handling (e.g. entanglement, falling material and the connections with the robot application or robot cell).

5.12.2 Manual load/unload stations and other manual stations

5.12.2.1 General

Measures shall be provided to ensure that operators are not exposed to further hazards due to the operation of the manual stations (for example, crushing, shearing, entanglement hazards).

When a perimeter safeguarding is established, allowable gaps and openings shall be in accordance with 5.8.5.2. Manual stations shall be designed to prevent access to hazards within the perimeter safeguarding. See also a) and b) below.

NOTE 1 Requirements for collaborative applications are given in 5.14.

For heights up to 1 400 mm, additional protective measures can be taken to:

a) prevent the exposure of the operator to application-related hazards within the safeguarded space, (e.g. ejected parts, welding sparks, etc.);

b) prevent the operator from accessing hazards inside the safeguarded space or bring these hazards to a safe state before they can be accessed.

When a robot application and an operator have access to the same space and the required risk reduction is that they not occupy the hazard zone at the same time, this may be fulfilled using a protective device to trigger a stop category 2 (IEC 60204-1:2016+AMD1:2021) protective stop, followed by a monitored-standstill according to 5.5.8. This protective device shall

— detect entry of the operator into the hazard zone which is occupied by any part of the robot application and bring the hazards to a safe state before they can be accessed; and

— prevent any part of a robot application from entering a hazard zone occupied by an operator or bring the hazards to a safe state before reaching the operator.

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NOTE 2 For ergonomic reasons, heights between 1 000 mm and 1 400 mm could be acceptable depending on the effectiveness of the impeding device. See also ISO 13857:2019 and ISO 13855:2010.

5.12.2.2 Moving manual stations

Moving manual stations (e.g. rotating turntables, sliding jigs) can themselves be hazardous. Safeguarding shall be provided in accordance with 5.8. Whether the workpiece is in position or not, gaps between the moving manual station and any fixed elements (e.g. machine parts, guards) including additional protective measures shall conform with ISO 13854:2017, Table 1 to prevent crushing.

Additional measures could be necessary to prevent shearing and trapping hazards created by those mechanical parts (e.g. guards) provided to conform with these requirements.

5.12.2.3 Manual stations inside the safeguarded space

When presence sensing is used to detect the operator in the safeguarded space, the detection zone of the device shall include the entire hazard zone. When presence sensing is not practicable and an operator can pass through the detection field of the SPE and access a hazard zone, the following shall be fulfilled:

— the SPE shall initiate a protective stop according to 5.8.6.2;

— a start/restart interlock shall be provided according to 5.5.7.1.

Other measures shall be provided to prevent inadvertent resetting of the start/restart interlock, thereby preventing the robot application from moving into the hazard zone while the operator remains in the hazard zone. Such measures can include the provision of a separate manual reset.

When manual reset is provided, the whole of the safeguarded space shall be visible from the reset device. If this is not possible, further measures in accordance with 5.8.10 shall be applied.

5.12.3 Material flow

Where materials enter or exit the safeguarded space:

— safeguarding shall be provided to prevent operators from coming into contact with hazards; or

— the hazards shall be brought to a safe state before the hazards can be accessed, without creating additional hazards.

NOTE See ISO 13857:2019 for partial body entry.

The dimensions of openings in guards to allow material entry and exit shall have the minimum dimensions necessary to allow the passage of the material. Possible crushing/shearing hazards between the material and the sides of the opening shall be eliminated by design and/ or additional safeguarding shall be provided to eliminate crushing/shearing hazards, e.g. using hinged interlocked doors.

Where openings for material entry and exit are safeguarded using ESPE, access to the safeguarded space shall be prevented by the material itself, or by other means according to IEC 62046:2018 and the ESPE shall allow the passage of materials by either one of the following functions:

a) a muting function that temporarily deactivates the ESPE function allowing material to pass through (entry/exit);

b) a change in protection (e.g. blanking) that enables materials to pass through; in this case the minimum distance indicated by the manufacturer of the ESPE shall be applied according to IEC 62046:2018.

The performance level of muting and blanking safety functions shall not adversely affect the performance level of the safety function for the ESPE.

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5.13 Adjacent robot cells

Safeguarding shall be provided to

a) ensure that operators in a robot cell are not exposed to hazards from adjacent robot cells;

b) reduce risks to operators due to the transfer of materials into and out of adjoining robot cells;

c) before operators would be exposed to hazards in or caused by adjacent robot cells, either

— prevent operator access to adjacent robot cells from within a robot cell; or

— bring hazards within adjacent robot cells to a safe state.

NOTE 1 See the requirements in 5.8.4 for when guards are used.

NOTE 2 See 5.3 for robot cell integration with other machines and sub-assemblies.

NOTE 3 See 5.12 for material handling, manual load/unload stations, material flow.

5.14 Collaborative applications

5.14.1 General

Operator(s) performing a collaborative task within a safeguarded space shall be protected from injury due to contact from moving parts of the robot application. Protective measures shall be provided for the safety of operator(s) in the event of such contact or stop the robot application motion and other hazards before contact occurs. As determined in the application risk assessment, protective measures shall address quasi-static and transient contact hazards to the operator. Contact exposure to sensitive body regions, including the skull, forehead, larynx, eyes, ears, or face shall be avoided according to 5.14.6.3. If not practicable, guards and/or protective devices shall be applied.

If one or more operator(s) are within the safeguarded space during robot application motion in automatic operation, all required safeguards shall be active.

Robots used for integration into a collaborative application shall conform with the relevant requirements in ISO 10218-1:2025, 5.10.

NOTE 1 See ISO 10218-1:2025 for requirements of safety functions for robots intended to be used in collaborative applications.

NOTE 2 See requirements in 5.7.2.1 for general mode requirements and 5.7.2.4 for mode selection.

Collaborative applications may consist of collaborative and non-collaborative tasks within common safeguarded spaces. Robot applications that include collaborative tasks should have a visual indication for when collaborative tasks may be performed.

NOTE 3 See the requirements in 5.14.3 for transitions between collaborative and non-collaborative tasks.

Sharp edges shall be rounded and softened as far as practicable to reduce human contact forces or pressures (e.g. using smooth and compliant surfaces). Mass should be as low as practicable to minimize the forces or pressures associated with a collaborative application transient contact (e.g. minimizing momentum and kinetic energy). Therefore, robot manipulators and end-effectors should be selected with as low masses as practicable for the application. Padding and cushioning materials, as well as deformable components, can reduce impact energy transfer.

Motion shall be prevented, or operators safeguarded where edges can result in unacceptable contact force(s) or pressure(s). Risk reduction to reduce and limit impact forces and/or energy transfer can include the following:

a) increasing the contact surface area;

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b) use of

- rounded edges and corners;
- smooth surfaces;
- compliant surfaces (e.g. padding, cushioning, deformable components) to absorb energy, extend energy transfer time, or reduce impact forces;
- compliant joints or links;

c) reducing or limiting

- moving masses;
- velocities of moving parts;
- forces or torques;

d) use of

- monitored-standstill safety function(s);
- software-based limiting safety function(s);
- protective device(s) implemented to anticipate or detect contact.

As determined by the application risk assessment, application of protective measures shall address the expected exposure of the operator.

NOTE 4 A combination of safety functions can be required, e.g. the force limiting safety function can be effective only up to a certain speed limit. In such a case, an additional speed limiting safety function could be necessary.

NOTE 5 See the requirements in 5.9 for end-effectors.

When designing a collaborative application, safety functions shall be selected to ensure a safe work environment for all personnel exposed to potential hazards in the robot application.

The collaborative application shall be provided with a means for extrication from trapping situations.

5.14.2 Safeguarded spaces

The design of the safeguarded space shall be such that the operator can perform all intended tasks and be protected from hazards. The layout and location of equipment and machinery shall not introduce additional hazards.

NOTE 1 See Annex B for illustrations of spaces.

The robot application shall be

a) controlled to prevent any hazardous contact; and

b) controlled to prevent any clearance risks.

NOTE 2 See ISO 13854:2017 for guidance.

NOTE 3 See Annex M for guidance on contact limits.

If there is coordinated or synchronized motion (e.g. line tracking), special considerations could be needed.

The safeguarded space where the operator(s) can interact directly with the robot application shall be clearly defined (e.g. floor marking, signs).

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5.14.3 Transitions

Transitions are particularly critical aspects of a collaborative application.

Transitions include the following:

a) between collaborative tasks using HGC, SSM or PFL and between combinations of HGC, SSM and PFL;

b) between collaborative tasks and non-collaborative tasks.

Operators shall be protected from hazardous situations during transitions. If the transition is from collaborative to non-collaborative task, the start of the non-collaborative task shall be prevented until the operator is outside the safeguarded space.

NOTE A visual indicator to identify transitions between collaborative and non-collaborative tasks can be used.

5.14.4 Hand-guided control (HGC)

5.14.4.1 General

HGC reduces the risk associated with unexpected motion. For HGC use, the robot application shall be designed to allow direct control of the robot application movement by the operator.

The robot application shall have the following:

— monitored-speed safety function according to 5.5.6.2;

— stop category 2 (IEC 60204-1:2016+AMD1:2021) protective stop according to 5.6.3; and

— monitored-standstill safety function according to 5.5.8.

A risk assessment shall be used to determine the monitored-speed limit value. If operator safety is dependent on limiting the range of motion, the robot application motion shall be limited using software-based limiting safety functions conforming with ISO 10218-1:2025, 5.7.4.

NOTE 1 See the requirements in 5.4.7.3 for non-mechanical limiting devices.

NOTE 2 For guidance, also see ISO 10218-1:2025, 5.4.3 and 5.5.2.

Hand-guided collaborative applications shall fulfil the following requirements:

a) HGC may be activated by either

   — the robot and end-effector shall reach its pre-determined position and achieves a monitored standstill before HGC becomes active; or

   — approaching the robot and actuating the HGC if PFL according to 5.14.6 or SSM according to 5.14.5 is implemented;

b) the hand-guided controls (HGC) conform with ISO 10218-1:2025, 5.10.2;

c) when the operator actuates the HGC hold-to-run control, the monitored-standstill is released, and the operator performs the hand-guided collaborative task;

d) the operator shall have clear visibility of the hazard zone while hand-guiding to the intended position(s);

e) upon release of the HGC, a protective stop shall occur followed by a monitored-standstill (5.5.8), unless one or both of the following provides acceptable risk reduction:

   — power and force limiting (PFL) according to 5.14.6;

   — speed and separation monitoring (SSM) according to 5.14.5.

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f) shall be designed, positioned, and integrated considering the user operation of controlling the robot such that pinching, crushing sharp edges and other “caught-in” or “compressed by objects” injury risks are reduced or eliminated through design.

A 3P enabling device and function may be used instead of a hold-to-run device and function, if the design and integration addresses ergonomic risks due to sustained actuation in the centre-on position.

5.14.4.2 Location or positioning of HGC

The location, layout and control of motion through the HGC device shall be considered for a HGC type of collaborative application.

The mapping of actuation direction of the HGC to the motion of axes, robot and end-effectors shall be clearly shown. The direction of motion of the robot and end-effector shall be easily controlled by the HGC.

Specific risks associated with hand-guided collaborative applications are the exposure to the moving robot, end-effector, and workpieces, exposure to hanging loads and the possibility of non-ergonomic postures and associated physical strain.

The HGC shall fulfil the following:

a) be located so that the operator has an unobstructed view of entire hand-guided task zone, including workpiece motion, any hazards that might arise from motion and visibility of operators entering the task zone;

b) minimize exposure of the operator to moving workpieces;

c) be located such that operator positioning and posture does not cause additional hazards (e.g. operator is not under heavy loads, under the manipulator);

d) provide an ergonomically favourable posture for the operator which can include mounting HGC on the end-effector structure, at a fixed station, or providing as a portable control station carried by the operator;

e) end-effector safety functions shall be provided to prevent inadvertent release of a workpiece which causes a hazardous situation according to 5.9;

f) conform with 5.2.10 to ensure that loss or change of power shall not lead to loss of load, unexpected motion, or other hazards.

5.14.5 Speed and separation monitoring (SSM)

5.14.5.1 General

With speed and separation monitoring, risk reduction is achieved by maintaining the separation distance between any person and moving parts of the application, robot, end-effector and workpiece during robot application motion.

Speed and separation monitoring shall be applied for all people within the safeguarded space. If the performance of the protective device is limited by the number of people in the safeguarded space, and that limit is exceeded, a protective stop shall occur.

Speed and separation monitoring shall be implemented in accordance with Annex L, ISO 13855:2010 and IEC 62046:2018.

Collaborative applications using SSM shall use a SPE that detects entry into the safeguarded space and/or monitors the presence of any person. When a presence-sensing device (PSD) (e.g. laser scanner), is used to define detection zones, the size and location of the detection zones shall be set so that the separation distance shall be maintained, even during detection zone transitions.

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The time from activation of a stop command and for the robot application to decelerate to stop (v_s in Annex L) shall be included in the separation distance.

If stopping performance is not monitored by a safety function, then the stopping performance shall be checked and the SSM application or safety function parameters modified when the stopping performance degrades.

NOTE 1 Stopping performance can be monitored by stopping time limiting or stopping distance limiting safety functions.

NOTE 2 The speed and separation monitoring capabilities can be integral to the robot, provided by an external protective device, or a mixture of both.

When the distance between the operator(s) and moving parts of the application decreases to a value below the separation distance, a stop of the robot application shall occur in accordance with 5.6.3.

With PFL according to ISO 10218-1:2025, 5.10.4, the separation distance may be reduced to zero (0) when contact to an operator(s) is within acceptable biomechanical limits. The transition time for PFL parameters to become active shall be included in the minimum separation distance.

5.14.5.2 Enabling SSM

The SSM collaborative application shall have the following safety functions:

a) monitored-speed safety function(s) and a means for adjusting the parameters of the robot monitored-speed safety function(s) according to 5.5.6.2; and

b) speed and separation monitoring (SSM) safety function to continuously monitor relative distances and speeds of person(s) and the robot application.

Stopping time or stopping distance safety function should be provided.

If the implementation of speed and separation monitoring is dependent on limiting the range of motion of the robot application for operator safety, the robot shall have software-based limiting safety function(s) in accordance with ISO 10218-1:2025, 5.7.4. Other robot safety functions can also facilitate the implementation of speed and separation monitoring.

Delays in communication to realize SSM shall be included in the separation distance monitoring safety function.

After a protective stop (5.6.3) and monitored-standstill according to 5.5.8 have occurred, the robot application may resume operation automatically when the following are fulfilled:

— the separation distance shall be maintained;

— no people shall be within the SSM safeguarded space.

5.14.5.3 Separation distance

The speeds and the separation distances in an application can be either variable or constant.

Monitoring the separation distances shall be provided by safety function(s) (5.14.5.2).

The separation distance can be provided by the following to achieve a safe state:

— speed reduction, which may transition to a monitored-standstill according to 5.5.8;

— execution of an alternative path which complies with the required separation distance.

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5.14.6 Power and force limiting (PFL)

5.14.6.1 General

In a PFL collaborative application, contact between moving parts of the robot application and operator(s) can occur. Collaborative applications designed to rely upon power and force limiting shall use robots that conform with the requirements of ISO 10218-1:2025, 5.10.4. The collaborative application shall be designed to adequately reduce risks of injury by not exceeding the applicable threshold limits for contact events. Contact events between moving parts of a collaborative application and operator(s) are identified during the risk assessment. Contact parameters of pressure and force shall be verified of the identified contact event(s).

NOTE 1 See Annex M for guidance in determining limits for PFL collaborative applications.

NOTE 2 See Annex N for guidance on measuring the forces and/or pressures of PFL collaborative applications. There could be means other than measurement (e.g. advanced computational) by which to verify and validate the forces and/or pressures.

NOTE 3 The moving parts of a PFL robot application can contact operator(s) either intentionally or unintentionally.

Risk reduction is achieved, either through inherently safe means in the robot application and/or through safety functions, to keep contact events below threshold limit values that are determined during the risk assessment.

Safety functions (e.g. speed limiting, power and force limiting) shall be used and configured for the robot application such that the risk of injury is lessened to an acceptable level.

NOTE 4 Annex M contains guidance about the biomechanical limits associated with exposed body regions.

NOTE 5 For verification and validation requirements, see Clause 6 and Annex H.

NOTE 6 During testing (Annex N), contact parameter adjustments (speed, contact surface area, mass, compliance) are adjusted to result in contact situations being below threshold limit values.

NOTE 7 Ergonomic limits can be different from the biomechanical limits. For frequent contacts or other special cases, the applicable threshold limit values can be further reduced to an ergonomically acceptable level.

5.14.6.2 Contact situations

When using power and force limiting, contact events to the operator could occur in several ways:

— intended non-hazardous contact situations that are part of the application sequence;

— incidental contact situations, which can be a consequence of not following working procedures, but without a technical failure.

Contact from moving parts of the robot application to body regions shall be categorized as either quasi-static contact events as shown in Figure 4 or transient contact events as shown in Figure 5:

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Figure 4 — Quasi-static contact event

NOTE 1 Quasi-static contact includes clamping or crushing situations in which a body part is trapped between a moving part of the robot application and another fixed or moving part of the work cell for an extended time interval until the condition can be alleviated.



Figure 5 — Transient contact event

NOTE 2 Transient contacts are also referred to as "dynamic impact" and describes a situation in which an operator's body part is impacted by a moving part of the robot application and the body part can recoil or retract from the robot application without clamping or trapping the contacted body region, thus making for a short duration of the actual contact. Transient contact is dependent on the combination of the inertia of the robot application, the inertia of the person's body part (Annex M), and the relative speed of the two.

NOTE 3 The relevant inertia of the robot application is the moving mass as computed at the contact location. This might be anywhere along the length of the kinematic chain (i.e. the manipulator, linkages, tooling, and workpiece), so estimating this value makes use of the specific robot pose, link speeds, mass distribution and contact location or uses a worst-case value.

NOTE 4 The inertia of human body parts is addressed in reference documents listed in the Bibliography.

5.14.6.3 Risk reduction of contact events

The severity and probability of occurrence of contact events from the moving parts of the robot application to an operator(s) shall be reduced. Contact from the moving parts of the robot application can happen because the operator is in a location to which the application moved, or the operator moves towards the robot application when the robot, end-effector and workpiece are moving in the direction of the operator.

In particular, the hazards associated with contact to the face, skull and forehead shall be considered in the risk assessment.

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The severity and probability of occurrence of contact events shall be reduced by fulfilling the below requirements, as necessary for risk reduction:

a) layout design (5.4), robot application design (5.4.3), use of safety functions according to 5.5 and Annex C:

   1) position the base of the robot away from the operator to reduce the total space that can be occupied by both the robot application and the operator;

   2) minimize the restricted space of the collaborative application by use of limiting devices according to 5.4.7;

   3) minimize application requirements for an operator to move into or be positioned to locations of contact events;

   4) utilize rounded shapes according to 5.9.3 and 5.14.1;

   5) pad surfaces to absorb energy of contact(s), according to 5.9.3 and 5.14.1;

   6) improve process reliability and stability to lessen the need for interventions;

b) end-effector design, selection and implementation in accordance with 5.9;

c) end-effector exchange systems, if provided, design, selection and implementation in accordance with 5.9.6;

d) reduce speed by one or more of the following:

   1) speed limiting safety function, according to 5.5.6;

   2) when approaching a potential clamping contact event (e.g. workpiece pick-up or release), trigger a lower speed value for the speed limiting safety function;

   3) use a protective device that triggers either:

      — the speed reduction when an operator is detected;

      — a protective stop to prevent contact from occurring;

e) implement the PFL collaborative application to avoid potential contact(s) by keeping the tool direction away from operator(s), which can be implemented with a safety function for pose limiting or orientation limiting;

f) reduce the effective mass of moving parts of the robot application by selection of robot, end-effector and other payload influences;

g) keep movements away from the operator by implementation of limiting devices according to 5.4.7;

h) the use of guards and/or protective devices to protect sensitive body regions, including the skull, forehead, larynx, eyes, ears, or face.

Other safety functions in accordance with 5.5 may be implemented and used.

The risks due to contact with the face, skull and forehead (Annex M, Table M3, Body Regions 1, 2 and 3) in a collaborative application shall be reduced. A collaborative application shall avoid foreseeable contacts with sensitive parts of the body including the skull, forehead, larynx, eyes, ears, or face. Preventive measures shall reduce risk of contact with these sensitive body parts due to unintentional or reasonably foreseeable misuse considering that residual risk of contact can remain.

NOTE Risk reduction measures can be recommended for implementation by the user including personal protective equipment, such as head protection (e.g. industrial helmet), face shields, visors, eye protection (e.g. safety glasses) and protective clothing.

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5.15 Assembly, installation and commissioning

5.15.1 Commissioning of robot applications

5.15.1.1 General

A commissioning plan shall include information for protective measures for operators during commissioning of robot applications and robot cells. These measures also apply to robot applications after significant changes or after maintenance that could affect their safe operation.

5.15.1.2 Selection of interim safeguards

Interim safeguards shall protect personnel against the same hazards as originally identified in the risk assessment. If the intended safeguards are not yet available or in place prior to initiating power-on start-up testing and verification, an appropriate means of safeguarding shall be in place before proceeding.

Personnel shall be protected from risks during the initial assembly of a robot application and a robot cell, before all the final safeguards are installed. Reduced-speed manual mode shall be used. Alternative safeguarding, such as chains or portable walls, shall provide effective protection during the initial start-up of the equipment. Factors to consider in selecting the alternative safeguards can include:

— expected duration required for this interim situation;

— accessibility to the robot by all personnel;

— the type of equipment operating;

— which equipment is operating at a given time;

— the hazards presented by this equipment;

— training level of personnel involved.

Awareness means shall be installed to indicate the boundary of the restricted space.

Interim safeguards and protective measures could include:

a) the same as for the finished system, but installed in an interim manner;

b) different devices used in optional applications;

c) temporary obstructions;

d) specific written procedures;

e) awareness means;

f) specific training.

5.15.1.3 Initial start-up procedure

An initial start-up procedure shall be established and shall include, but not necessarily be limited to, the following:

a) It shall be verified before applying power, that the following have been installed as intended:

   1) mechanical mounting and stability;

   2) electrical connections;

   3) utility connections;

   4) communications connections;

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5) peripheral equipment and systems;

6) limiting devices for reducing the range of motion to a subset of the maximum space.

b) Instructions shall be provided that all operators shall exit the safeguarded space prior to applying drive power for the first time.

c) It shall be verified after applying power that:

1) emergency stop devices and functions operate;

2) each axis moves and is restricted as intended;

3) robot application responds to basic operating system motion commands as expected;

4) awareness means (audio/visual) function as expected;

5) all safeguarding devices or interim safeguards function as expected;

6) manual mode is activated and functioning as expected.

NOTE This is critical during initial power-on to ensure that the robot application and other equipment move/operate in the expected manner.

5.15.2 Environmental conditions

The robot application and protective measures of the robot cell shall be designed considering environmental conditions like surrounding temperature, humidity, electro-magnetic disturbances, lighting, etc. These can lead to some requirements for the surrounding environment due to technical restrictions.

The robot application, sub-assemblies, machinery and robot cell components shall be selected and implemented to withstand the expected use and environmental conditions.

5.15.3 Power

All sources of robot application and other equipment power (e.g. pneumatic, hydraulic, mechanical, electrical) shall meet the requirements as specified by the machine and component manufacturers.

Installations shall be in accordance with the relevant requirements of IEC 60204-1:2016+AMD1:2021, ISO 4413:2010and ISO 4414:2010. See 5.2.13.

5.15.4 Lighting

When darkness or shadows due to lighting cause hazardous situation(s) for operators to perform tasks, suitable lighting shall be provided in accordance with relevant standards. For requirements of lighting of workplaces, ISO 8995-1:2002 shall be applied for indoors and ISO/CIE 8995-3:2018 shall be applied for outdoors.

NOTE 1 Hazardous situations can include irritating dazzle, stroboscopic effects, etc.

Hazard zones where frequent inspection, adjustment or maintenance is required, shall be provided with appropriate additional lighting where it is foreseeable that illumination by ambient lighting of normal intensity could be inadequate. The additional lighting shall result in a minimum illumination intensity of 500 lux at the areas where frequent tasks (e.g. loading/unloading, inspection, adjustment) are performed.

NOTE 2 Locations to be considered for lighting include control stations, entry zones, serviceable parts inside housings (internal parts), etc.

5.15.5 Labelling

Controls shall be labelled to clearly indicate their function, according to IEC 60204-1:2016+AMD1:2021, IEC 61310-1:2007 and IEC 61310-2:2007, (e.g. power on "|", power off "O"). See Annex G.

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5.16 Maintenance

5.16.1 General

As far as practicable adjustment, maintenance, repair, cleaning and servicing tasks shall be possible while the robot application is at a safe state. The robot cell shall be designed and constructed in such a way as to allow safe access to where intervention is necessary during maintenance. Maintenance should be performed from outside safeguarded space(s). When it is necessary to perform maintenance within these spaces, selection of the preferred means of safeguarding shall be as follows:

a) the system shall be provided with the local means of controlling and isolating hazardous energy (e.g. disconnector, pressure relief device, energy isolation control system);

b) for maintenance tasks that are anticipated, integral to production, and these tasks need to be performed without energy isolation, then effective alternative protective measures shall be provided;

c) when alternative protective measures are provided in accordance with b), the protective measures for the control of hazardous energy or for position monitoring shall include one or more of the following:

   1) one or more safeguards that meets the requirements of 5.8;

   2) placing the equipment in a monitored-standstill that meets the requirements of 5.5.8;

   3) providing single-point-of-control (5.7.5) for personnel entering the safeguarded space (procedures shall be defined and provided in the information for use);

   4) providing a specific operating mode according to 5.7.2 for specific identified tasks. When guards are provided to allow access for maintenance, the guards shall be of sufficient size to allow easy access for the necessary tools, materials, and operators.

5.16.2 Movement without drive power

If the application requires movement without drive power capability, the integration shall fulfil this requirement. When the robot's capabilities of movement without drive power are used, the implementation shall conform with the instructions for use of the robot's movement without drive power capabilities. The integrator shall update any warnings and information.

The integration shall have the means to actuate the end-effector if there is a hazardous situation, e.g. gripper needs to be opened to release object or operator.

6 Verification and validation

6.1 General

The integrator shall perform the verification and validation of design and construction of robot applications and robot cells including appropriate safeguarding in accordance with Clauses 4 and 5.

6.2 Verification and validation methods

Annex H lists the methods to verify and validate the requirements stated in Clause 5. Using one or more methods, each requirement shall be verified or validated, or both verified and validated.

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6.3 Verification and validation of guards, protective devices, safety function parameter settings and biomechanical threshold limits

6.3.1 Guards and protective devices

Guards and protective devices shall be verified whether, as installed, the guards and protective devices:

— reduce identified risks consistent with the manufacturers' (e.g. guards, protective devices) and integrator's information for use; and

— have been appropriately applied.

a) Prevention of access to the hazard shall be achieved by:

   1) causing the hazard to cease before access;

   2) preventing the creation of a hazard by unintended operation;

   3) containing parts and tooling (e.g. loose objects, flying projectiles);

   4) controlling other process hazards (e.g. noise, laser, radiation).

b) The installed guards and protective devices shall be verified as to:

   1) type of guards, size of openings, placing of guards, correct safety distances, heights;

   2) the reset control being at a location that cannot be accessed from inside the safeguarded space;

   3) types of protective devices, detecting capabilities, placing of protective devices, correct distances, sizes, etc., and;

   4) bypass and muting functions.

6.3.2 Safety function parameter settings

Safety function parameter settings shall be tested to ensure that the settings achieve the needed risk reduction and fulfil the requirements specification.

6.3.3 Biomechanical limits

Validation of requirements regarding biomechanical limits for PFL collaborative applications shall include all relevant parts of robot application, e.g. manipulators, end-effectors, tools, fixtures, workpieces, jigs.

For the relevant contact points between moving parts to a specified region of the human body, verification of contact forces and pressures is first performed. For this verification, force and pressure measurements shall be performed. Suitable advanced computational means may be used.

6.4 Complementary protective measures

It shall be verified that complementary protective measures are provided:

a) instructions;

b) training materials;

c) warnings;

d) information about the required personal protective equipment;

e) procedures;

f) other appropriate measures.

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7 Information for use

7.1 General

The information for use shall be in accordance with ISO 12100:2010, 6.4 and address the different phases of the robot application's use, including transport, assembly and installation, commissioning, operational use (including start-up, shut-down, setting, teaching/programming or process change over, operation, cleaning, fault finding and maintenance) and, where relevant, decommissioning, dismantling and disposal.

The information for use shall describe the limitations of use and the intended use(s) of the robot application. It shall inform the user about ways in which the robot application should not be used for which experience has shown that these occur.

Information for use is an integral part of the design of a robot application and a robot cell. The information for use consists of:

a) signals and warning devices;

b) markings, signs (warning labels) and written warnings;

c) accompanying documents (e.g. instruction handbook).

The information for use shall conform with the requirements of:

— ISO 4413:2010, Clause 7 for hydraulic systems;

— ISO 4414:2010, Clause 7 for pneumatic systems;

— IEC 60204-1:2016+AMD1:2021, Clauses 16 and 17.

Unless otherwise required by national law, the information for use shall be in the language of the country where the robot application is to be used, in accordance with ISO 20607:2019, 6.2.

7.2 Signals and warning devices

Where provided, visual (e.g. flashing lights) and audible signals (e.g. buzzers) shall conform with ISO 12100:2010, 6.4.3.

7.3 Marking

The robot application and robot cell shall be marked in a distinct, legible and durable manner with the following:

a) the integrator's information:

   — business name;

   — full address;

   — if an authorized representative or authorized supplier is applicable, then their business name and full address;

   NOTE The integrator can be referred to as the "manufacturer" of the supplied robot application or robot cell.

b) robot application information:

   — type of robot application (e.g. robot welding system);

   — robot application series name or designation, if applicable;

   — model number or reference number, if any;

   — the year of manufacture;

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c) supply data for electrical and, where applicable, hydraulic and pneumatic systems (e.g. minimum and maximum pneumatic pressures);

d) lifting points for transportation and installation purposes, where applicable.

The following requirements shall be applied:

— IEC 60204-1:2016+AMD1:2021, Clause 16 for electrical equipment;

— ISO 4413:2010, 7.4 for hydraulic;

— ISO 4414:2010, 7.4 for pneumatic.

7.4 Signs (pictograms) and written warnings

Signs and written warnings shall conform with ISO 12100:2010, 6.4.4.

Registered signs according to ISO 7010:2019 shall be used as applicable. Where no registered signs are applicable, safety signs and markings with written warnings shall be in accordance with ISO 3864-1:2011, ISO 3864-2:2016, ISO 3864-3:2024 and ISO 3864-4:2011.

Robot applications containing functions for lifting goods only and with a carrier which allows access to persons, shall have a clear and indelible warning prohibiting the lifting of persons. This warning shall be visible at the position which allows access to the carrier.

The requirements of IEC 60825-1 shall be applied when laser equipment is part of the application.

7.5 Instruction handbook

7.5.1 General

The system integrator shall provide an instruction handbook in accordance with ISO 12100:2010, 6.4.5 and ISO 20607:2019.

For the electrical equipment, the information shall conform with the requirements of IEC 60204-1:2016+AMD1:2021, Clause 17.

In addition, the instruction handbook shall include the information in accordance with 7.5.2 to 7.5.23.

7.5.2 Identification

Information shall be provided about the system integrator as follows:

— the business name;

— full address;

— contact information of the system integrator, e.g. telephone number, service/ support website address;

— if an authorized representative or authorized supplier is applicable, also provide the business name, full address, and contact information;

— the designation of the machinery as marked on the machinery itself, except for the serial number.

7.5.3 Intended use

The following shall be provided:

a) description of the range of applications for which the robot application is intended;

b) the robot application components (e.g. robots, external controllers, teach pendants, safeguards);

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c) detailed description of the system, its fittings, its guards, and/or protective devices;

d) the intended use(s) and prohibited usages, taking into account reasonably foreseeable misuse(s);

e) the conditions in which the requirements of stability are met, e.g. during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

f) the limitations of use, included intended life of the system;

g) the limits for the range of motion(s) and robot payload capacity, including maximum mass and size;

h) any conditions that restrict the workpiece, payload or material subject to the robot application;

i) description of the residual risks, which are those that could not be eliminated by the protective measures implemented in the robot application;

j) interface requirements to other machines;

k) data concerning other hazards, for example, gases, vapours, dust, and vibration generated with reference to the measuring methods used;

l) for collaborative applications, inform that residual risks can include psychological stress due to cognitive and physical ergonomics.

7.5.4 Transport, handling and lifting

If transport, handling and storage of a robot application is required by the user, the Instructions for use shall include information relating to transport, handling and storage of the robot application and or its components shall include:

a) storage conditions for the individual robot applications;

b) dimensions, mass value(s), position of the centre(s) of gravity where applicable;

c) where applicable indications for handling (e.g. drawings indicating application points for lifting equipment).

7.5.5 Installation

If the robot application is intended to be installed by the user, the information relating to installation of the robot application shall include:

a) fixing/anchoring and if applicable vibration damping requirements;

b) assembly instructions;

c) space needed for use and maintenance;

d) permissible environmental conditions (e.g. temperature, moisture, vibration, electromagnetic radiation);

e) instructions for connecting the robot application to power supplies and other utilities (e.g. water, air);

f) advice about waste removal/disposal;

g) description of the installation requirements such as utility needs, floor loading, etc.

7.5.6 Commissioning and programming

If the robot application is intended to be commissioned and programmed by the user, the instructions handbook shall contain instructions about:

— commissioning,

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— programming;

— how to perform the initial test and examination of the robot application and its protective measures before being placed into production, including functional testing.

If necessary, recommendations shall be provided about protective measures which are to be taken by the user, e.g. additional or interim safeguards, separation distances, safety signs and signals.

The following instructions shall be included:

a) before applying power, it shall be verified that:

   1) all components have been properly mechanically mounted and are stable;

   2) the safety-related parts of the control system are installed as specified;

   3) if applicable, mechanical limiting devices are installed as specified;

   4) the appropriate safeguarding is installed as specified, including interim safeguards if applicable.

b) after applying the power, the following shall be verified to be located and function as intended:

   1) the start, stop and mode selection control devices;

   2) single-point-of-control;

   3) each axis' movements;

   4) the limiting devices that establish the restricted space;

   5) emergency stop and protective stop functions and their devices;

   6) all control stations;

   7) the peripheral equipment including interlocks;

   8) all safeguards, protective devices, enabling devices, and interlocks;

   9) all other safeguarding (e.g. barriers, interim safeguards), if applicable.

Instructions shall be provided for how to validate the version of all programs, both standard controls and SRP/CS. These instructions shall include how to determine the versions that are installed for their robot application and robot cell.

7.5.7 Abnormal and emergency situations

Instructions for emergency situations shall include, where applicable:

a) where blocking (5.10.3) cannot be avoided, the guidance to safely block and unblock the equipment;

b) guidance on the means for the release of operator(s) trapped;

c) type of fire-fighting equipment to be used, if specific;

d) warning about possible emission or leakage of harmful substance(s) and means to fight their effects (if practicable);

e) instructions and recommendations for training operator(s) on responding to emergency or abnormal situations including emergency recovery of system equipment.

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7.5.8 Settings and operation

Instructions shall be provided for safe operation and settings (e.g. setup, parameter entry, preparing for operation), including safe working practices and the training required to achieve the necessary skill level of operator(s) operating the equipment including:

a) risks that can be generated by certain applications, using certain fittings, and about specific safeguards that are necessary for such applications;

b) material flow;

c) operator tasks, locations, and routes to perform the tasks;

d) spans of control of the various control and protective devices (e.g. protective devices, reset of protective devices, enabling devices, emergency stops, control stations, disconnecting means);

e) description of manual controls (actuators), enabling devices, protective stops;

f) other controller functions, operator panels, teach pendants, enabling devices and indicators;

g) procedures for setting and adjustment, including as applicable:

   — use of single-point-of-control;

   — setting the TCP;

   — setting the payload;

h) modes and means for stopping;

i) procedures for fault identification and location, required intervention(s) and restarting after an intervention;

j) personal protective equipment that needs to be used and training required;

k) instructions that disconnected teach pendants shall be removed from access;

l) procedures for emergency situations;

m) procedures for local and remote control;

n) storage locations or design of unused cableless/detachable teach pendants to prevent use of an inactive emergency stop;

o) requirements for periodic functional testing of safety-related equipment;

p) instructions on avoidance of singularity conditions based on information from the robot manufacturer.

7.5.9 Maintenance

Information for maintenance shall include:

a) instructions for safe maintenance, including safe working practices and the training required to achieve the necessary skill level of operator(s) operating the equipment;

b) instructions and procedures to avoid errors of fitting during maintenance;

c) specification for any fluids or lubricants to be used in lubrication, braking, or transmission system internal to the robot, including guidance on correct selection, preparation, application and maintenance of expendables;

d) specifications of the spare parts to be used, when these affect the health and safety of operators (e.g. safety-related parts of the control system);

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e) nature and frequency of inspections for safety-related reasons;

f) instructions relating to maintenance operations which require a specific technical knowledge or particular skills and hence should be carried out exclusively by skilled operators (e.g. maintenance staff, specialists);

g) drawings and diagrams enabling maintenance personnel to carry out their task (especially fault-finding tasks) including technical documentation about electric, hydraulic and pneumatic equipment;

h) information and instructions to replace safety-related parts (e.g. manufacturer part number, specification of the parts) and instructions for any test or examination necessary after such a replacement;

i) tasks that require energy control and isolation;

j) safe working procedures where manual suspension of safeguards is unavoidable;

k) procedures for fault identification and location, repair, and restarting;

l) instructions to confirm safety function settings after an application is repaired or modified and to

   — evaluate if the repair or any modification results in increased risk(s), and

   — verification and validation shall be performed that safety-related parameters are set as required.

7.5.10 Decommissioning

Instructions for safe decommissioning, dismantling and disposal shall be included.

7.5.11 Remote interventions

The instructions for use shall prescribe the operating procedures for remote interventions that shall be followed by the remote and local operators involved.

7.5.12 Hazardous energy

Information shall be provided about hazardous energy including information about sources of energy, the type of energy and stored energy.

Details shall be provided about the maintenance tasks that:

a) require energy control and isolation; and

b) are anticipated to require hazardous energy to perform the maintenance task.

Instructions shall be provided about how to:

— isolate the energy including the isolation means and those having the capability of being locked or otherwise secured in the de-energized position;

— release stored energy in a controlled way.

When more than one disconnecting device is provided, each of its locations shall be described.

7.5.13 Limiting devices and restricted space

The instructions for use shall include the following information:

— the type of limiting devices provided and for what axes;

— the configured limits of software-based limiting safety functions, if the safety functions are used;

— the restricted space dimensions and the stopping time, if applicable;

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— dimensions and locations of the dynamic limiting;

— for non-mechanical limiting devices, the position where a stop is initiated and the location where the movement stops as this defines the restricted space;

— a description of how all axes are limited.

7.5.14 Movement without drive power

Information shall be provided about the movement, without drive power, of robot axes, robot actuators, additional axes, end-effectors and other equipment in the robot application and robot cell. The information shall include the following:

— a description of this capability; instructions for how to move the robot without drive power;

— recommendations for training operator(s) on responding to emergency or abnormal situations (e.g. situations that could require movement without drive power);

— warning of the potential hazard(s);

— warnings that gravity and the release of braking devices can create additional hazards.

7.5.15 Control station(s)

The instructions for use shall provide information about the use and functions of all control stations including teach pendants provided with the robot. For any control stations that are detachable or cableless, a description shall be provided of the storage or design to prevent confusion between active and inactive control stations.

7.5.16 Functional safety

7.5.16.1 General

The description, of each safety function or combination of safety functions used in the application, shall be provided including the following:

— intended function;

— functional safety performance;

— inputs and outputs as applicable;

— availability.

This requirement also applies to safety functions associated with any external safety controllers.

Instructions on location and function of all control systems including diagrams of the interface of electrical, hydraulic, and pneumatic systems necessary for setup and installation.

NOTE This does not include schematics of the intellectual property of the robot or robot application components.

7.5.16.2 Safety-related parametrization of software

The following information about safety-related parametrization of software shall be provided:

— how safety parameters are secured;

— safety functions affected by unsecured settings, e.g. workpiece dimension;

— what robot and robot application safety function(s) are included in the identifier, e.g. checksum;

— how to view and document the settings and parameters (5.5.5);

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— the maximum response time for any parameter limit change to become effective.

Information and guidance shall be provided about robot application settings and software limitations that are related to safety function configuration. The importance of verifying and validating safety function parameters before starting the use of the robot application shall be emphasized. This includes the initial setting and any changes to parameters.

7.5.16.3 Response time of safety functions

Response time(s) and if applicable the transition time(s) of each safety function shall be provided.

For movements without stopping distance and/or stopping time monitoring safety functions, the following shall be provided:

— stopping time and distance or angle from initiation of stop signal;

— recommended interval for periodic stopping time/stopping distance testing.

7.5.16.4 Stop functions including emergency stop

For all stop functions, including emergency stop, the following information shall be provided:

a) stop category according to IEC 60204-1:2016+AMD1:2021;

b) span-of-control of every stop device and protective device;

c) maximum response time for any stop, as measured from input state change until the termination of hazardous function of the robot application.

7.5.16.5 Speed limiting safety functions

When a speed limiting safety function is implemented, the configured speed limit and the purpose of using this safety function shall be provided.

NOTE See 5.5.6.

7.5.17 Operating modes

Instructions and warnings that

a) reduced-speed manual mode tasks should be performed with all operators outside the safeguarded space;

b) when reduced-speed manual mode tasks are performed within the safeguarded space, the operator causing movements shall be provided with a teach pendant and any other operators shall be provided with a 3P enabling device;

c) high-speed manual mode shall only be used when all operators are outside the safeguarded space;

d) high-speed manual mode shall only be used for the purpose of program verification;

Instructions shall be provided about how to use the manual mode (e.g. reduced-speed, high-speed). Information shall be provided about the residual risks associated with these modes.

7.5.18 Enabling devices

Enabling device information shall include a description of the operation of each enabling device and intended functionality if multiple enabling devices shall be used.

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7.5.19 Vibration

If the robot application uses hand-guided control (5.14.4), the instructions shall contain the following information concerning vibrations transmitted:

a) the vibration total value, according to ISO 20643:2005, to which the hand-arm system is subjected, if it exceeds 2,5 m/s^2;

b) if the vibration total value does not exceed 2,5 m/s^2, this shall be stated;

c) the uncertainty of measurement if the vibration total value is described.

7.5.20 End-effector(s)

The instructions for use, associated with end-effectors, shall include the following information:

a) the intended life of end-effectors, based on expected parameters in normal operation;

b) if the end-effectors have movable parts or points where parts of the human body could be trapped, how to escape from this situation, both with and without power (e.g. electrical, pneumatic, hydraulic, kinetic);

c) if the end-effectors are designed to contact or be touched by operator(s) during intended operation and the expected frequency of contact for which it is designed;

d) recommendations on how to restart after a stop if special actions are needed for the end-effector (e.g. if a workpiece is to be removed manually, a separate controller needs to be restarted);

e) how much can be changed or adjusted (e.g. gripper positioning and/or workpiece) without exceeding the application limits for the use of the end-effector;

f) worst case pressures and forces for inherently safe grippers.

NOTE See Annex I for information about end-effectors.

7.5.21 Manual load/ unload stations

The instructions for use shall contain the information required for the correct use of the manual load/ unload station. Residual risk information and warnings shall be provided to the user.

Examples of symbols used for safety signs include:

— no climbing, see ISO 7010:2019-P009;

— no stepping on surface, see ISO 7010:2019-P019.

NOTE The ISO 7000 database (available from: https://www.iso.org/obp) contains graphical symbols for signs and related uses. See also ISO 3864-1:2011 and ISO 3868-4.

7.5.22 Collaborative applications

7.5.22.1 General

The instructions for use, associated with collaborative applications, shall additionally include the following:

a) the risk reduction measures implemented according to 5.14.1;

b) If any safety functions are used to reduce risks (e.g. speed limiting), the safety functions shall be described and the limit settings shall be documented.

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7.5.22.2 SSM applications

The instructions for use, associated with SSM applications, shall include the following information in addition to that which is required in 7.5.22.1:

a) the maximum number of people protected by the protective device shall be stated;

b) if stopping performance is not monitored by a safety function, instructions about how to check stopping performance shall be provided and include instructions to adjust the SSM application if stopping performance degrades.

NOTE Stopping performance can be monitored by stopping time limiting or stopping distance limiting safety functions.

7.5.22.3 Power and force limiting applications

The instructions for use, associated with PFL applications, shall include the following information in addition to that which is required in 7.5.22.1:

a) information specific to the robot, end-effector and workpiece including:

   — the effective mass of the payload for the robot application (m_L);

   — the mass per manipulator (M);

   — the total mass of other moving parts of the application.

   NOTE The mass per manipulator (M) is required to be provided with the robot as described in ISO 10218-1:2025, 7.5.3.

b) anticipated and reasonably foreseeable contact situations between moving parts of the robot application and people, including:

   — the specific body area(s) that could be contacted;

   — whether the contact is transient or quasi-static;

   — the anticipated surface area or geometric conditions associated with the contact surfaces;

   — the biomechanical limit(s) associated with the contact.

c) instructions to confirm safety function settings after a PFL collaborative application is repaired or modified and to:

   — evaluate if the repair or any modification results in increased risk(s), high pressures or forces, and

   — verification and validation shall be performed that safety-related parameters are set as required.

NOTE See Annex N.

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7.5.23 Cybersecurity

Information shall be provided regarding any implemented cybersecurity features and methodologies to enable the user to implement measures such as firewalls, creation of a recovery plan and implementation of a continuous lifecycle approach (e.g. review of security risk assessment in light of new threats and vulnerabilities and to implement required software patches).

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Annex A
(informative)

List of significant hazards

Table A.1 provides a list of significant hazards for robot applications.

Table A.1 — List of significant hazards

No.	Type or group	Table A.1 Example of hazards		Subclause reference
		Origin	Potential consequences	
1	**Mechanical**	— inappropriate selection of — robot, robot safety functions — end-effector, end-effector safety functions — application machines, components and equipment and their safety functions — robot application components, equipment and task programs — end-effector design not suitable for the workpiece variability — unintended or intended movements (linear or rotational or a combination of the two due to singularity) of — any part of the robot arm (including back), end-effector, workpiece, component machines or associated parts of robot cell — additional axis (including end-effector tool at servicing position) — jigs or fixtures — sharp tool on end-effector or of additional axes, part being handled, and associated equipment — machines or robot cell components during handling operations	— crushing — shearing — cutting or severing — entanglement — drawing-in or trapping — impact — stabbing or puncture — friction, abrasion — high-pressure fluid/gas injection or ejection	Clause 4, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.12, 5.14, 5.15, 5.16, Annex B, Annex C, Table C.2, Annex D, Annex F, Annex I, Annex J, Annex K, Annex M

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Table A.1 *(continued)*

No.	Type or group	Table A.1 Example of hazards		Subclause reference
		Origin	**Potential consequences**	
		— caught between — robot arm and any fixed object — end-effector and robot manipulator, workpieces fixtures or other objects in robot cell — end-effector or workpiece and any fixed object (guard, beam, etc.) — axis and any fixed object — fixtures, shuttles, utilities		
	Mechanical continued	— unintended activation of an end-effector or associated equipment (including additional axes, process specific for grinding wheels, etc.) — materials and products falling or ejection — falling into fixtures or shuttles — end-effector failure (separation) — end-effector wear — grasp failure, not grasping, or dropping of the workpiece — ejected or falling workpieces or parts of the end-effector — unintended release of end-effector, tool, workpiece or fixture — unintended or unexpected release of workpiece failure in mechanical interface adapter or end-effector exchange (tool changing) system — not exiting robot cell (via interlocked guard or guarding) for a trapped operator in automatic mode — no means of preventing restart for a trapped operator in automatic mode — unexpected release of hazardous stored energy — cable related issues (e.g. snags, breaks, whipping) — broken sensors — high-pressure fluid/gas injection or ejection — loose clothing, long hair	— crushing — shearing — cutting or severing — entanglement — drawing-in or trapping — impact — stabbing or puncture — friction, abrasion	Clause 4, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.12, 5.14, 5.15, 5.16, Annex B, Annex C, Table C.2, Annex D, Annex F, Annex I, Annex J, Annex K, Annex M

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Table A.1 *(continued)*

No.	Type or group	Table A.1 Example of hazards		Subclause reference
		Origin	Potential consequences	
2	**Electrical hazards**	— contact with live parts or connections (electrical cabinet, terminal boxes, control panels at machine) — confusion of various voltages within a system, electrical cabinet and terminals, e.g. drive power, control power (24 V versus 110 V) — contact with discrete components in the electrical (electronic) circuitry, capacitors — exposure to arc flash — process using high voltage or high frequency, e.g. electrostatic painting, inductive heating — welding applications using high voltage — projection of molten particles	— electrocution — shock — burn	4.1, 4.2, 4.3, 5.2.10, 5.2.12.1, 5.2.12.2, 5.2.13, 5.5.1, 5.7.8.2, 5.9.1, 5.15.1.3, 5.15.3, Table C.2, I.1.1, I.3
3	**Thermal hazards**	— hot surfaces associated with the end-effector, or associated equipment or work piece (e.g. welding torches, hot materials in forging presses, injection moulding, grinding and de-burring) — cold surfaces or objects (cryogenic processes) — temperature extremes required to support the process [molten materials; ovens for cooking or heating (autoclaves); freezer or chillers, etc.] — flammable materials (inside dust collector systems, cleaning tanks, sealant applicators) projection of molten particles	— burn (hot or cold) — radiation injury — injury due to explosion (e.g. combination of burn and mechanical injury)	4.1, 4.2, 4.3, 5.2.6, 5.2.12, 5.4.4, 5.5.2, 5.8.6.1, 5.9.2, Table C.2
4	**Noise hazards**	— specific applications which are sources of high noise (e.g. a water jet cutter, stamping presses, pumps and valving, metal removing operations) — noise level preventing hearing or understanding audible danger warning signals, including inability of operators to coordinate their actions through normal conversation	— loss of hearing — loss of balance — loss of awareness, disorientation — any other (e.g. mechanical) because of ambient conditions or distraction	Noise is excluded from the scope of this document
5	**Vibration hazards**	— direct contact with the source — loosening of connections, fasteners — misalignment of components or parts	— fatigue — neurological damage — vascular disorder — impact	4.1, 4.2, 4.3, Table C.2

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Table A.1 *(continued)*

No.	Type or group	Table A.1 Example of hazards		Subclause reference
		Origin	Potential consequences	
6	**Radiation hazards**	— EMF interference with proper operation of the robot application — exposed to process-related radiation, e.g. arc welding, laser.	— burn — damage to eyes and skin — related illnesses	4.1, 4.2, 4.3, 5.5.10, 5.8.6.1, 5.11, I.2.2
7	**Material/ substance hazards**	— contact with components covered in harmful fluids — failures of mechanical and electrical components — corrosive fumes and dust	— sensitization — fire — chemical burn — inhalation illnesses — any other (e.g. mechanical) because of failure of components due to hazardous or corrosive substances	4.1, 4.2, 4.3, 5.2.2, 5.2.4, 5.8.1, 5.8.6.1, Table C.2
8	**Ergonomic hazards**	— inappropriate selection of robot, robot features, robot safety functions — poorly designed teach pendant, HMI touch screen or operator panel (too far or high) — poorly designed loading/unloading post (e.g. long distance between components box location and loading/ unloading area) — poorly designed enabling devices — inappropriate location or identification of controls (e.g. hard to reach) — inappropriate location of components that require access (troubleshooting, repair, adjustment) — obscured hazards, inadequate or blocked local lighting	— unhealthy postures or excessive effort leading to injury in the short term (e.g. sprained wrist or shoulder) — unhealthy postures or excessive effort leading to repetitive strain injury over the long term (e.g. carpal tunnel syndrome, or similar long-term damage to tendons, joints, nerves) — fatigue	4.1, 4.2, 4.3, 5.4.1, 5.4.3, 5.4.4, 5.8.6.1, 5.12.2.1, 5.14.4.1, 5.14.4.2, 5.14.6.1, Table C.2, J.2.1, J.2.10
9	**Hazards associated with environment in which the machine is used**	— installations in earthquake zones — electromagnetic interference or surges in energy source — moisture — temperature	— burn — disease or illness — slipping, falling — respiratory damage — impact — any other consequence of combinations of hazards and hazardous situations	4.1, 4.2, 5.2, 5.3, 5.4, 5.8.6.1, 5.15.2, Table C.2

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Table A.1 *(continued)*

No.	Type or group	Table A.1 Example of hazards		Subclause reference
		Origin	Potential consequences	
10	**Combinations of hazards**	— inappropriate selection of robot, robot features, robot safety functions — robot application directed to start by one operator, but this action is not expected by another operator — hazards encountered due to multiple failures/situations — misidentification of actual problem and compound problem by making incorrect or unnecessary actions — action increases severity of harm, e.g. in avoiding a sharp edge, contact is made with a hot surface instead — unintended release of holding devices allowing motion under residual forces (inertia, gravity, spring/energy storage means) — failure of a safeguarding device to function as expected	— any other consequence of combinations of hazards and hazardous situations	4.1, 4.2, 4.3 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.14, 5.15, 5.16, Annex B, Annex C, Annex D, Annex I, Annex J

Table A.2 provides a list of significant hazards for end-effectors used in robot applications.

Table A.2 — List of significant hazards by the functions of end-effector

No.	Function	Type	Table A.2 Example of hazards associated with the functions of end-effectors		Subclause reference
			Hazard origin	Potential consequences	
1	**General**	(General)	— sharp edge — poor alignment with mechanical interface — unintended or uncontrolled release of detachable tool(s)	— abrasion, irritation — laceration — shearing — stabbing — puncture/penetration — amputation/severing — entanglement — bruise — bone break — crush	5.2.1, 5.2.2.4, 5.4.4, 5.9, 5.9.3, 5.9.4, 5.9.5, 5.9.6, 5.14.1, 5.14.4.2, C.2.1.2.2, Annex I

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Table A.2 *(continued)*

No.	Function	Type	Table A.2 Example of hazards associated with the functions of end-effectors		Subclause reference
			Hazard origin	Potential consequences	
2	**Gripping**	(General)	— workpiece (gravity) — excessive gripping forces	— bruise — bone break — crush	5.4.3, 5.4.4, 5.9, 5.9.1, 5.9.4, C.2.1.2.2, Annex I, I.1.1, I.3, I.3.2, I.4
		Mechanical grippers	— grasping structure	— bruise — bone break — crush	5.9.1, 5.9.4, I.1.1, I.1.2, I.4
		Vacuum grippers	— loss of workpiece	— abrasion — laceration — crushing	5.2.8, 5.9.1, I.1.1, I.1.3, I.4
		Magnet grippers	— EMF (electromagnetic fields)	— thermal effects — stimulation of muscles, nerves, or sensory organs — effect on implanted medical devices	I.1.1, I.1.4
		Pin grippers	— penetration of body part	— stabbing — puncture	I.1.2
3	**Welding**	Spot welding gun	— welding current — welding spatter — high temperature — EMF (electromagnetic fields)	— electric shock/burn — burn — burn — effect on implanted medical devices	I.2.2, I.2.3
		Arc welding gun	— welding current — arc light (UV) — high temperature — EMF (electromagnetic fields) — fumes	— electric shock — lightning ophthalmia — burn — effect on implanted medical devices — breathing difficulties, irritation, poisoning	I.2.2, I.2.3
		Laser welding gun	— laser beam (direct, reflection) — fumes, gasses — high temperature	— burn, loss of sight — breathing difficulties, irritation, poisoning	5.11, I.2.2, I.2.3

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Table A.2 *(continued)*

No.	Function	Type	Table A.2 Example of hazards associated with the functions of end-effectors		Subclause reference
			Hazard origin	Potential consequences	
		Ultrasonic welding gun	— ultrasonic	— hearing damage — tinnitus — nausea — dizziness — headache — fatigue	I.2.2, I.2.3
4	**Painting**	General	— painting material	— in accordance with a safety data sheet of the material	5.2.4, I.2.2
		Static spray gun	— static	— electric shock, ignition source	5.2.4, I.2.2
		Non-static spray gun	— material application to body	— eye damage, loss of sight — breathing difficulties, irritation, poisoning	5.2.4, I.2.2
		Application (glue, sealer)	— sharp end- effector or grasped tool — adhesive or sealant material	— irritation of skin — stabbing — penetration — in accordance with a safety data sheet of the material	I.2, M.3.3
5	**Cutting, drilling**	Mechanical	— saw blade, drill	— irritation, — laceration, — severing, — entanglement	5.2.1, 5.4.4, 5.9.3, 5.9.4, 5.14.2, I.2
		Plasma torch	— plasma — fumes, gasses — high temperature	— burn, loss of sight — breathing difficulties — respiratory irritation — poisoning — burn	5.2.1, 5.9.2
		Laser	— laser beam — fumes, gasses — high temperature	— burn — loss of sight — breathing difficulties — respiratory irritation — poisoning	5.11, I.2.2
		Water jet	— high pressure water	— penetration — necrosis — infection	I.2.2

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Table A.2 *(continued)*

No.	Function	Type	Table A.2 Example of hazards associated with the functions of end-effectors		Subclause reference
			Hazard origin	Potential consequences	
6	**Polishing**	Polish end-effector or grasped tool	— rotating end-effector or grasped tool	— abrasion, irritation — severing — entanglement	5.9, I.2.2
		Ink jet	— nozzle	— penetration	I.2, M.3.3
7	**Sewing**	Mechanical (e.g. drill, needle)	— needle	— penetration	5.2.1, 5.4.4 5.9.3, 5.9.4, 5.14.2, I.2, M.3.3
8	**Marking**	Ink jet	— nozzle	— penetration	I.2
		Laser	— laser beam — fumes, gasses — high temperature	— burn — loss of sight — breathing difficulties — respiratory irritation — poisoning	5.11, I.2.2
9	**Screwing**	Screwdriver	— rotating grasped screwdriver	— abrasion, irritation — puncture — severing — entanglement	I.2
10	**Bending**	(General)	— contact area	— crush — penetration	5.9.1, 5.9.2, 5.9.4, I.2, I.4
11	**Lifting**	(General)	— workpiece (gravity)	— bruise — crush	5.4.3, 5.4.4, 5.9.1, 5.9.4, I.2
12	**Inspecting**	Laser	— laser beam	— loss of sight	5.11, I.2.2

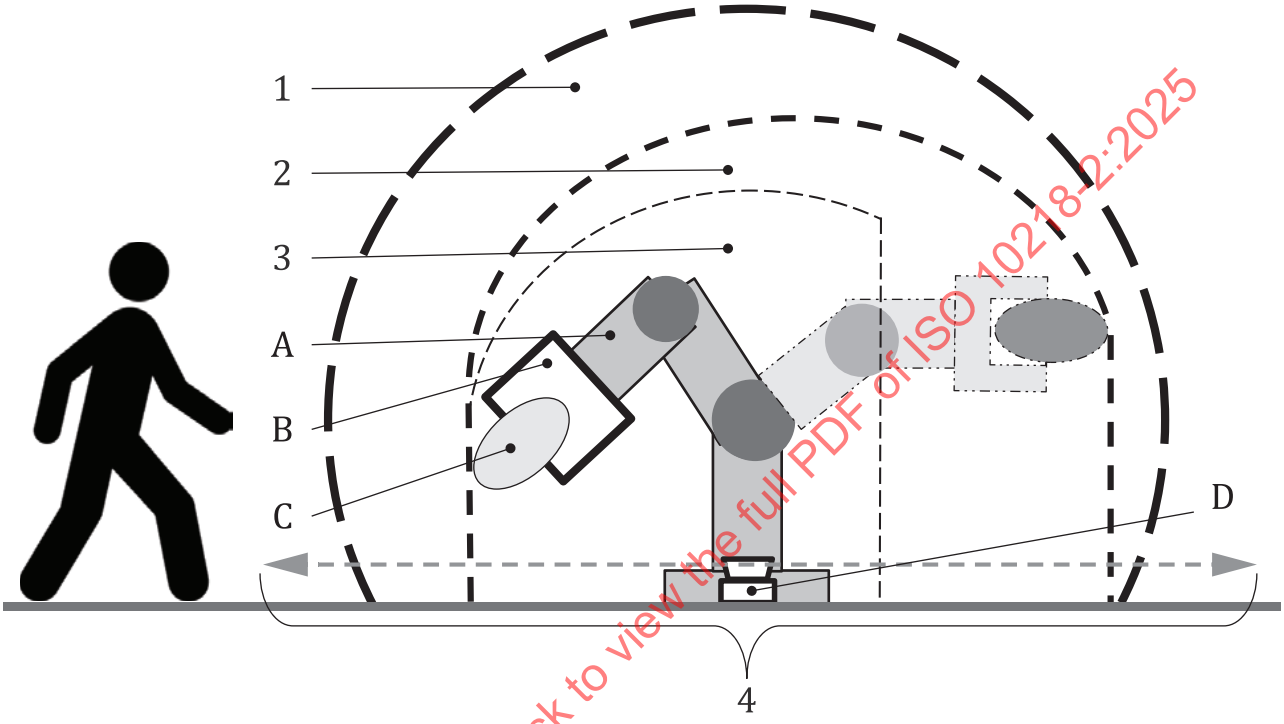
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Annex B
(informative)

Illustrations of spaces

Figure B.1 shows an overview of all the various “spaces” associated with a robot application.



Key

1	maximum space	A	manipulator
2	restricted space	B	end-effector
3	operating space	C	workpiece
4	safeguarded space	D	protective device (safety laser scanner shown)

NOTE 1 The maximum space is greater or equal to the restricted space and the restricted space is greater or equal to the operating space.

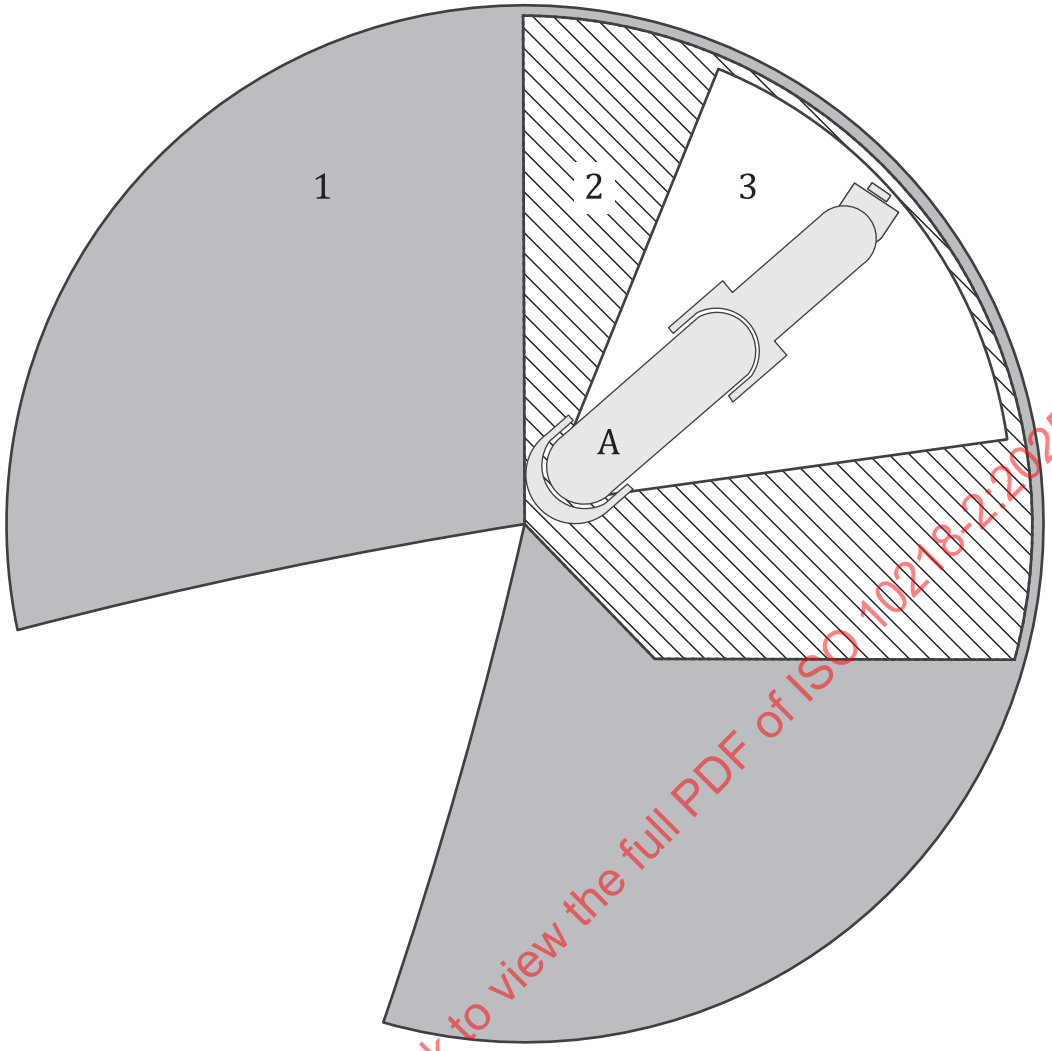
NOTE 2 This figure shows concepts without dimensions, and it is not shown to scale. The detection zone border could be closer to the restricted space.

Figure B.1 — Spaces

Figure B.2 shows the spaces associated with a robot, where there is no end-effector and no workpiece. See ISO 10218-1:2025, Annex B, Figure B.2.

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Key

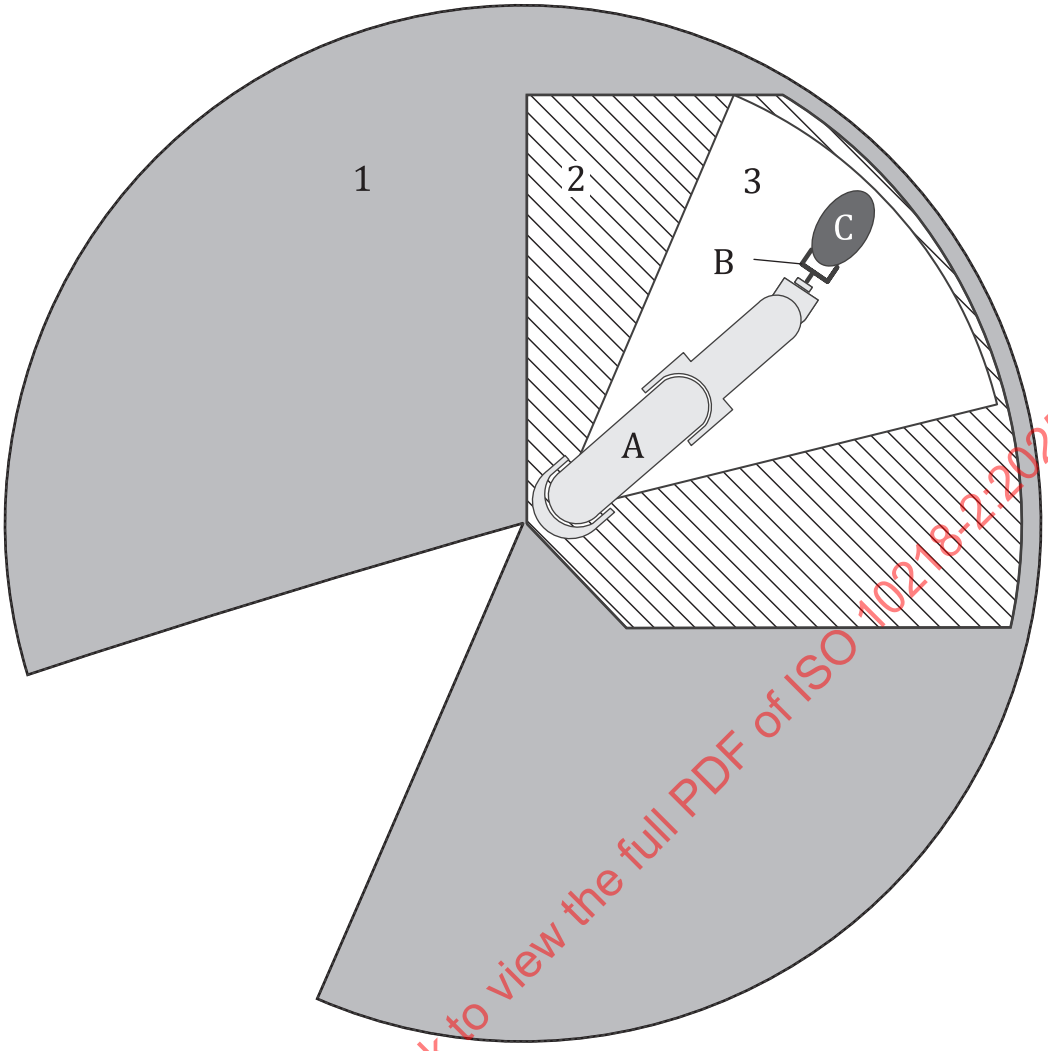
1	maximum space	A	manipulator
2	restricted space		
3	operating space		

Figure B.2 — Spaces of a robot (without end-effector and without workpiece)

Figure B.3 shows the spaces associated with a robot system (robot and end-effector) plus showing a workpiece without reference to a specific application.

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Key

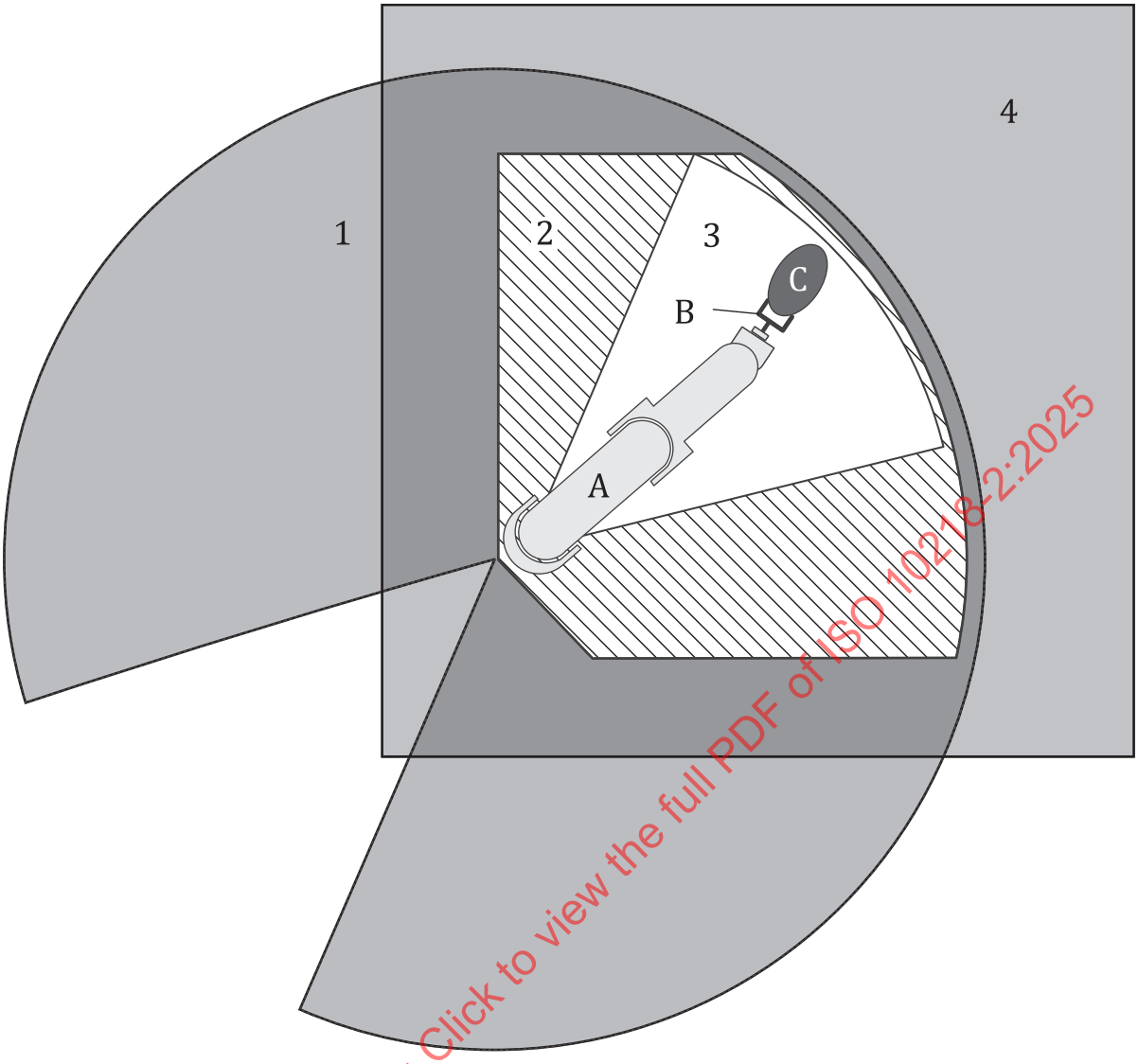
1	maximum space	A	manipulator
2	restricted space	B	end-effector
3	operating space	C	workpiece

Figure B.3 — Spaces of a robot system plus a workpiece

Figure B.4 shows the spaces associated with the moving parts of the robot application, with an end-effector and workpiece, without reference to a specific application.

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Key

1	maximum space	A	manipulator
2	restricted space	B	end-effector
3	operating space	C	workpiece
4	safeguarded space		

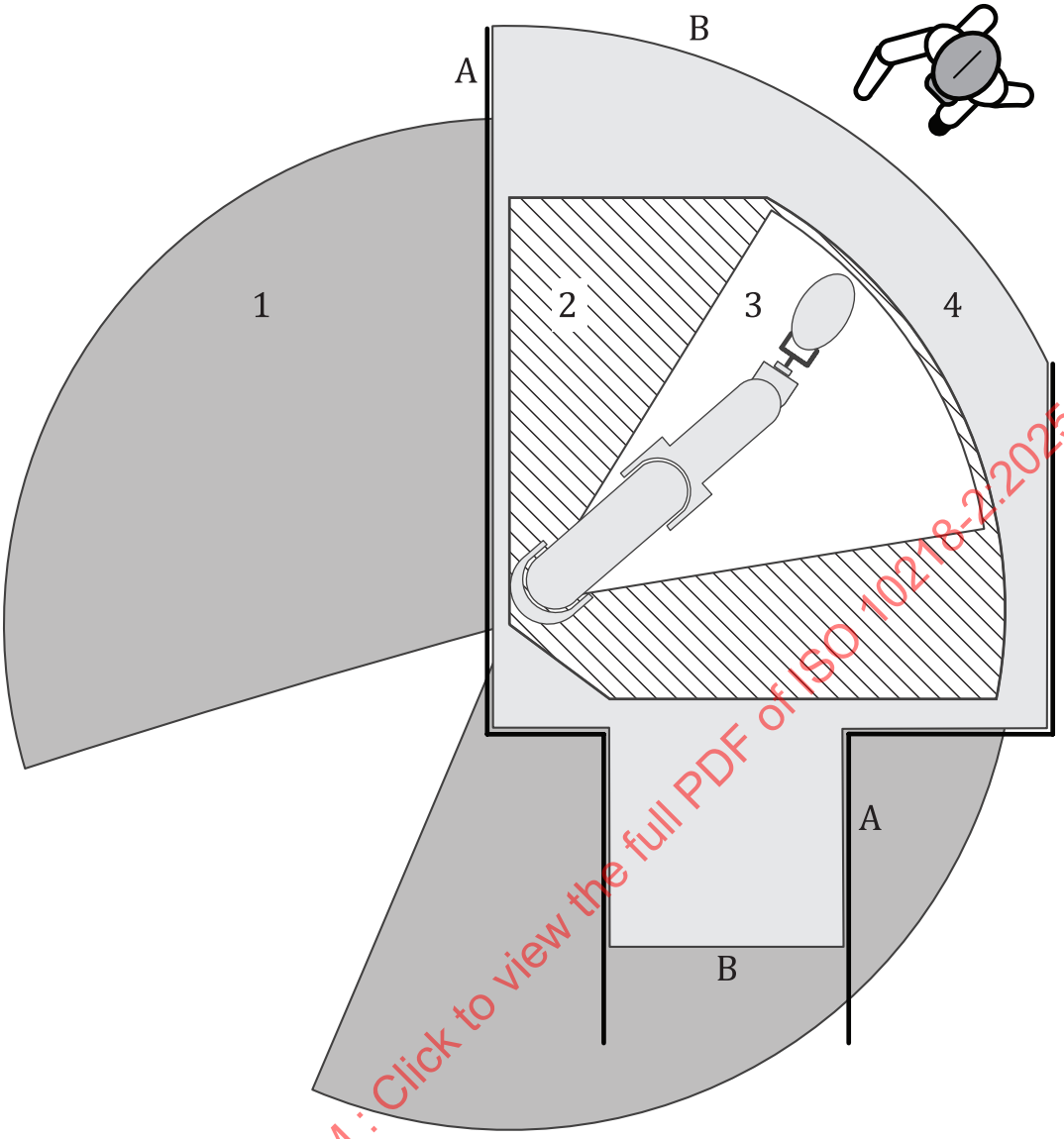
Figure B.4 — Spaces of the moving parts of a robot application

Figure B.5 shows the spaces associated with a robot application, which is an example of perimeter safeguarding used as a boundary of the safeguarded space. Figure B.5 does not show other parts of the application.

A safeguarded space can be implemented by combinations of guards and protective devices. The space between the restricted space and the guards illustrates distances for guard opening and/or clearance. Minimum distances for SPE, according to ISO 13855:2010, extend the safeguarded space beyond the restricted and maximum spaces to access to the hazard(s). Guards shown on the right side could be part of adjacent machinery.

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Key

1	maximum space	A	perimeter safeguarding as a part of the boundary of the safeguarded space (SPE not shown – see B)
2	restricted space	B	border of SPE detection zone (SPE not shown)
3	operating space		
4	safeguarded space		

Figure B.5 — Spaces of a robot application (includes end-effector and workpiece) with safeguards

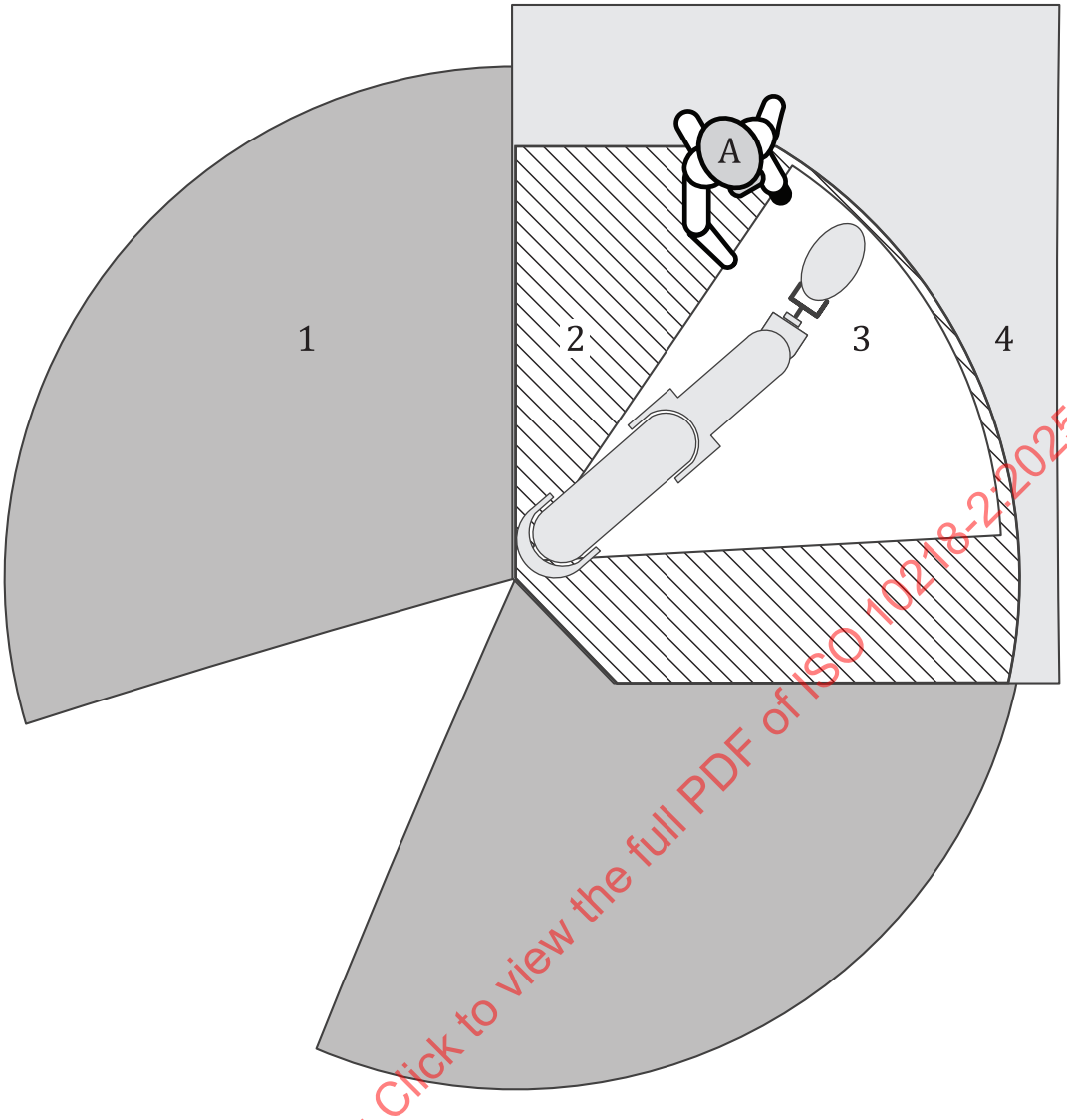
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Figure B.6 shows the spaces associated with a robot application, which is an example of a collaborative application where contacts from the moving parts of the robot application to the operator can occur inside the restricted space. In Figure B.6, the safeguarded space is greater than the restricted space due to the separation distance required by the protective devices (e.g. limiting devices, SPE) for either:

— intrusion detection and stopping.; or

— reduction of speed (i.e. speed limiting safety function according to 5.5) and possibly for another safety function to become effective, so that contact events will be within acceptable biomechanical limits.

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Key

1	maximum space	4	safeguarded space
2	restricted space	A	operator in a collaborative application where contact is permitted
3	operating space		

NOTE An operator (A) is shown, inside the safeguarded space and the restricted space, approaching the end-effector and workpiece. See Annex M for guidance on threshold limits.

Figure B.6 — Spaces of a robot application depicting a PFL collaborative application where contact from the robot application to the operator is permitted

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Annex C
(normative)

Safety function performance requirements

C.1 Determining safety function performance level

Table C.1 describes safety functions in terms of the triggering event and the intended result. The listed safety functions may be provided with the robot, the integration of the robot application/ robot cell, or a combination.

For functional safety requirements (e.g. PL and architecture, SIL and hardware fault tolerance), see 5.5.3.

NOTE There can be some exceptional cases with application risks requiring PLe or SIL 3 safety functions.

Table C.1 — Safety functions

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.2.8	**Conditional**	**position holding monitoring**	Robot application exceeds movement tolerance after drive power is removed while the robot application is stopped	After power is restored, the robot application does not move until there is a deliberate manual action to reset or acknowledge	**PL d or SIL 2**
5.2.9	**Conditional**	**position holding monitoring of additional axis**	Additional axis exceeds movement tolerance after drive power is removed while the axis is stopped	After power is restored, the auxiliary axis does not move until there is a deliberate manual action to reset or acknowledge	**PL d or SIL 2**
5.2.9	**Conditional**	**additional axis (axes) speed monitoring**	Exceed the speed limit	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Continuous monitoring until reaching the point where a reaction is initiated so that the configured limit will not be exceeded	— Prevent exceeding the limit by slowing or stopping (protective stop) before the limit is exceeded	
5.4.7.3	**Conditional**	**axis limiting**	Exceed the limit	Protective stop (5.6.3). A reset is required if the protective stop is a stop category 2 according to IEC 60204-1:2016+AMD1:2021.	**PL d or SIL 2**
			Reach the point where a stop is initiated so that the limit will not be exceeded	Protective stop (5.6.3)	
5.4.7.3	**Conditional**	**non-mechanical axis limiting** *including software-based limiting*	Exceed the limit	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Ensure that the limit will not be exceeded (e.g. decrease speed, initiate a stop)	— Prevent exceeding the limit by slowing or stopping (protective stop)	

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.4.7.4	**Optional** *switching of axis limiting (5.4.7.3) settings*	**dynamic limiting**	Safety-related input to switch active axis limit(s) (5.4.7.3)	— Axis limiting according to 5.4.7.3 — Only 1 set of axis limits shall be active at a time	**PL d or SIL 2**
5.5.6.1	**Mandatory**	**reduced-speed**	Activating manual mode	— Speed shall be limited to the reduced-speed parameter for the application, which shall be no greater than 250 mm/s	**PL d or SIL 2**
5.5.6.2 5.9.4 **d)**	**Optional** **Mandatory** for Hand-guided robot applications (5.14.4)	**monitored-speed**	Exceed the configured limit	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Continuous monitoring until reaching the point where a stop shall be initiated so that the configured limit will not be exceeded	— Prevent exceeding the limit by slowing or stopping (protective stop) before the limit is exceeded	
5.5.7.1	**Mandatory**	**Start/restart interlock**	When in manual mode, the power is interrupted and restored	— Movements, operation and potentially hazardous functions are prevented — This condition is maintained until a specific local control device is actuated	**PL d or SIL 2**
			After change in mode or when in manual mode after a protective stop is initiated by any enabled protective function	— Movements, operation and potentially hazardous functions are prevented; and — this condition is maintained until a specific local control device is actuated	
5.5.7.2	**Mandatory**	**reset**	Stop that requires a reset, initiated by a safeguard or safety function	— Operation can resume after a separate deliberate action	**PL b or SIL 1**

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.5.8	**Conditional Mandatory** for Monitored position (5.2.8), Simultaneous motion (5.7.9), Hand-guided robot applications (5.14.4), Hold-to-run (5.14.4), Power and force limiting (5.14.6)	**monitored-standstill**	Internal safety function triggers OR Actuation of a protective device that is connected to the protective stop input	— Position is monitored and maintained; and — Stop category 0 or 1 (5.5.4) if position changes. The monitored standstill output indicates that the robot application standstill is maintained	**PL d or SIL 2**
5.6.2	**Mandatory**	**emergency stop**	Manual actuation of an emergency stop device	— Cease all hazardous machine functions	**PL c or SIL 1**
5.6.3	**Mandatory**	**protective stop**	Actuation of a related protective device (e.g. body passes through ESPE, opening an interlocked guard, enabling device)	— Cease all hazardous machine functions intended to be controlled by the protective device	**PL d or SIL 2**
5.6.4	**Mandatory**	**normal stop**	Manual actuation of a normal stop device	— Stop motion and hazardous functions. — Remove energy sources to all hazards.	**PL b or SIL 1**
5.7.2.3.2	**Mandatory**	**manual mode, reduced-speed**	Change of active mode to manual mode with reduced-speed	— Initiation of a protective stop; — Disable automatic mode and remote control; — Activation of reduced-speed and the enabling function; — Disable manual high-speed mode; — Activation of the appropriate safety functions	**PL d or SIL 2**

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.7.2.3.3	**Optional**	**manual mode, high-speed**	Change of active mode to manual mode with high-speed	— Initiation of a protective stop; — Disable automatic mode and remote control; — Activation of monitored-speed and the enabling function; — Disable manual reduced-speed mode; — Activation of the appropriate safety functions	**PL d or SIL 2**
5.7.2.5	**Conditional Mandatory** if there is a change in active risk reduction with mode activation	**mode activation**	Activation of the selected mode	— Protective stop; — Activation of the selected mode and its safety functions appropriate for each mode. — Separate action required for resuming operation (manual or automatic)	**PL d or SIL 2**
5.7.5	**Conditional**	**single-point-of-control**	Selection of active point of control	— Shall respond only to the active point of control	**PL a**
5.7.7	**Conditional**	**enabling function**	In manual mode, releasing/compression of the enabling device from the centre position	— Protective stop	**PL d or SIL 2**
5.7.9	**Conditional Mandatory** for simultaneous motion	**simultaneous motion – restriction of robot selection**	Selection of robots to be under simultaneous motion	— Only robots in the same mode can be selected for simultaneous motion	**PL d or SIL 2**
5.7.9	**Conditional Mandatory** for simultaneous motion	**restriction of non-selected robot(s) motion**	Selection of robots to be under simultaneous motion	— Any robot not selected shall be either powered off or in a monitored-standstill	**PL d or SIL 2**
5.9.1 d)	**Conditional**	**end-effector position [c]**	Robot pose/ end-effector position is not in the correct position for the intended operation of the end-effector (e.g. open, close, on, off)	— Prevent the intended operation of the end-effector (e.g. open, close, on, off)	**PL c or SIL 1**

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.9.1 d) 5.9.4 c)	Optional	end-effector gripping force [c]	Gripping force is outside of set parameter(s)	— Protective stop (e.g. low gripping force could result in loss of workpiece); and/or — Reverse of the closing movement (e.g. when high gripping force could result in injury)	PL c or SIL 1
5.9.1 j) 5.9.6	Optional	release of detachable tool monitoring [c]	Detachable tool not in designated location/ condition	— Prevent release of detachable tool	PL c or SIL1
5.9.4 a)	Optional	end-effector force sensing [c]	Applied force is outside of set parameters for the end-effector	**One of the following:** — Protective stop requiring a reset (5.5.7.2); — Stop category 0 or 1 (5.5.4)	PL c or SIL 1
5.9.4 b)	Optional	end-effector orientation monitoring [c]	End-effector pose/ position is not in intended orientation	— Prevent the intended operation of the end-effector	PL c or SIL 1
5.9.4 b)	Optional	orientation limiting [c]	activate (by inputs or internally triggered) orientation limiting safety function	— Restrict orientation of the end-effector or wrist	PL c or SIL 1
5.9.4 e)	Optional	end-effector presence sensing [c]	Person is contacted or within a detection zone around the end-effector	— Protective stop, reset could be required (5.5.7.2)	PL c or SIL 1
5.9.6	Conditional	correct end-effector selected [c]	Connection of incorrect end-effector	— Protective stop requiring a reset (5.5.7.2)	PL c or SIL 1
5.10.2	Conditional	carrier guard interlocking	Opening the guard(s); Unlocking the guard(s)	— Prevent carrier movement	PL d or SIL 2
5.10.2	Conditional	carrier movement interlocking	Movement of the carrier	— Prevent unlocking of the guard(s)	PL d or SIL 2
5.10.4	Conditional	carrier intended stop position monitoring	Carrier stops at unintended position	— Movement of carrier only by use of hold-to-run control device to get to the intended position	PL d or SIL 2
5.14.4.1 e)	Conditional Mandatory for Hand-guided robot applications (5.14.4)	hold-to-run	Release of the hold-to-run device	— Monitored standstill, unless PFL or SSM provide acceptable risk reduction	PL c or SIL 1

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
5.4.7 5.14.5.2	**Conditional Mandatory** for SSM applications that depend on limiting the range of motion	**software-based limiting**	Exceed the limit.	Stop category 0 or 1 OR Protective stop (5.4.3). A reset is required if the protective stop is a stop category 2 according to IEC 60204-1:2016+AMD1:2021.	**PL d or SIL 2**
			Monitor to ensure that the limit will not be exceeded (e.g. decrease speed, initiate a stop)	Prevent the robot application from exceeding the set limit. A stop can be initiated so that the limit will not be exceeded.	
5.14.5	**Conditional Mandatory** for SSM robot applications	**speed and separation monitoring (SSM)**	Distance between any human relative to moving parts lessens to the separation distance	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Monitors the relative distances and maintains the separation distance	**One or more of the following:** — Change robot application speed (e.g. down to speed zero — Change pose(s) and/or trajectory of the robot application to maintain the minimum separation distance; — Initiate a protective stop such that the separation distance is maintained	
5.14.6	**Conditional Mandatory** for PFL applications	**power and force limiting (PFL)**	Force exceeds limit(s) set for contact events	Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Monitors to prevent exceeding limit(s)	**One or more of the following:** — Protective Stop. — Stop the robot system, move to a position where the limit is not exceeded, then initiate a monitored-standstill. — Stop the robot system, hold position, then robot automatically goes into a force and torque-free state	
5.2.8, Annex O, O.7.1	Optional	**monitored position**	Robot and/or other robot application components reach configured position	— Enable safety outputs (signals configured position reached); — Monitored-standstill initiated.	**PL d or SIL 2**

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Table C.1 *(continued)*

Clause	Mandatory, conditional or optional [a]	Safety function name	Possible triggering event	Intended result *unless "OR" is stated within a given group, ALL are required*	default functional safety PL_r or required SIL
7.5.16.3, Annex L, L.2, Annex O, O.7.2	Optional	**stopping time limiting**	Exceed the limit	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Monitor to ensure that the limit will not be exceeded (e.g. decrease speed, initiate a stop)	— Prevent exceeding the limit by slowing or stopping (protective stop) such that the limit is not exceeded	
7.5.16.3, Annex L, L.2, Annex O, O.7.2	Optional	**stopping distance limiting**	Exceed the limit	— Stop category 0 or 1 (5.5.4)	**PL d or SIL 2**
			Monitor to ensure that the limit will not be exceeded (e.g. decrease speed, initiate a stop)	— Prevent exceeding the limit by slowing or stopping (protective stop) such that the limit is not exceeded	

[a] Mandatory: shall be provided
Conditional: shall be provided if certain conditions are met.
Optional: not required and can be provided as an option.

C.2 Parameters

When performing a comprehensive risk assessment according to Clause 4, the applicable risk parameters in C.2.1 should be used in the risk estimation.

Since not all risk parameters and thresholds in C.2.1 apply to all risk estimation methodologies, the integrator should only use those parameters and thresholds that apply to the methodology used.

C.2.1 General

C.2.1.1 Elements of risk

According to ISO 12100:2010, the risk associated with a particular hazardous situation depends on the following:

a) severity of harm;

b) probability of occurrence of that harm, which is a function of:

   1) Exposure: The exposure of person(s) to the hazard;

   2) Probability: The likelihood of occurrence of a hazardous event;

   3) Avoidance: The technical and human possibilities to avoid or limit the harm.

For the application of this annex, the parameters and ranges should be considered for each identified hazardous situation or hazardous event

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C.2.1.2 Severity of the harm

C.2.1.2.1 Ranges for the estimation of the severity of the harm

S1 MINOR: Negligible injury which does not require any treatment or only treatment that is limited to simple and normally available first aid methods and equipment and not necessarily with the help of trained personnel.

S2 MODERATE: Injuries which can be treated on-site using first aid equipment only with the help of trained personnel.

S3 SERIOUS: Injuries which require treatment by a medical practitioner but do not lead to permanent impairment or injuries which lead to the loss or permanent damage of parts of the human body (but not total loss) with reversible medical condition.

S4 CATASTROPHIC: Injuries which lead to the

- death of one or more persons; or
- injuries which require treatment by a medical practitioner in a hospital and can lead to at least one of the following:
  - a permanent impairment;
  - loss of parts of the body, limbs, or senses/abilities;
  - significant disfiguring injury to the face.

NOTE It is possible to combine severity ranges into 2 or 3 ranges for methodologies that only use 2 or 3 levels of severity.

C.2.1.2.2 Parameters for injury severity

Table C.2 shows the parameters that should be applied for the estimation of injury severity.

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Table C.2 — Examples for determining severity parameters

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
Mechanical	**Lacerations or Amputations**** [44], [38] Amputation force is derived from literature search that identified, when using an 80 mm diameter load cell, pain and fracture thresholds at — 150 N; — 400 N; — 2 000 N	Minor/superficial cuts requiring bandaging treatment; typically caused by: — stationary blunt surfaces; — blunt edges with loads less than 28 kPa.	Lacerations not requiring sutures or other closure in lieu of sutures, typically caused by the following: — stationary sharp edges; — blunt, sharp edges.	Lacerations requiring sutures or other closure in lieu of sutures or partial blindness typically caused by: — flying projectiles; — stationary sharp edges; — blunt, sharp edges. Amputation of finger(s) or toe(s) not leading to impaired hand use or impaired walking abilities (disabling injury), typically caused by: — sharp edges mechanically in motion (e.g. rotating, reciprocating, shearing); — offset, blunt edges with loads exceeding 28 kPa.	Lacerations or amputation that could result in death or permanently disabling injury such as blindness. E.g. amputation of hands, feet, arms, legs, or loss of eyes

Δ, * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
Mechanical *continued*	**Fractures** [44],[38] Fracture force is derived from literature search that identified, when using an 80 mm diameter load cell, pain and fracture thresholds at — 150 N; — 400 N; — 2 000 N	Contusions and skin abrasions: — no physical signs are typically caused by loads less than 83 kPa — physical signs of contusions and skin abrasions typically caused by loads between 83 kPa and 297 kPa.	Fracture of small bones*, typically caused by loads between 297 kPa and 399,9 kPa. * For example: — extremities (finger, toe, hand, foot) — single rib bone — nose — tooth	Fracture of long bones in arms, legs or fracture of the skull or spine*, typically caused by loads exceeding 297 kPa and 399,9 kPa and not leading to permanent disabling injury, e.g. tetraplegia. *For example:	Fracture of long bones in arms, legs or fracture of the skull or spine*, typically caused by loads exceeding 399,9 kPa and could result in death or permanently disabling injury, e.g. tetraplegia. * For example, fracture of spinal column.

Δ,* BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
				— wrist — arm — sternum — jaw — bones around the eye — ankle — leg (femur and lower leg) — leg (femur and lower leg) — hip — thigh — skull — spine (minor compression fracture) — larynx (no collapsing) — multiple rib fractures — blood or air in chest	

Δ, * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
Mechanical *continued*	**Crushing** [44]	Temporary deformation of small body parts (e.g. ears, nose) without impairing effect	Temporary deformation of other* body parts **without** impairing effect *For example: — extremities (fingers, toe, hand, foot) — elbow — ankle — wrist — forearm — leg — shoulder — trachea — larynx — pelvis	Permanent deformation of small body parts or other body parts* **with** impairing effect. *For example: — extremities (fingers, toe, hand, foot) — elbow — ankle — wrist — forearm — leg — shoulder — trachea — larynx — pelvis	Permanent deformation of critical body parts* **with** impairing effect or death. *For example: — spinal cord — mid-low neck — chest (massive crushing) — brain stem
	Bruising (abrasion, contusion, swelling, edema) [44], [38]	Contusions and skin abrasions:	Abrasions of larger surfaces (not superficial):	Bruising of internal organs:	Bruising of the

Δ, * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
		— **no** physical signs: typically caused by loads less than 83 kPa (12 psi) — physical signs, superficial: ≤ 25 cm^2 on face; ≤ 50 cm^2 on body. Typically caused by loads between 83 kPa (12 psi) and 297 kPa (43 psi).	> 25 cm^2 on face; > 50 cm^2 on body.	— any bruising of the following organs: — trachea; — heart; — brain; — lung with blood or air in chest (pneumothorax); — minor bruising of other internal organs.	— brain stem — spinal cord causing paralysis
Mechanical *continued*	**Dislocation** [44]	Not applicable	— extremities (finger, toe, hand, foot); — elbow; — loosening of a single tooth.	— ankle; — wrist; — shoulder; — hip; — knee; — jaw; — spine if no injury to the spinal cord and to the nerves.	— Spine; — spinal column,

Δ, * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
	Piercing, puncturing [44]	Limited depth, only skin involved	— deeper than skin; — abdominal wall (no organ involvement).	— eye (with no permanent loss of sight); — involvement of internal organs; — chest wall.	— aorta; — heart; — bronchial tube; — deep injuries in organs, e.g. liver, kidney, bowel.
	Entrapment/pinching [44]	Minor pinching	Use the final outcomes of bruising, crushing, fracture, dislocation, amputation, as applicable.		— fatal suffocation; — strangulation
	Concussion [44]	Not applicable	Person does not lose consciousness	Person loses consciousness	Coma
	Sprain, strain, musculoskeletal disorder [44]	— extremities — joints; — spine (no dislocation or fracture).	Knee ligaments strain	— ligament or tendon rupture or tear * — muscle tear * — whiplash ** If not leading to permanent functional losses*	If leading to permanent significant functional losses: — ligament or tendon rupture or tear; — muscle tear; — whiplash.
Mechanical, specific	**Eye injury, foreign body in eye** [44]	Temporary pain in eye without need for treatment	Temporary loss of sight	Partial loss of sight	Permanent loss of sight (one or both eyes)
	Hearing injury, foreign body in ear [44]	Temporary pain in ear without need for treatment	Temporary impairment of hearing	Partial loss of hearing	Complete loss of hearing (one or both ears)

Δ, * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
Electrical	**Electrical shock affecting the human body** Parameters include: — current and voltage, resistance; — path through the body; — duration of contact; — individual's health; — promptness of first aid.	No physical signs but threshold of feeling; — discomfort or tingling sensation can be felt at 1 – 2 mA.	Pain or awareness of electrical shock — painful shock at 3 mA; — muscle contractions at 5 mA; — person can let go at an average of 10 mA.	Breathing issues, loss of consciousness, or minor burns — breathing difficulties / unconsciousness at 30 mA; — severe burns[Δ] and muscle contractions can occur at range of 200 mA to 300 mA.	Serious impairment or stopping of breathing or heart, major burns, or death — heart fibrillation can occur at range of 50 mA to 100 mA (fatal if continued); — major burns[Δ] and irreversible body damage at several amps; — death with prolonged exposure at less than 1 A.
Thermal[Δ]	**Burns[Δ] by contact with hot surfaces *** (The severity of injury is relative to the following: — amount of body surface area; — duration of exposure; — temperature of the hot surface; — thermal conductivity	1st degree burns[Δ] up to 100 % of body surface, typically caused by temperatures ranging from 44 °C to 59 °C, with exposure durations of 1 s. 2nd degree burns[Δ] up to 6 % of body surface, typically caused by temperatures ranging from 60 °C to 68 °C, with exposure durations of 1 s.	2nd degree burns[Δ] of 6-15 % of body surface, typically caused by temperatures ranging from 60 °C to 68 °C, with exposure durations of 1 s.	2nd degree burns[Δ] of 16-35 % of body surface, typically caused by temperatures ranging from 60 °C to 68 °C, with exposure durations of 1 s. 3rd degree burns[Δ] of body surface up to 35 % of the body surface, typically caused by temperatures greater than 68 °C with exposure durations of 1 s. Inhalation burn	2nd or 3rd degree burns[Δ] on over 35 % of the body surface, typically caused by temperatures ranging from 60 °C to 68 °C for 2nd degree and greater than 68 °C for 3rd degree, with exposure durations of 1 s. Inhalation burn requiring respiratory assistance.

[Δ], * BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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Table C.2 *(continued)*

Injury severity parameters and ranges					
Hazard Type	**Injury Type**	**Minor (S1)**	**Moderate (S2)**	**Serious (S3)**	**Catastrophic (S4)**
	ISO 13732-1:2006 provides guidance about injuries due to contact with hot surfaces. ISO 13732-3:2005 provides guidance about injuries due to contact with cold surfaces.				
	Burn$^{\Delta}$ by contact with vapours or splash of viscous material Vapor exposure assumes instantaneous contact; viscous materials assume continuous contact greater than 1 s.	1st degree burns$^{\Delta}$; typically caused by temperatures ranging from 38 °C to 43 °C.	2nd degree burns$^{\Delta}$; typically caused by temperatures ranging from 44 °C to 59 °C.	3rd degree burns$^{\Delta}$ on skin surface areas less than 1 % of the body: — 3rd degree burns$^{\Delta}$ typically caused by temperatures greater than 60 °C; — inhalation burns$^{\Delta}$.	3rd degree burns$^{\Delta}$ on skin surface areas on 1 % or more of the body e.g. palm of hand: 3rd degree burnsΔ typically caused by temperatures greater than 60 °C inhalation burnsΔ requiring respiratory assistance.
Vibration	For hand-guided control (HGC), according to ISO 20643:2005.				
Ergonomics	According to the ISO 15534:2000 series. ***				
Hazards of the environment	Excluded				
Combination of hazards	Can only consider combinations of hazards that are included in the scope of this document. The severity of combinations of hazards should be considered using the ranges for each individual hazard.				

$^{\Delta, *}$ BURNS: Contact with a hot surface is based upon contact with aluminium less than 1 s. Temperature threshold will vary dependent upon the material contacted and the duration of contact.

See ISO 13732-1:2006 for data on burn thresholds of contact with other materials and for methods of assessment of human responses to contact with hot surfaces.

See ISO 13732-3:2005 for methods of assessment of human responses to contact with cold surfaces.

** FORCES: Fracture and amputation force are derived from literature search that identified pain and fracture thresholds at 150 N, 400 N, and 2 000 N using an 80 mm (3.15 in) diameter load cell.

*** ERGONOMICS: See ISO/TR 22100-3:2016 for guidance on implementation of ergonomic principles.

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C.2.1.3 Exposure to hazard

C.2.1.3.1 Determination of range of exposure

One of the two following methods should be used to determine the exposure to the hazard:

a) Where the exposure is determined by estimation without frequency and duration exposure parameters, according to C.2.1.3.2; or

b) When considering frequency and duration exposure parameters, use either:

— Range determination according to C.2.1.3.3 (Table C.3); or

— Range determination for risk estimation methods without exposure parameters according to C.2.1.3.4.

C.2.1.3.2 Ranges of the exposure to hazard

The exposure to the hazard results from the combination of the frequency, the duration of the exposure to the hazard and the number of persons which can be affected. The following ranges should be applied

— **E1** LOW The exposure is seldom and the accumulated duration is short (< 1/20 of the total operational time)

— **E2** HIGH The exposure is often, or the accumulated duration is long

C.2.1.3.3 Type of interaction and exposure parameters

Where the risk estimation method uses parameters for the determination of the Exposure, Table C.3 should be applied for the intended interaction of the operator(s).

— **Group A** Occasional, not cyclic or regular interaction.

— **Group B** Cyclic interaction while the machine is operating (e.g. for loading or unloading), or regular interaction (e.g. cleaning, tool changing, etc.) but while the machine is not operating.

— **Group C** Constant interaction required during machine operation.

Table C.3 — Examples for determining exposure parameters

Element of risk according to ISO 12100:2010	Parameter	Application Group A: seldom interaction	Application Group B: cyclic interaction	Application Group C: constant interaction	Range
Exposure	Frequency	$F \leq \frac{2}{48\,\text{h}}$	$\frac{2}{48\,\text{h}} < F < \frac{2}{8\,\text{h}}$	Not applicable	**Low**
		Refer to Group B →	$\frac{2}{8\,\text{h}} \leq F < \frac{20}{8\,\text{h}}$	Not applicable	**Medium**
		Refer to Group B →	$\frac{20}{8\,\text{h}} \leq F$	$\frac{20}{8\,\text{h}} \leq F$	**High**
	Duration[1]	Maximum 1 h total per week	$T < 1$ min	Not applicable	**Short**
		Refer to Group B →	1 min $\leq T < 3$ min	Not applicable	**Medium**
		Refer to Group B →	$T \geq 3$ min	$T \geq 3$ min	**Long**

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Table C.3 *(continued)*

Element of risk according to ISO 12100:2010	Parameter	Application Group A: seldom interaction	Application Group B: cyclic interaction	Application Group C: constant interaction	Range
	Number of persons exposed	Certain persons are exposed but are not related to any specific task			**Some**
		One person exposed			**One**
		More than one person exposed			**More than 1**

C.2.1.3.4 Range determination for risk estimation methods without exposure parameters

Where the risk estimation method applied does not consider separately the frequency and duration of the exposure as well as the number of persons exposed, Formula C.1 may be applied:

$$E = F \times D \times N_r \quad \text{(C.1)}$$

where

E is the resulting exposure value in min/48 h

F is the frequency of the number of exposures in a 48 h period

D is the duration of each single exposure (in minutes)

N_r is a factor for the number of persons exposed:

$N_r = N \times 0{,}2$ where N-persons are exposed but are not related to any specific task;

$N_r = 1$ where one person is exposed to the hazard;

$N_r = N$ where N-persons are exposed.

For the following values, the exposure should be considered as high (**E2**):

$E > 144$ min/48 h; or

$F > 4$/h.

Otherwise, the exposure may be considered as low (**E1**).

NOTE According to ISO 13849-1:2023, Annex A, A.3.2: 144 m per 48 h corresponds to 1/20 of the operational time, for a maximum of 48 h (8 h shifts in 6 days).

C.2.1.3.5 Probability of occurrence

C.2.1.3.5.1 Ranges of the probability of occurrence

The probability of occurrence can be due to, but not limited to the following:

— machine malfunctions (including the control system);

— jams;

— properties of the processed materials; or

— inappropriate human behaviour.

For the probability of occurrence, the following ranges should be applied;

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O1 LOW: Hazardous events, which lead to the assumed harm (injury), are seldom and are not foreseeable.

O2 MEDIUM: Hazardous events, which lead to the assumed harm (injury), are seldom, but foreseeable.

O3 HIGH: Hazardous events, which lead to the assumed harm (injury) are expected to occur.

C.2.1.3.5.2 Determination of range of probability of occurrence

The following parameters should be used in determining the probability of occurrence:

a) system robustness;

b) incident history; and

c) likelihood of assumed harm/damage occurring during the event.

Depending on the availability of accurate and statistically reliable data about parameters a) through c), the probability of occurrence is determined. The probability of the occurrence of a hazardous situation or a hazardous event may be estimated if reliable and confident data are available (see ISO 12100:2010, 5.5.2.3.2). Where the robot application risks comparison to those of similar machinery is possible according to ISO 12100:2010, 5.6.3, data of the similar machinery can be applied provided data are confident and reliable.

NOTE See ISO 12100:2010, 5.2 for further guidance about the reliability of data.

— When the applied risk estimation method considers parameters for probability of occurrence and accurate and statistically reliable data are available for all the parameters (system robustness, incident history and harm/damage likelihood), the probability of occurrence may be determined, according to C.2.1.3.3 (Table C.4);

— When the applied risk estimation method considers parameters for probability of occurrence and accurate and statistically reliable data is not available or not known for one (1) of the parameters (system robustness, incident history and harm/damage likelihood), the probability of occurrence should be determined according to C.2.1.3.5.3 (Table C.5);

— When accurate and statistically reliable data is not available or not known for more than one of the parameters (system robustness, incident history, and harm/damage likelihood), the probability of occurrence should be considered as High (O3).

C.2.1.3.5.3 Parameters for the probability of occurrence

The occurrence of a hazardous event influences the probability of occurrence of harm. The factors in Table C.4 should be used when estimating the occurrence of a hazardous event and there are confident and reliable data for the parameters. For the estimation of the probability of occurrence, Table C.4 and Table C.5 should be applied.

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Table C.4 — Examples for determining probability of occurrence parameters

Element of risk according to ISO 12100:2010	Parameter	Consideration of confident and reliable data	Range
Probability of Occurrence	**System robustness**	System availability > or = 95 % of the operation time	**Not prone to trouble**
		System availability <95 % of the operation time	**Prone to trouble**
	Incident history	Near 0 %	**No incident**
		<3 % of running systems	**Seldom any incidents**
		> or = 3 % of the running systems	**Several incidents**
	Harm / damage likelihood	≤ 3 %	**Seldom**
		>3 % to 70 %	**Possible**
		> or = 70 %	**Will Happen**

C.2.1.3.5.4 Range determination for risk estimation methods

Where the risk estimation method does not consider one of the parameters (system robustness (SR), incident history (IH) and harm/damage likelihood (DL)) or where no accurate and statistically reliable data are available for one or more of those, Table C.5 should be applied for the limitation of the range for the probability of occurrence.

Table C.5 — Limitation of the probability of occurrence for missing or unknown data for one (1) parameter

Limitation of probability of occurrence due to lack of confident and reliable data			
SR	**IH**	**DL**	**Lowest allowed probability of occurrence**
1	**1**	**1**	**O1** = Low
0	**1**	**1**	
1	**0**	**1**	**O2** = Medium
1	**1**	**0**	
1	**0**	**0**	
0	**1**	**0**	
0	**0**	**1**	**O3** = High
0	**0**	**0**	

KEY
SR System robustness
IH Incident history
DL Harm/ damage likelihood
0 = data unavailable or parameter unknown
1 = data available or parameter known

C.2.1.4 Possibility of avoidance (AP) or limiting of the harm

C.2.1.4.1 Ranges of the possibility of avoidance (AP) or limiting of the harm

For the possibility of avoidance, the following ranges should be applied;

— **A1** AVOIDABLE
The conditions that allow the avoidance of harm are almost always present, e.g. as skilled workers, very slow movements, infrequent intervention, low-complexity processes, and no sudden or unexpected movements with high acceleration.

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— **A2** REASONABLY AVOIDABLE
Some conditions that allow the avoidance of harm are present but not always, e.g. as skilled workers, slow movements, infrequent intervention, low-complexity processes, and no sudden or unexpected movements with high acceleration.

— **A3** NOT AVOIDABLE
The avoidance is nearly impossible due to the lack of indication or awareness of the hazardous situation, e.g. fast hazardous events, insufficient surrounding space for evasion, high complexity processes, and/or the effect of routine on hazard awareness.

C.2.1.4.2 Determination of range of avoidance or limiting of the harm

— When the applied risk estimation method considers operator skill / information (OS), the hazard perception (HP), and the possibility of avoidance (AP), the method according to C.2.1.4.3 (Table C.6) should be used to determine the range for the possibility of avoidance or limiting of the harm;

— When the applied risk estimation method does not consider operator skill / information (OS), the hazard perception (HP), or the possibility of avoidance (AP), the method according to C.2.1.4.4 (Table C.7) should be used to determine the range for the possibility of avoidance or limiting of the harm;

C.2.1.4.3 Range determination for methods considering harm avoidance parameters

The determination of the possibility to avoid the harm should consider the foreseen physical ability of the operator, the speed at which the hazard or the hazardous situation can appear, the surrounding space which can improve (or hinder) the avoidance of the harm, and other circumstances which depend on the specific robot application. For the estimation of the possibility of avoidance, Table C.6 should be applied:

Table C.6 — Examples for determining harm avoidance parameters

Element of risk according to ISO 12100:2010	Parameter	Consideration of confident and reliable data	Range
	Operator skill and information (OS)	Skilled persons who are informed about the risks associated with the task	**Skilled**
		Unskilled persons who are informed about the risks associated with the task	**Unskilled**
		No operator is required for the task(s). Exposed persons are unskilled or uninformed.	**Unmanned**
	Hazard perception (HP)	Warnings and signs available and hazards easy to perceive	**Easy**
		Warnings and signs NOT available BUT hazards are easy to recognize and perceive OR Warnings and signs available BUT hazards are difficult to perceive	**Possible**
		No warnings or signs available AND hazards are difficult to perceive	**Difficult**

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Table C.6 *(continued)*

Element of risk according to ISO 12100:2010	Parameter	Consideration of confident and reliable data	Range
Harm avoidance or limiting of harm	**Possibility of avoidance (AP)**	**Possibility to avoid by limiting:** — Movement speed(s) $< 150 \frac{mm}{s}$ and/or — Acceleration $< 150 \frac{mm}{s^2}$ (suddenness); Clearance for endangered body parts according to ISO 13854:2017 with a 1,5 multiplier	**Possible**
		Possibility to avoid by limiting: — Movement speed(s) $< 250 \frac{mm}{s}$ and/or — Acceleration $< 250 \frac{mm}{s^2}$ (suddenness); Clearance for endangered body parts according to ISO 13854:2017 with a 1,1 multiplier	**Almost Possible**
		Movement speed(s) $\geq 250 \frac{mm}{s}$ or Acceleration $\geq 250 \frac{mm}{s^2}$ (suddenness)	**Impossible**

NOTE See 5.5.1 about safety functions (e.g. acceleration limiting) that can be provided but that not detailed in this document.

C.2.1.4.4 Range determination for methods not considering harm avoidance parameters or where some parameters are unknown

Where the risk estimation method does not consider the operators skill and information (OS), the hazard perception (HP) or the possibility of avoidance (AP), Table C.7 should be applied for the limitation of the range.

Table C.7 — Limitation of the possibility of avoidance (AP) or limiting the harm for unknown parameters

Limitation of probability of occurrence due to lack of confident and reliable data			
Operator skills and information (OS)	**Hazard perception (HP)**	**Possibility to avoid (AP)**	**Avoidability**
1	**1**	**1**	**A1 = Avoidable**
1	**0**	**1**	
1	**1**	**0**	**A2 = Reasonably avoidable**
1	**0**	**0**	
0	**1**	**1**	
0	**0**	**1**	**A3 = Not avoidable**
0	**1**	**0**	
0	**0**	**0**	
0 = data unavailable or parameter unknown 1 = data available or parameter known			

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Annex D
(Informative)

Required safety function information

Safety function information shall be provided in accordance with 7.5.16. Table D.1 is an example format that can be used to present the information for each safety function. More information may be provided.

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Table D.1 — Safety function information example

Clause	Included in Checksum	Safety function name	Active in what mode(s)	Triggering event	Span-of-control	Intended result [b, c] *If applicable, include Stop Category and description*	Reset required [d]	Assumptions and conditions of use [e]	Diagnostic Coverage	Functional safety performance [a]		PFH	Response time(s), Test rate [f]
										PL and Category	SIL and HFT		
Example: 5.4.3	Yes In robot For cell, see cell PLC	Protective stop	only Automatic	internal safety function or external protective device	Robot, end-effector, CNC machine, conveyor	1) Robot stops (stop category 2). While stopping, trajectory is maintained. 2) After stopping, a monitored standstill occurs. 3) CNC and conveyors: Stop Category 1 with reset and restart required.	Yes, for the cell	1) external protective device fulfils same functional safety requirements 2) dual inputs	medium	PL d, Cat 3	----	1.20E-07 without external protective device	Time to stop depends on stopping time safety function setting

[a] In accordance with either ISO 13849-1:2023 or IEC 62061:2021

[b] Stop category according to IEC 60204-1:2016+AMD1:2021. If applicable, as described in IEC 61800-5-2:2016.

[c] For example, inhibit restart. See 5.3.4 for Failure or fault detection.

[d] Example: Where is the reset? Is the reset manual or automatic?

[e] Assumptions: N_{op}, shared outputs, fault exclusion, and any resulting installation requirements that lessen a fault...

Conditions of use: configuration parameters, maximum activation frequency, diagnostics tests...

[f] Describe applicable response time(s), test rate(s) or both.

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Annex E
(informative)

Example of determination of the PL_r or required SIL

E.1 General

Determination of the PL_r or required SIL of a safety function can be based on the results of the risk estimation process using the parameters and thresholds described in Annex C, C.2. For the application of the risk estimation parameters, different risk assessment processes use different terminology. Table E.1 shows a comparison (not an equivalency) of the terminology used in different risk estimation methodologies.

Table E.1 — Comparison of parameters for risk elements used in applicable standards and technical reports

Risk element according to ISO 12100:2010	Annex C	ISO 13849-1:2023, Annex A	IEC 62061:2021, Annex A	RIA TR R15.306:2016 risk estimation
Severity of harm	Severity of the harm S1, S2, S3, S4	Severity of injury S1, S2	Severity Se1, Se2, Se3, Se4	Severity of injury S1, S2, S3
Exposure of person(s) to the hazard	Exposure to hazard E1, E2	Frequency and/or exposure to hazard F1, F2	Frequency and duration Fr2, Fr3, Fr4, Fr5	Exposure to the hazard E0 (*Prevented)**, E1, E2 ** E0 (Prevented) is when exposure is eliminated, or exposure is controlled by the SRP/CS as the intended result of a safety function*
Occurrence of a hazardous event	Probability of occurrence O1, O2, O3	Not applicable *If comparing, use highest (O3 or Pr3)*	Probability of hazardous event Pr1, Pr2, Pr3, Pr4, Pr5	Not applicable *If comparing, use highest (O3 or Pr3)*
Possibility to avoid or limit the harm	Possibility of avoidance or limiting the harm A1, A2, A3	Possibility of avoiding hazard or limiting harm P1, P2	Avoidance Av1, Av3, Av5	Avoidance of the hazard A1, A2, A3

There are many methods and tools available for risk estimation and for the determination of the PL_r or required SIL. A few examples are shown in this Annex.

E.2 Examples

E.2.1 Example 1 – based on ISO 12100:2010

PL_r is estimated from a results of risk estimation described in Annex C, C.2, as shown in Table E.2 below.

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Table E.2 — PL_r assignment matrix

Severity	Exposure	Avoidance	Occurrence		
			O1	O2	O3
S1	E1	A1	a	a	a
		A2	a	a	a
		A3	a	a	a
	E2	A1	a	a	a
		A2	a	a	b
		A3	a	b	c
S2	E1	A1	a	a	a
		A2	a	a	b
		A3	a	b	c
	E2	A1	a	a	b
		A2	a	b	b
		A3	b	b	c
S3	E1	A1	b	c	c
		A2	c	c	c
		A3	c	c	d
	E2	A1	c	d	d
		A2	d	d	d
		A3	d	d	e
S4	E1	A1	d	d	d
		A2	d	d	d
		A3	d	d	e
	E2	A1	d	e	e
		A2	e	e	e
		A3	e	e	e
PL d and PL e: the architecture is according to 5.5.3					

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E.2.2 Example 2 – based on IEC 62061

The required SIL is estimated from the results of risk estimation using parameters and thresholds described in Annex C, C.2, as shown in Table E.3 and Table E.4 below.

Table E.3 — Parameters used to determine required SIL

Frequency and duration of exposure (Fr)		Probability of occurrence of hazardous event (Pr)		Probability of avoiding or limiting harm (Av)	
Fr >1 year	**2**	Negligible	**1**	Likely	**1**
2 weeks < Fr ≦ 1 year	**3**	Rarely	**2**	Possible	**3**
24 h < Fr ≦ 2 weeks	**4**	Possible	**3**	Impossible	**5**
1 h < Fr ≦ 24 h	**5**	Likely	**4**		
Fr ≦ 1 h	**5**	Very high	**5**		

The required SIL is calculated by Formula E.1:

$$\text{Required SIL} = (Fr+Pr+Av) \quad \text{(E.1)}$$

EXAMPLE With a Se (Severity) of 3, Fr of 4, Pr of 3 and Av of 5, then the Required SIL would be:

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Required SIL = Fr + Pr + Av = 4 + 5 + 5 = 12, which is SIL 2 according to E.4.

Table E.4 — Claim Limit (CL) to SIL assignment matrix

Consequences	Severity Se	Required SIL = (Fr+Pr+Av)				
		3~4	5~7	8~10	11~13	14~15
Reversible, first aid	1					SIL1
Reversible, medical attention	2				SIL1	SIL2
Permanent, losing fingers	3			SIL1	SIL2	SIL3
Death, losing an eye or arm	4	SIL2	SIL2	SIL2	SIL3	SIL3

E.2.3 Example 3 – based on RIA TR R15.306

When a safety function is used for risk reduction, RIA TR R15.306:2016 risk estimation methodology can be used to determine the PL_r.

Table E.5 — PL_r assignment matrix [a] for safety functions

Severity	Exposure	Avoidance	PL_r
S1	E1	A1	a
		A2	a
		A3	a
	E2	A1	a
		A2	b
		A3	c
S2	E1	A1	a
		A2	b
		A3	c
	E2	A1	b
		A2	b
		A3	c
S3	E1	A1	c
		A2	c
		A3	d
	E2	A1	d
		A2	d
		A3	e

[a] Applications that result in the need for PLe are likely due to non-robotic hazards.

Architecture is according to 5.5.3.

The derived PL_r is established by Annex C.2 estimation of Severity, Exposure and Avoidance. Results can be different from those found in RIA TR R15.306-2016.

When E0 is applicable, the risk is either negligible or low, thereby resulting in PL b as the PL_r

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Annex F
(informative)

Comparison of stop functions

Table F.1 — Comparison of the stop functions

Parameter	Emergency stop (5.6.2)	Protective Stop (5.6.3)		Stop due to safety-related control system failure detection (5.5.4)	Normal stop (5.6.4)
		Triggered by protective device (detection or absence) (5.8)	Risk reduction measure by limiting safety functions (Annex C and Annex O)		
Purpose	Emergency situation	Safeguarding	Limiting functions to reduce risks	To safely react to detected safety-related control system failures	Stopping, off
Effect	Cease machine functions in safe manner and remove energy	Safely control the safeguarded hazard(s)	Safely limit the machine performance thus generally reducing the severity of the potential injury and/or increasing the probability of avoidance	Cease machine functions in safe manner and remove energy	Bring safely to a complete stop including all machine functions and then cut off energy supply
Location of initiation means	Operator has quick unobstructed access	For protective devices, location is determined by the minimum distance formulae (ISO 13855) or the SSM minimum separation distance (5.14.5.3) as applicable	Internal to control system	Internal to control system	At each control station
Initiation	Manual activation of the emergency stop device	Manual, automatic or automatically initiated by safety-related I/O or safety function(s)	Automatically initiated by safety-related I/O or safety function	Automatic	Manual activation of the normal stop device
Stop category (IEC 60204-1:2016 +AMD1:2021)	0 or 1 *See also ISO 13850:2015*	0, 1 or 2	0, 1 or 2, 1 or 2 are typical Can vary with each limiting safety function	0 or 1	0 or 1
SRP/CS functional safety	5.5 and Annex C	5.5 and Annex C	5.5 and Annex C	5.5.4, 5.5 and Annex C	5.5 and Annex C

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Table F.1 *(continued)*

Parameter	Emergency stop (5.6.2)	Protective Stop (5.6.3)		Stop due to safety-related control system failure detection (5.5.4)	Normal stop (5.6.4)
		Triggered by protective device (detection or absence) (5.8)	Risk reduction measure by limiting safety functions (Annex C and Annex O)		
Reset	Manually disengaged	Manual or Automatic Can vary with each safety function that initiates a protective stop		Manual action	Not applicable
Restart	Separate manual actuation	Ensure no undetected presence in the hazard zone, otherwise additional intentional actions will be required	Can vary with each safety function	Separate manual actuation	Not applicable
Use frequency	Infrequent	Variable; from on-going (e.g. internal robot safety functions, safety functions of components of the application) to infrequent		Infrequent	Frequent
Prevent unexpected start-up	Yes	Yes	Yes	Yes	No

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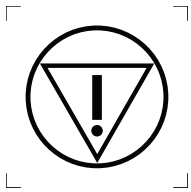
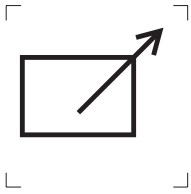
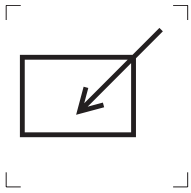
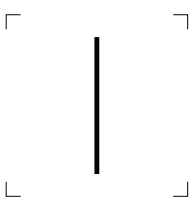
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Annex G
(informative)

Graphical symbols

Table G.1 provides guidance for graphical symbols. Additional text can be included.

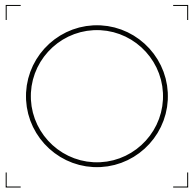
Table G.1 — Graphical symbols

Subclause	Description	Symbol	Reference
5.6.2 Figure P.1	**Emergency stop** To identify an emergency stop control device		**IEC 60417-0017** Emergency stop
5.7.2.2	**Automatic**		**ISO 7000-0017** Automatic control (closed loop)
5.7.2.3	**Manual**		**ISO 7000-0096** Manual control
5.7.6.3	**Remote control ON** **Activate** To identify the control for changing over to remote control		**ISO 7000-1108** Remote control, switch on Remote control, activate
5.7.6.2	**Remote control OFF** **Deactivate** **(Local control ON)** To identify the control for changing over to local control		**ISO 7000-1109** Remote control, switch off Remote control, deactivate
5.15.5	**Power ON** To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.		**ISO 7000-5007** “ON” (power)

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Table G.1 *(continued)*

Subclause	Description	Symbol	Reference
5.15.5	**Power OFF** To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.		**ISO 7000-5008** "OFF" (power)

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Annex H
(informative)

Means of verification and validation of the design and protective measures

Clause 5 specifies requirements that are essential to the safety of operators associated with the use of the robot applications and robot cells. Table H.1 lists the specific performance requirements that shall be verified or validated, or both, in accordance with Clause 6. Table H.1 lists methods for verification, validation or both of each listed requirement from Clause 5.

Verification and validation can be performed using one or more of the below methods in Table H.1. For each clause listed, there are possible methods (A through J), as shown by the X in each row. One or more of the methods are used per each requirement to achieve verification and validation. Multiple methods could be required. For a requirement, the acceptable method for validation may be different than the method for verification.

Table H.1 — Means of verification and validation of the design and protective measures in Clause 5

Clause	Applicable design requirements and/or protective measures	Verification and/or validation methods **A** visual inspection **B** practical tests **C** measurement **D** observation during operation **E** review of application specific schematics, circuit diagrams and design material **F** review of safety-related application software and/ or software documentation **G** review of task-based risk assessment **H** review of layout drawings and documents **I** review of specifications and information for use **J** review of robotic application process simulation models, virtual commissioning tools									
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5	**Design and protective measures**										
5.1	**General**										
5.1	Robot applications and robot cells are designed according to ISO 12100:2010 for relevant but not significant hazards which are not dealt with by this document.							X			
5.1	Robots applied in robot applications conforms with the requirements of ISO 10218-1:2025.								X		
5.2	**Design**										
5.2.1	Design is based on the information for use provided with the robot, end-effector and the associated machinery and equipment.									X	
5.2.1	The design conforms with the requirements described in 5.2.2 through 5.2.16.					X					
5.2.2.1	Robot applications and robot cells are designed and constructed so failures do not lead to a hazardous situation due to fatigue or wear.		X	X		X			X	X	
5.2.2.1	Design and manufacturing take into account the lifecycle of the intended use.					X			X	X	
5.2.2.1	The design and construction take into account the constraints to which the operator is subject as a result of the use of personal protective equipment for the intended application.		X			X			X	X	

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Table H.1 *(continued)*

Clause	Applicable design requirements and/or protective measures	Verification and/or validation methods **A** visual inspection **B** practical tests **C** measurement **D** observation during operation **E** review of application specific schematics, circuit diagrams and design material **F** review of safety-related application software and/ or software documentation **G** review of task-based risk assessment **H** review of layout drawings and documents **I** review of specifications and information for use **J** review of robotic application process simulation models, virtual commissioning tools									
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.2.2.2	Selected materials are appropriate for the intended use (e.g. resistance to corrosion, abrasion, impacts, fatigue, deformation, ageing).		X	X		X				X	
5.2.2.2	Materials do not endanger persons' safety or health.		X	X		X				X	
5.2.2.2	Materials are non-toxic in all reasonably foreseeable conditions of use.					X				X	
5.2.2.2	Materials are not prone to brittle fracture, excessive deformation, or emission of toxic or flammable fumes.		X	X		X				X	
5.2.2.2	Materials retain their properties in the reasonably foreseeable range of climatic and workplace conditions, including temperature variations or sudden changes.		X	X		X				X	
5.2.2.2	Where fluids are used, the design and construction address risks due to filling, use, recovery, or draining.	X	X	X		X				X	
5.2.2.3	The parts of the robot application are designed and constructed to withstand the loads expected for the intended application and the expected operating conditions.		X	X		X				X	
5.2.2.3	The parts of the robot application involved in lifting operations are designed and constructed to withstand an overload in static tests without permanent deformation or patent defect, where strength calculations have a minimum static test coefficient of 1,25.	X	X	X						X	X
5.2.2.3	The parts of the robot application involved in lifting operations are designed and constructed to undergo, without failure, dynamic tests using the maximum payload multiplied by the dynamic test coefficient, where the dynamic test coefficient is at least 1,1.	X	X	X						X	X
5.2.2.3	Dynamic tests are performed at maximum speeds.									X	
5.2.2.3	If simultaneous movements can be programmed, the tests are done using the least favourable conditions.			X			X		X		X
5.2.2.3	Where complete ropes are used for lifting functions, the ropes and their endings have a minimum working coefficient of 5.		X	X						X	
5.2.2.3	Where chains are used for lifting functions, they have a minimum working coefficient of 4.		X	X						X	
5.2.2.4	The parts of the robot application are designed and constructed such that any exposed sharp edges and sharp corners that are unnecessary for the robot application are eliminated.	X		X				X		X	
5.2.2.4	The parts of the robot application are designed and constructed such that any hazardous projections that are unnecessary for the robot application are eliminated.	X		X				X		X	
5.2.2.4	The parts of the robot application are designed and constructed such that any exposed sharp edges and sharp corners that are necessary for the robot application are reduced as far as reasonably practicable.	X		X				X		X	
5.2.2.4	Hazardous mechanisms that enable motion are installed or mounted such that they are normally inaccessible.	X	X	X					X		X

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Table H.1 *(continued)*

Clause	Applicable design requirements and/or protective measures	Verification and/or validation methods **A** visual inspection **B** practical tests **C** measurement **D** observation during operation **E** review of application specific schematics, circuit diagrams and design material **F** review of safety-related application software and/ or software documentation **G** review of task-based risk assessment **H** review of layout drawings and documents **I** review of specifications and information for use **J** review of robotic application process simulation models, virtual commissioning tools									
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.2.2.4	Exposure to hazards caused by components such as motor shafts, gears, drive belts, or linkages which are not protected by integral covers are prevented either by fixed guards or movable guards according to ISO 14120:2015.	X	X					X	X	X	X
5.2.2.4	The fixing systems of the fixed guards which are intended to be removed for routine service actions remain attached to the robot, machine or equipment or remain attached to the guard.	X	X			X			X	X	
5.2.2.4	Movable guards are interlocked with the hazardous movements in such a way that the hazardous machine functions cease before they can be reached.		X			X	X			X	X
5.2.2.4	Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned are mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.									X	X
5.2.2.4	The design ensures that errors when fitting or refitting certain parts which could be a source of risk are prevented by the design and construction of such parts.		X						X	X	
5.2.2.4	Information for use includes information on parts which are not designed to prevent errors in fitting.									X	
5.2.3	Instructions and provisions for lifting or moving parts of the application are provided when intended to be moved after initial installation.	X								X	
5.2.3	The lifting provisions are capable of handling the anticipated load.	X								X	
5.2.4	Robot applications are designed and constructed in such a way that risks of inhalation, ingestion or contact of hazardous materials and substances is prevented.					X				X	
5.2.4	Where the use of hazardous substances cannot be eliminated, the robot application is designed such that those substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another effective method.									X	
5.2.4	Where the application does not allow the total enclosure of the substances during normal operation, containment and/ or evacuation is designed to be effective.		X							X	
5.2.5	To prevent tipping and falling-over, components of robot applications are — Affixed to be stable (e.g. to other components, rails, tracks, to the floor or parts of the building structure); or — stable itself for installation, operation and use.					X				X	
5.2.5	Where components are used that move on rails, they are provided with means to prevent derailment when practicable.		X						X	X	
5.2.5	If risk of derailment persists due to a failure of a rail or of a running component, means are provided to prevent the components or workpiece from falling or overturning.		X			X		X	X	X	
5.2.6	Designed such that the temperatures of accessible surfaces are according to ISO 13732-1:2006 and ISO 13732-3:2005.		X	X		X				X	

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Table H.1 *(continued)*

Clause	Applicable design requirements and/or protective measures	Verification and/or validation methods **A** visual inspection **B** practical tests **C** measurement **D** observation during operation **E** review of application specific schematics, circuit diagrams and design material **F** review of safety-related application software and/ or software documentation **G** review of task-based risk assessment **H** review of layout drawings and documents **I** review of specifications and information for use **J** review of robotic application process simulation models, virtual commissioning tools									
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.2.6	Where there is a risk of fire or overheating, the design principles of ISO 19353:2019 are applied.		X	X					X	X	
5.2.7	Special equipment and accessories to enable the robot application to be adjusted, maintained and used safely is supplied or made available.	X				X			X	X	
5.2.8	Hazardous motion of the robot application is prevented by position holding when drive power is lost.		X								X
5.2.8	Position holding conforms with ISO 10218-1:2025, 5.1.8.		X	X		X				X	
5.2.8	When provided as part of the robot, it is implemented according to the robot's information for use.		X							X	
5.2.8	Position holding means are designed and constructed to withstand an overload during static testing according to 5.2.2.3.		X								
5.2.9	Additional axes that lift or hold a suspended mass conform with relevant requirements in this document.		X			X				X	
5.2.9	When additional axis motion affects the TCP speed in reduced-speed manual mode, the requirements of reduced speed (5.5.6.1) apply to the additional axes.		X			X				X	
5.2.9	Safeguarding and/or safety functions are implemented to protect operators from the associated risks when coordinated axes move at different speeds.	X	X			X		X			
5.2.9	Cannot actuate other axes when the speed of an additional axis can operate at a speed greater than reduced-speed.		X			X			X		X
5.2.10	Loss or change of electrical, hydraulic, pneumatic or vacuum power does not result in a hazardous situation.		X			X				X	
5.2.10	Re-initiation of power does not lead to any hazardous movements or a change of the safety-related parameters.		X			X					
5.2.10	Unexpected start-up is prevented in accordance with ISO 14118:2017.		X			X	X		X	X	
5.2.11	Robot application components are designed, constructed, secured, or contained in accordance with 5.2.2 so that risks caused by breaking or loosening, or releasing stored energy are prevented as far as practicable.									X	
5.2.12.1	Release of stored energy does not cause hazardous situation(s).		X			X			X	X	
5.2.12.1	A means is provided to prevent uncontrolled or hazardous release of stored energy.	X	X			X			X	X	
5.2.12.1	If the hazardous energy is potential, there is a means to secure it in a position which can be either the energized or de-energized position.	X	X			X				X	
5.2.12.1	Safe release or containment is provided in accordance with ISO 14118:2017.	X	X			X		X	X	X	
5.2.12.1	A label is affixed to identify the stored energy hazard.	X									
5.2.12.1	Where additional axes can sink, drop or drift, means are applied either to prevent axis motion or to ensure that resulting motions can be initiated and result in a de-energized position in a controlled way.		X							X	

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Table H.1 *(continued)*

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.2.12.2	Hazardous energy isolating means are provided and have the capability of being locked or otherwise secured only in the de-energized position.	X	X			X				X	
5.2.12.2	Each isolation device is readily identifiable as what it isolates.	X									
5.2.12.2	The span-of-control for each device is clearly marked near the disconnecting device.	X									
5.2.12.2	Electrical supply disconnecting devices conform with IEC 60204-1:2016+AMD1:2021, 5.3.1.					X					
5.2.12.2	Energy separation and dissipation requirements conform with ISO 14118:2017.					X					
5.2.13	Electrical parts are designed and implemented in accordance with the relevant requirements of IEC 60204-1:2016+AMD1:2021.	X	X			X				X	
5.2.13	Pneumatic parts are designed and implemented in accordance with the relevant requirements of ISO 4414:2010.		X			X				X	
5.2.13	Hydraulic parts are designed and implemented in accordance with the relevant requirements of ISO 4413:2010.		X			X				X	
5.2.13	Electric, pneumatic, and hydraulic connectors are selected to prevent erroneous connections when this could lead to a hazardous situation.	X	X			X			X	X	
5.2.13	Where it is not practicable to select connectors to prevent erroneous connections, connectors are labelled to lessen the likelihood of erroneous connection(s).	X								X	
5.2.14	When the capability to enter the tool centre point (TCP) settings is provided and failure to enter these settings can create a hazard, the TCP setting is entered in accordance with the robot information for use.		X							X	
5.2.15	When the payload setting is provided and failure to enter these settings can create a hazard, the robot application does not operate until the payload setting is entered in accordance with the robot information for use.		X							X	
5.2.16	A cybersecurity threat assessment is conducted.								X	X	
5.2.16	If a cybersecurity threat assessment identifies a threat that can result in safety risk(s), cybersecurity measures are provided to prevent unauthorized access to the control system(s), hardware, software, configuration data and application program(s).					X	X	X		X	
5.3	**Robot cell integration**										
5.3.1	If associated machinery and equipment have relevant type-C standards, these standards are applied.					X	X	X		X	X
5.3.1	Safety-related control interfaces between the robot application(s), robot cell(s), other machines, and if applicable, an IMS conforms with 5.5 and Annex C.		X			X	X			X	
5.3.1	Safeguarding protects operators against access to hazards from other machines, within each hazard zone, and at the interfaces to adjacent hazard zones.	X	X					X	X	X	X

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5.3.2	Span-of-control is set according to the requirements of the task(s) to be performed or the characteristics of the system when multiple robot applications, multiple robot cells or other machinery require separate span-of-control.	X	X					X	X	X	
5.3.3	Actuation of an emergency stop function stops — all hazardous motion of the robot, end-effector, workpiece; — other hazardous movements and hazardous functions: — in the robot application or robot cell; and — at the interface(s) between robots, end-effectors, robot applications and robot cells.	X	X			X			X	X	X
5.3.3	The span-of-control is in accordance with ISO 13850:2015, 4.1.2 and is perspicuous or clearly marked near each emergency stop device.	X								X	
5.3.3	Emergency stop functions for the robot and its end-effector have the same span-of-control.		X			X			X	X	
5.3.3	All emergency stop devices for the same hazard zone have the same span-of-control.		X			X			X		
5.3.4	Robot applications with more than one mode that are not operated manually remain in a safe state, independent of the operational mode selected and do not create a hazard.		X			X		X			
5.3.5	Determining what is remote control, local control, and single-point-of-control is according to 5.7.6.2, 5.7.6.3 and 5.7.5 respectively.		X			X	X		X	X	
5.3.5	When local control is selected, other machines and their control system are notified of this condition.	X	X								
5.3.5	Local control is not overridden by remote controls.		X								
5.3.5	The local control is to be located adjacent to and have a direct view of the robot cell.	X							X		
5.3.5	Emergency and protective stop functions remain operational during both local control and remote control, in accordance with 5.6.1.		X			X					X
5.3.6	Where workpieces are automatically fed, the hazards caused by breakage is prevented or the risks are minimized by design and integration.	X	X			X				X	
5.4	**Layout**										
5.4.1	Operator can safely perform all intended and reasonably foreseeable tasks.	X	X						X	X	
5.4.1	Protective measures are applied according to Clauses 4 and 5 when additional hazards are introduced.		X			X		X		X	
5.4.1	Design and construction are such that risks due to access of controls and equipment during automatic operation have been assessed and reduced.					X			X	X	X

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5.4.1	The layout and anticipated tasks are reviewed to eliminate trapping and crushing possibilities within the robot application's restricted space.		X					X	X	X	X
5.4.1	The layout allows tasks to be performed outside the safeguarded space.	X	X						X	X	X
5.4.1	Safe and adequate access to task locations within the safeguarded space is provided.	X	X					X	X	X	
5.4.1	Access paths and means do not expose operators to hazards, including slipping, tripping, and falling hazards.	X						X	X	X	
5.4.1	Access design considers cable channels, stumble areas.	X						X	X	X	
5.4.1	Access design considers frequency of the required access for manual loading/unloading.	X						X	X	X	
5.4.1	Access design considers physical characteristics of the load.	X						X	X	X	
5.4.1	Access design considers abidance and observation zones.	X						X	X	X	
5.4.1	Access design considers service positions.	X	X					X	X	X	
5.4.1	Access design considers easily accessible maintenance locations.	X						X	X	X	
5.4.1	Components which have to be changed frequently are capable of being removed and replaced easily and safely.	X	X			X			X	X	X
5.4.1	Permanent means of access are provided, considering the task's frequency and ergonomic aspect.	X						X	X	X	
5.4.1	Platforms, walkways, stairs, stepladders and fixed ladders are in accordance with the ISO 14122:2016 series.	X		X					X	X	
5.4.1	Workstations are designed according to ISO 14738:2002.	X	X						X	X	
5.4.1	Access openings are designed according to ISO 15534-2:2000.	X		X					X	X	
5.4.1	Openings dimensions for the purpose of providing whole body access conform with ISO 15534-1:2000.	X		X					X	X	
5.4.2	Limits considered include use, operator tasks, space, time, end-effector and workpiece.	X						X	X		
5.4.3	Design considerations include: — the need for manual intervention(s); — allowing tasks requiring manual intervention to be performed outside the safeguarded space; — ergonomics and human interface with equipment; — requirements for and location of emergency stop devices and possible spans-of-control — requirements for and location of additional enabling devices.		X			X		X	X		X

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5.4.3	Design considerations include the: — intended use of all components; — specifications of — robot cell safety functions; — end-effector safety functions; — robot mass, payload, velocity, shape, dimensions; — mass, shape, dimensions of the end-effector and workpiece(s).		X			X		X	X	X	X
5.4.4	In collaborative applications, design considers the spatial (three dimensional) limits of the safeguarded spaces.		X			X		X	X	X	X
5.4.4	In collaborative applications, design considers access and clearance, and contacts.		X			X		X	X	X	X
5.4.4	In collaborative applications, design considers ergonomics and human interface with equipment.	X	X			X		X	X	X	X
5.4.4	In collaborative applications, design considers transitions (time limits).		X			X		X	X	X	X
5.4.5	Robot application is designed and constructed such that it prevents an operator from being trapped within the robot application or robot cell.		X			X			X		X
5.4.5	Safeguarded space is designed, constructed, or fitted with a means of preventing an operator from being trapped within the safeguarded space.		X			X			X		X
5.4.5	If design, construction and safeguarding is not practicable to prevent being trapped within the safeguarded space, the following is provided: — a means to stop the robot application; — a means to prevent the start of the robot application; — a means to summon help; and — a means to release a trapped operator.	X	X			X	X	X	X		
5.4.5	When means to stop and means to prevent the start/restart are provided, these means are readily accessible and located away from hazardous zone(s).	X				X			X		
5.4.6	The restricted space of the robot application has been established by limiting motion of the robot, end-effector, and workpiece.		X	X					X		
5.4.6	When the maximum space is required for the robot application, the maximum space is considered to be the restricted space.					X			X		X
5.4.7.1	Robot applications are designed and integrated to reduce the potential exposure of personnel to hazards by implementing limiting devices.		X					X		X	

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5.4.7.1	Limiting devices prevent motion beyond the limit by either mechanical limiting devices or software-based limiting safety functions that prevent reaching the limit or initiate a protective stop.		X	X					X	X	
5.4.7.2	Mechanical limiting devices, when used, conform with ISO 10218-1:2025, 5.7.1 or 5.7.4.		X	X					X	X	
5.4.7.2	Mechanical limiting devices have been correctly installed and adjusted.	X	X	X			X			X	
5.4.7.2	When the perimeter guard is designed to be the limiting device, the results of the risk assessment and ISO 14120:2015 have been used to determine the requirements for the design, strength and deflection for that guard.			X				X	X	X	
5.4.7.2	The perimeter guard is not used as a limiting device when robot applications can cause hazardous deformations of the guard.		X					X			
5.4.7.3	Non-mechanical limiting devices conforms with 5.4.7.3 and ISO 10218-1:2025, 5.7.1 and either 5.7.3 or 5.7.4.					X	X				
5.4.7.3	Functional safety performance conforms with 5.5 and Annex C.					X	X				
5.4.7.3	If the robot has software-based limiting safety function(s), the safety function(s) are configured for the robot application using the robot manufacturer's instructions.		X	X			X			X	
5.4.7.3	When non-mechanical limiting devices are used, the robot application restricted space is determined where the moving parts of the robot application stop.		X	X			X		X	X	
5.4.7.3	If the speed of the robot TCP is limited by monitored-speed safety function, the restricted space is based on the maximum speed of the robot application.		X	X		X				X	
5.4.7.3	When the limiting device functions by initiating a protective stop when the limit is reached or exceeded, the stopping distance and time are used to determine the restricted space of the robot application.		X	X		X				X	
5.4.7.4	When provided, dynamic limiting conforms with 5.4.7.3 and ISO 10218-1:2025, 5.7.5 when provided with the robot.		X			X				X	
5.5	**Safety functions**										
5.5.1	Control systems are designed so reasonably foreseeable human error during operation does not lead to hazardous situations.		X			X	X				X
5.5.1	Robots are selected with suitable safety functions for the requirements of the robot application.					X	X			X	
5.5.1	The selected robots are in accordance with ISO 10218-1:2025, 5.3.					X	X			X	
5.5.1	Safety-related control systems conform with 5.5 and Annex C.					X	X				
5.5.1	Safety-related control system performance information, of all safety functions, is provided according to 7.5.16.	X				X	X			X	
5.5.1	If safety functions are provided that are not described in this document, are described according to 7.5.16.	X				X	X			X	

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5.5.2	Safety-related control system performance is stated as either Performance Levels (PL) and categories according to ISO 13849-1:2023 or Safety Integrity Levels (SIL) and hardware fault tolerance requirements (HFT), with a 20-year proof-test-interval, according to IEC 62061:2021.					X	X			X	
5.5.2	Requirements in ISO 13849-1:2023 or IEC 62061:2021 are used for the respective safety functions for which they are intended.					X	X			X	
5.5.3	Required performance of each required safety function is either determined by the Minimum Functional Safety PL_r or required SIL listed in Annex C, Table C.1 OR the results of a comprehensive risk assessment where the risk estimation meets the requirements of ISO 12100:2010 and either ISO 13849-1:2023 or IEC 62061:2021.					X	X			X	
5.5.3	Robot application has the required SRP/CS for each safety function in accordance with the determined performance requirements.					X	X			X	
5.5.3	When using performance levels and PL d is required, the safety function achieves PL d using either a Category 3 architecture or the PFH is less than $4{,}43 \times 10^{-7}$/h.					X	X			X	
5.5.3	When using SILs and SIL2 is required, either the hardware fault tolerance (HFT) is at least 1 or the PFH is less than $4{,}43 \times 10^{-7}$/h.					X	X			X	
5.5.4	Detected faults of the safety-related control system results in an appropriate reaction, which can include finishing the cycle or initiating a stop category 0 or 1 according to IEC 60204-1:2016+AMD1:2021.					X					
5.5.5	Safety function parameter settings are according to ISO 13849-1:2023 or IEC 62061:2021.									X	
5.5.5	Changes to safety function parameters are secured and only changeable by authorized operator(s).		X							X	
5.5.5	Safety function parameter security is separate from that which allows access for programming non-safety functions and configuring parameters.	X								X	
5.5.5	Activated safety function(s) are always activated upon power-up.		X			X				X	
5.5.5	Safety function settings generate an identifier (e.g. checksum) so setting changes can be identified.		X								
5.5.5	This identifier for setting changes is capable of being output, as a non-safety function.		X			X					
5.5.5	Manual changes are not capable of being reconfigured during automatic execution of the task program and require re-initialization after manual changes.		X								
5.5.5	Software on-line tools that directly influence the safety-related system, as defined in IEC 61508-4: 2010, 3.2.10, are not used.									X	
5.5.5	Safety function parameters are verified and validated before starting use of the robot application.		X	X			X		X		X
5.5.5	Information on the active settings and configuration of the safety functions can be viewed and documented.	X	X							X	

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5.5.6.1	Maximum reduced-speed of accessible moving parts does not exceed 250 mm/s or the set maximum limit is less than 250 mm/s.			X							
5.5.6.1	Reduced-speed is used with manual mode.	X	X				X				
5.5.6.1	If robot and additional axis are operating in a coordinated manner, the speed of the TCP and any exposed part of the manipulator does not exceed 250 mm/s.			X						X	
5.5.6.1	If a reduced-speed setting less than 250 mm/s is required for the application, the reduced-speed parameter is configured.	X	X				X				
5.5.6.2	If a monitored-speed safety function is provided, the robot application is configured with the monitored-speed value that achieves the results required as determined by risk assessment.	X	X	X			X		X		
5.5.7.1	The control system has a start/restart interlock function to prevent the automatic start/restart.		X			X					
5.5.7.1	Automatic restart conforms with ISO 13849-1:2023, 5.2.2.4.					X	X				
5.5.7.1	The start/restart interlock safety function conforms with 5.5 and Annex C, Table C.1.					X	X				
5.5.7.1	Automatic start/restart is prevented after a change in the mode of operation; — from automatic mode to manual mode; — from reduced-speed manual mode to high-speed manual mode; — from high-speed manual mode to reduced-speed manual mode; and — from modes described in 5.7.2 to other modes and vice versa, when the automatic start/restart can lead to a hazard.		X			X	X				
5.5.7.1	Automatic start/restart is prevented: — in manual mode, after a protective stop is initiated by any enabled protective device; — after actuation of a safeguarding function when that safeguard allows undetected presence in the safeguarded space(s).		X			X	X				
5.5.7.2	The reset safety function and the reset actuator location conform with ISO 13849-1:2023, 5.2.2.3.		X			X	X		X		
5.5.7.2	The reset safety function is in accordance with 5.5 and Annex C, Table C.1, with a minimum functional safety performance of PL b.					X	X				
5.5.7.2	Resetting is by a deliberate manual action on a specific control device in a control station according to 5.7.8.		X			X	X				
5.5.7.2	Unintended reset is prevented by either only accepting the release of the actuator from its energized (on) position or another suitable method (e.g. two activation zones on a touch sensitive screen).		X			X	X				

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5.5.7.2	Unintended reset is prevented by either only accepting the release of the actuator from its energized (on) position or another suitable method.		X			X	X				
5.5.7.2	Where whole body access is possible, supplementary protective measures is provided in accordance with 5.8.10 to prevent resetting the start/restart interlock.		X			X	X	X	X		
5.5.8	When a monitored-standstill safety function is needed to prevent unintended motion, the standstill position is monitored and maintained according to 5.5.3.		X			X	X				
5.5.8	Any unintended motion from a monitored standstill position results in a stop category 0 or 1 in accordance with IEC 60204-1:2016+AMD1:2021.		X			X	V				
5.5.8	When a monitored-standstill safety function is needed to prevent unintended motion, a detected failure conforms with 5.5.4.		X			X	X				
5.5.9	When data communications are used in the implementation of a safety function, the requirements of IEC 61508-2:2010, 7.4.11 are applied.					X	X			X	
5.5.9	When a robot application has an internal network, the network is considered as a transmission category 1 network according to Table 1.									X	
5.5.9	When a robot application has an external network, the network is considered as a transmission category 2 or transition category 3 network according to Table 1.					X	X			X	
5.5.10	Safety-related control systems fulfil the requirements of IEC 61000-6-7:2014.					X	X			X	
5.6	**Stopping**										
5.6.1	Every robot application has a protective stop function, a normal stop and an independent emergency stop function.		X			X				X	
5.6.1	The control system is designed such that stop functions have precedence over any other control functions.		X			X				X	
5.6.1	When a stop function has been initiated, no other control functions can enable robot application functions until the stop condition has been achieved.		X			X				X	
5.6.2.1	Each control station capable of initiating robot motion or other hazardous functions has a manually initiated emergency stop function conforming with IEC 60204-1:2016+AMD1:2021 and ISO 13850:2015.	X	X			X				X	
5.6.2.1	Selection of stop category 0 or 1 according to IEC 60204-1:2016+AMD1:2021 is determined from the risk assessment.					X		X		X	
5.6.2.1	Robot applications have a single emergency stop function with a span-of-control for all parts of the robot application, including fixtures.		X			X				X	
5.6.2.1	Emergency stops remain functional even if the control station is not powered.		X			X	X		X	X	
5.6.2.1	The capability to connect additional emergency stop devices is provided.	X	X			X				X	

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5.6.2.1	Emergency stop function conforms to 5.5 and Annex C.		X	X		X				X	
5.6.2.2	Each control station, including pendants, capable of initiating robot motion or other hazardous situations has a manually initiated emergency stop function that complies with 5.6.2, takes precedence over all other robot control functions, stops all hazards within a span-of-control, removes drive power from the robot actuators and remains active until the emergency stop device is disengaged in accordance with ISO 13850:2015, 4.1.4.		X			X				X	
5.6.2.2	Emergency stop function can only be reset by a deliberate manual action that does not cause a restart after resetting but only permits a restart to occur.		X			X				X	
5.6.2.3	Any safety function input for emergency stop remains operative when the power is removed and recovered.		X	X						X	
5.6.2.4	Emergency stop outputs, if provided, continue to function when power is removed.		X	X						X	
5.6.2.4	When a safety function output for an emergency stop is provided, the function remains operative when drive power is removed and recovered.		X			X				X	
5.6.3	Robot application has at least one protective stop function with capability to be initiated by an internal safety function or external protective devices.					X	X		X		
5.6.3	Selection of a stop category 0, 1 or 2, according to IEC 60204-1:2016+AMD1:2021 is determined by a risk assessment.		X			X		X		X	
5.6.3	The protective stop function conforms with 5.5.					X				X	
5.6.3	When provided, a monitored standstill uses a Category 2 stop according to IEC 60204-1:2016+AMD1:2021.		X			X				X	
5.6.4	A normal stop control device is fitted to the control stations(s) to stop some or all the functions of the robot application, according to the span-of-control.		X			X		X	X	X	
5.6.4	When activated, the normal stop function results in a category 0 or category 1, according to IEC 60204-1:2016+AMD1:2021.		X			X					
5.6.4	Normal stop safety function is in accordance with 5.5 and shall have a minimum functional safety performance of PL b (Annex C, Table C.2)										
5.6.4	Emergency stop devices are not used as normal stop devices.		X			X	X			X	
5.6.5	Stopping of associated equipment does not result in a hazard or hazardous situation(s).	X	X	X				X		X	X
5.7	**Control functions**										
5.7.1	Controls meet the requirements of IEC 60204-1:2016+AMD1:2021 and are designed consistent with ISO 10218-1:2025.		X			X	X		X	X	
5.7.1	Controls that initiate power or motion are designed and implemented to 5.7.2 to 5.7.9.		X			X	X			X	
5.7.2.2	The robot application and robot cell have an automatic mode.		X			X				X	
5.7.2.2	In automatic, the application executes the intended function(s) and associated safety functions are active.		X			X				X	

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5.7.2.2	Changing from automatic mode to any other mode results in a protective stop.		X			X				X	
5.7.2.2	Automatic operation does not start until a separate confirmation from outside the safeguarded space is provided by the operator.		X			X				X	
5.7.2.3.1	A manual mode is provided.		X			X	X				
5.7.2.3.1	When operated in manual mode, all other equipment not required for the task is placed in, and maintained in, a safe state.		X			X				X	
5.7.2.3.1	When operated in manual mode, if it is necessary for other machines, equipment or processes to operate, they operate under reduced risk conditions.		X			X				X	
5.7.2.3.1	When operated in manual mode, the robot application is under local control according to 5.7.6.2 with single-point-of-control according to 5.7.5.		X			X				X	
5.7.2.3.1	When operated in manual mode, automatic operation is prevented.		X			X				X	
5.7.2.3.1	Movements in manual mode are only possible by use of a control station according to 5.7.8 where that control station is the single-point-of control per 5.7.5.		X			X				X	
5.7.2.3.2	A reduced-speed manual mode is provided for jogging, teaching, programming, program verification and manual intervention tasks.		X				X			X	
5.7.2.3.2	Where these tasks require control of the functions of the robot application or robot application while a person(s) is in the safeguarded space, a teach pendant provides this control.		X				X			X	
5.7.2.3.2	Movements are only possible with reduced-speed (according to 5.5.6.1) during the actuation of the enabling device on the control station that enables movements of the robot application/ robot cell.		X				X			X	
5.7.2.3.2	A separate deliberate manual action is required to initiate motion.		X			X	X				
5.7.2.3.2	If a speed less than 250 mm/s is needed for the robot application, the robot is configured to have the required reduced-speed limit for the robot application.		X				X	X		X	
5.7.2.3.2	If a speed less than 250 mm/s is needed for the robot application, and if the end-effector and/or other machinery/ equipment in the robot application need to be operated at a configurable reduced-speed setting, this safety function (and the required speed value) is implemented for the end-effector and/or other machinery/equipment as needed.		X				X	X		X	
5.7.2.3.3	When provided, high-speed manual mode is a selection within manual mode which has a monitored-speed safety function according to 5.5.6.2.		X				X			X	
5.7.2.3.3	When provided, high-speed manual mode is integrated such that it can only be used for the purpose of program verification and not production.	X	X				X			X	
5.7.2.3.3	If high-speed manual mode is provided and enabled, the robot conforms with the requirements of ISO 10218-1:2025, 5.2.7.2.3.		X				X			X	

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.7.2.3.3 a)	a) High-speed manual mode for the application has a teach pendant that — fulfils the requirements of ISO 10218-1:2025, 5.2.8.4 and if applicable also 5.2.8.5 for the robot; — has an enabling device according to ISO 10218-1:2025, 5.5.4 for the robot.		X				X			X	
5.7.2.3.3 a)	a) If high-speed manual mode is provided and enabled for use, the enabling device function according to 5.7.7, associated with the teach pendant is integrated with the relevant equipment and/or machines within the safeguarded space.		X				X			X	
5.7.2.3.3 b)	b) Hazards from other machines, equipment and processes are at a safe state or operating under reduced conditions, e.g. reduced-speed, reduced torque, reduced force, limited movement, by jogging which can be in conjunction with an enabling device.		X				X			X	
5.7.2.3.3 c)	c) Safeguarding is the same as when the application is in automatic mode such that access to hazards is prevented or access is detected, thereby resulting in a safe state and/or protective stop of all hazardous conditions.		X				X			X	
5.7.2.3.3 d)	d) when perimeter safeguarding establishes the safeguarded space, entering the safeguarded space in high-speed manual mode causes a protective stop of all equipment that could present a hazard.		X				X			X	
5.7.2.4	An appropriate operating mode is provided if the application is operated with guards displaced or protective devices disabled.		X				X			X	
5.7.2.4	This mode disables all other control modes; permits operation only by sustained control action devices; permits operation only in reduced risk conditions; and prevents operation by application sensors.		X			X	X			X	
5.7.2.4	If a) through c) conditions cannot be fulfilled simultaneously, the control or operating mode selector automatically activates alternative safeguarding in accordance with 5.8, which is implemented to ensure safe intervention(s).		X			X					
5.7.2.5	Selection of the operating mode requires a deliberate manual action, e.g., use of a key switch, selection on a touch screen.		X			X	X			X	
5.7.2.5	The active mode is clearly identifiable and unambiguously indicated.	X	X								
5.7.2.5	Unauthorized and/or inadvertent activation of mode is prevented by suitable means.		X			X					
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, then the activation, but not starting operation, of the selected mode is considered a safety function.		X			X	X			X	
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, mode selection requires a deliberate action.		X			X				X	

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5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, activating a different mode results in a protective stop.		X			X				X	
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, motion is initiated according to 5.5.7.		X			X				X	
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, each mode has the required risk reduction measures active for that mode.		X			X				X	
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, mode selection does not initiate robot motion or other hazards.		X			X					
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, only one operating mode is active at a time.		X			X					
5.7.2.5	If the activation of a mode results in a change in the safeguarding or active safety functions, activation of safety functions shall result from the output of the logic for mode activation.					X	X				
5.7.2.5	When activation or selection of mode are safety functions, then the safety function(s) conform with ISO 13849-1:2023, 5.2.2.9 .					X	X				
5.7.3	Controls are implemented and/or located for prevention of unexpected start-up and conform with ISO 14118:2017.		X			X			X	X	
5.7.4	Status of the controls are clearly indicated (e.g. power on, fault detected, automatic operation), suitable for the installed location and conform with IEC 60204-1:2016+AMD1:2021 and IEC 60073:2002.	X	X							X	
5.7.4	When provided, warning devices conform with ISO 12100:2010, IEC 60204-1:2016+AMD1:2021 and IEC 60073:2002.	X	X							X	
5.7.5	Single-point-of-control is provided when the robot application or robot cell is under local control.		X				X			X	
5.7.5	Only one source of control is accepted at one time.		X				X			X	
5.7.6.1	If the only means of control is by network or a connection to a computer, it is considered to be remote control.		X							X	
5.7.6.2	When a local control function is provided, it conforms with ISO 13849-1:2023, 5.2.2.5.					X	X				
5.7.6.2	When in local control, the control station is the single-point-of-control according to 5.7.5.		X			X				X	
5.7.6.2	When manual intervention is required, local control is affected by a single teach pendant or similar control station to the requirements of ISO 10218-1:2025, 5.2.8.4 for the robot and 5.7.8 for the robot application.		X			X	X			X	
5.7.6.2	If local control is provided by a teach pendant, the teach pendant has direct control of the robot.		X				X			X	
5.7.6.2	If local control is provided by a teach pendant, the teach pendant is the local control, which has priority over all other sources of control to the robot application and overrides these other sources of control to the robot application.		X				X			X	

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5.7.6.2	If there is no teach pendant and local control is provided by a control station located near the application, this local control station has local control priority over other sources of control to the robot application and overrides these other sources of control to the robot application.		X				X			X	
5.7.6.2	Local controls have an indication when remote control is active.	X	X							X	
5.7.6.2	Means of selecting and deselecting local control are near the robot application area being placed under local control.	X	X			X			X	X	
5.7.6.2	If local control can be deselected from within the safeguarded space, a separate confirmation from outside the safeguarded space is required prior to any hazardous conditions being present.		X			X			X	X	
5.7.6.2	Means of deselecting local control from within the safeguarded space does not initiate hazardous conditions.		X				X			X	
5.7.6.3	If remote access to the control system is provided, it shall conform with ISO 13849-1:2023, 5.2.4.					X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, activation of the remote control function requires a manual command from the local control (5.7.6.2).		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, any operation start requires one of the following: — a separate confirmation from the local control (5.7.6.2); or — a separate confirmation from the remote control where the remote control provides means for an unobstructed view to the entire robot cell.		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, the requirements of 5.7.2.3 apply in manual mode.		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, functions that can cause a hazard are only possible from the selected single-point-of-control according to 5.7.5.		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, remote control does not override the local control and does not cause any local hazardous situation(s).		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, any machines, equipment, processes and sub-assemblies that could create a hazard and that are not needed for remote control are in a safe state.		X			X	X				

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5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, safeguarding operators while in remote control are in accordance with 5.8 such that the following are fulfilled: — access to hazards is prevented; and/or — access is detected, thereby resulting in a safe state and/or protective stop of all hazardous situations such that the safe state and/or protective stop is achieved before the hazard(s) is reached.		X			X	X				
5.7.6.3	If a robot application can be remotely controlled by an operator who is physically away from the robot cell, remote change(s) to safety-related parameters requires the following before the change(s) take effect: — a local action to confirm the acceptability of the change(s); and verification that the change(s) did not create any hazardous situations.		X			X	X				
5.7.6.3	Activation of a mode change by remote control requires a local deliberate manual confirmation.			X		X	X				
5.7.7	Enabling devices on the teach pendant and additional enabling devices conform with ISO 10218-1:2025, 5.5.3 and IEC 60204-1:2016+AMD1:2021.		X				X			X	
5.7.7	Enabling devices are provided for each operator within the safeguarded space.	X				X		X	X	X	
5.7.7	All enabling devices associated with a robot application have the same span-of-control.		X				X			X	
5.7.7	Enabling devices are interlocked to control all hazards within the span-of-control in areas of the cell where personnel are exposed to a hazard from additional robot or other equipment.		X			X	X	X	X	X	
5.7.7	Robot application motion and hazardous operations are only allowed while the enabling device is continuously held in a centre-enabled position.		X				X			X	
5.7.7	Interlocked equipment requires a separate act to restart after a protective stop initiated by the enabling device.		X			X				X	
5.7.8.1	The robot application has the means to control, program/ teach, configure and troubleshoot from either the control panel or teach pendant, or remote control capability and the corresponding connectivity (cabled or wireless).	X	X			X				X	
5.7.8.1	Each control station or teach pendant that has the capability of initiating motion or hazardous functions has an emergency stop device in accordance with ISO 13850:2015, 4.3.5 for the initiation of an emergency stop function in accordance with 5.6.2.		X			X				X	
5.7.8.1	Pendant has an integrated 3P enabling device if entering the safeguarded space in manual mode would lead to a hazardous situation.		X			X				X	
5.7.8.1	Teach pendants and control panels are in accordance with the requirements of the IEC 61310:2015 series.		X			X				X	

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5.7.8.1	A visual signal at the control station indicates the active status of a control station, e.g. an indicator light on a control panel or a warning at a teach pendant display.	X	X			X				X	
5.7.8.1	For robot applications with remote control capability, control stations (including teach pendants) indicate when remote control is active.	X	X			X				X	
5.7.8.2	Control stations, pendants, teach pendants, electrical cabinets and equipment are located for access by operators while the operators are safeguarded.	X	X	X		X			X	X	
5.7.8.2	Control stations, pendants, teach pendants, electrical cabinets and equipment are located or positioned to allow an operator to have an unobstructed view of the application.	X	X	X		X			X	X	
5.7.8.2	Fixed control stations and electrical cabinets are located outside of the perimeter safeguard when a perimeter safeguard is provided.	X				X			X	X	
5.7.8.2	Portable/movable control stations and pendants not in use are located outside of the perimeter safeguard when a perimeter safeguard is provided.	X				X			X	X	
5.7.8.2	Control stations, pendants, teach pendants, electrical cabinets and equipment that have the capability of mode selection, local/ remote control selection, or use within the safeguarded space(s) are placed near the access means for improved ease of use by the operators.	X				X			X	X	
5.7.8.2	When electrical equipment, containing elements that require access, are above the normal reach, a means for access is provided (e.g. a work platform) according to the ISO 14122:2016 series.		X	X		X		X	X	X	
5.7.8.2	The results of a risk assessment are used to determine the means for providing access to the relevant devices between a height of 400 mm and 2 000 mm from the access level (see also IEC 60204-1:2016+AMD1:2021).		X	X		X		X	X	X	
5.7.8.2	Electric enclosures are mounted so their doors can be fully opened and escape routes are always available by clearance or design of the doors.	X	X						X	X	
5.7.8.2	Selection and design of platforms, walkways, stairs, stepladders and fixed ladders are in accordance with the relevant parts of ISO 14122:2016.			X					X	X	
5.7.8.3	Pendants and teach pendants that can cause motion or hazardous movements have an emergency stop in accordance with 5.6.2.		X	X		X			X	X	
5.7.8.3	Pendants and teach pendants that can cause motion or hazardous movements have an enabling device in accordance with 5.7.7.		X	X		X			X	X	
5.7.8.3	Pendants and teach pendants that can cause motion or hazardous movements have a single-point-of-control, in accordance with 5.7.5, when in manual mode.		X	X		X			X	X	
5.7.8.3	Cabled pendants have sufficient cable length to perform tasks in a safe manner.	X	X	X					X	X	

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5.7.8.3	A cabled pendant has a cable that is capable of withstanding the anticipated environmental conditions of the location in which it is to be used.		X	X					X	X	
5.7.8.3	Cabled pendant has means for proper placement to minimize the possibility of damage which could result in a hazard.	X				X		X	X	X	
5.7.8.3	Cabled pendant has means of cable stowage to reduce entanglement and tripping hazards.	X				X		X	X	X	
5.7.8.3	Cableless or detachable pendants and teach pendants conform with 5.7.8.4.		X			X				X	
5.7.8.3	Teach pendants conform with the requirements in ISO 10218-1:2025, 5.7.2.		X			X	X			X	
5.7.8.4	Cableless teach pendant has unambiguous means that identify the robot application being operated.	X	X			X	X			X	
5.7.8.4	Cableless teach pendant has connection means to ensure integrity of communication (e.g. login, encryption, firewalls).		X			X	X			X	
5.7.8.4	Cableless teach pendant has unambiguous means to indicate connection continuity (e.g. screen display).	X	X			X			X	X	
5.7.8.4	Cableless pendant is not simultaneously connected to more than one robot or robot application.		X			X	X			X	
5.7.8.4	Loss of safety-related communication on any active pendant causes protective stop and restoration of communications does not allow a restart without a separate deliberate action.		X			X				X	
5.7.8.4	Unambiguous means to disconnect controllers from the pendant are provided.		X			X			X	X	
5.7.8.4	When devices are logged out, it is clearly recognizable that the relevant safety functions are not active anymore.	X	X			X				X	
5.7.8.4	Appropriate storage or design is provided to avoid confusion between active and inactive emergency stop devices.	X	X			X			X	X	
5.7.9	Each robot (and if necessary, end-effectors and additional axes) is selected before it can be activated.		X			X					
5.7.9	Each robot selected is in the same operating mode.	X	X			X				X	
5.7.9	An indication of what will be activated is provided according to ISO 10218-1.	X	X						X	X	
5.7.9	Only what is selected is activated.		X			X				X	
5.7.9	Robots not selected do not move and do not present hazards, according to 5.2.8.		X			X			X	X	
5.8	**Safeguards and their use**										
5.8.1	Guards and protective devices are used to prevent access to the hazard(s), cause hazard(s) to cease before access, prevent unintended operation, contain ejected parts and tooling, and limit other process hazards.		X	X		X	X	X	X	X	
5.8.1	Protective devices which initiate a protective stop remain active while an operator is in the safeguarded space.		X	X				X	X	X	

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5.8.1	If whole body access exists or if it is possible for parts of an operator to be undetected within a safeguarded space and also hidden from view at the reset control, the requirements of 5.5.7 and 5.8.10 are fulfilled.		X	X		X	X	X	X	X	
5.8.1	Risks of whole body trapping or body parts being crushed between moving portions of the robot application with, for example, parts of buildings, structures, utilities, other machines, and equipment, are reduced to acceptable levels.		X			X	X	X	X		
5.8.1	Safeguarding is provided when clearance is not in accordance with ISO 13854:2017.					X	X	X	X		
5.8.2	Safeguarded space is defined.	X		X					X	X	
5.8.2	When provided, dynamic changing is part of the functional safety of the limiting device implementation.			X					X	X	
5.8.2	The restricted space(s) is defined within the safeguarded space.			X		X			X	X	
5.8.3	When required, perimeter safeguarding is implemented using guards in accordance with 5.8.5 and/or sensitive protective equipment in accordance 5.8.5.		X			X		X		X	
5.8.3	Minimum gaps to prevent crushing or trapping conform with ISO 13854:2017.			X					X	X	
5.8.3	Unless allowed by 5.12.2, the height of the perimeter guard is at least 1 400 mm from adjacent walking surfaces.		X						X		
5.8.3	Perimeter guards are not installed closer to the hazard than the restricted space, unless guards are designed to be the limiting device in accordance with 5.4.7.			X				X	X	X	
5.8.4	When provided, overriding protective device capability complies with 5.7.2.4.						X			X	
5.8.4	When provided, overriding means provides same level of risk reduction as the protective device.						X			X	
5.8.5	**Guards**										
5.8.5.1	Guards conform with ISO 14120:2015.									X	
5.8.5.1	Non-interlocked guards require tools to remove and cannot be easily circumvented without a tool.	X	X								
5.8.5.1	Fixing systems remain attached to the guards or machinery when guards are removed.	X	X							X	
5.8.5.1	Guards are located at a safety distance in accordance with 5.8.5.2.		X	X					X		
5.8.5.1	Guards do not allow an operator to reach over, under, around or through (an opening or gap) the guard and access a hazard zone.	X		X					X	X	
5.8.5.2	Fixed and movable guards conform with ISO 14120:2015.									X	
5.8.5.2	Fixed and movable guards' minimum distance from any hazard meets relevant requirements of ISO 13857:2019 and ISO 13855:2010, except as permitted in 5.12.2.		X			X			X		
5.8.5.2	Minimum distances associated with openings in guards meet the relevant requirements of ISO 13857:2019.		X			X				X	

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5.8.5.3	Interlocking devices associated with moveable guards meet requirements of ISO 14119:2024.		X			X				X	
5.8.5.3	Movable guards open laterally or away from the hazard, and not into the safeguarded space.	X	X						X	X	
5.8.5.3	Movable guards used to initiate starting on closure (control guards) meet the requirements of ISO 14120:2015.		X			X				X	
5.8.5.3	The interlocking function meets at least the requirements of 5.5.		X			X				X	
5.8.5.3	Resets are in accordance with 5.5.7.2.		X			X				X	
5.8.5.4	When it is possible for the operator to open an interlocked movable guard and reach the hazard zone before the hazard is brought to a safe state, guard locking is provided in addition to the interlock function.		X			X			X	X	
5.8.5.4	Guard locking only permits actuation of hazardous machine function if the guard is closed and locked.		X			X	X			X	
5.8.5.4	Guard locking keeps the guard in the closed and locked position if the risk of harm due to hazardous functions of the machine exists and conform with ISO 14119:2024, 6.6.		X			X	X	X		X	
5.8.5.4	Process parameters used as a condition for locking or unlocking meet the same functional performance requirements as the interlocking function.		X			X	X	X		X	
5.8.6	**Sensitive protective equipment**										
5.8.6.1	Electro-sensitive protective equipment meets the relevant requirements in the IEC 61496 series.					X	X			X	
5.8.6.1	Pressure-sensitive protective equipment meets the relevant requirements in ISO 13856-1:2013, ISO 13856-2:2013 and ISO 13856-3:2013.					X	X			X	
5.8.6.1	Application of the protective devices are according to IEC 62046.		X			X				X	
5.8.6.1	Where an operator or part of an operator can be in the safe-guarded space and remain undetected by the SPE, additional measures are provided according to 5.8.1 to prevent hazardous situations arising.		X			X	X				
5.8.6.1	Detecting an operator inside a manual load/unload station complies with 5.12.2.		X			X	X				
5.8.6.2	Where the sensitive protective equipment is used to initiate a protective stop, it is positioned at a distance from each hazard sufficient to ensure the hazard is removed or otherwise obtains a safe condition before any part of an approaching operator can reach the hazard.		X	X		X			X		
5.8.6.2	Sensitive protective equipment is securely installed and located such that an operator cannot circumvent (i.e. cannot reach over, under, around or through) the detection zone and reach a hazard.		X			X			X	X	X
5.8.6.2	A protective stop is initiated if the sensitive protective equipment is actuated while the hazardous conditions are operating.		X			X			X		

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5.8.6.2	Following actuation, the hazardous conditions being safeguarded by the sensitive protective equipment prevents any hazardous motion or situation until the sensitive protective equipment is reset.		X	X			X			X	X
5.8.6.2	The formulae in ISO 13855:2010 are used to determine the minimum distance from the hazard zone to the sensitive protective equipment for all directions of approach.		X	X							X
5.8.6.3	The detection zone of presence-sensing devices is positioned and configured so that an operator or part of an operator will be detected throughout the detection zone and a protective stop maintained.		X	X				X	X		X
5.8.6.3	Where necessary, supplementary measures are provided to ensure that the detection zone cannot be circumvented.		X	X				X	X	X	
5.8.6.3	Where the sensitive protective equipment is only used for a presence-sensing function, it is used in conjunction with other protective devices to ensure the machine(s) is/are in a non-hazardous state before hazards can be reached.		X	X		X	X		X	X	
5.8.6.4	Use of blanking is according to IEC 62046:2018.									X	
5.8.7	When muting is applied, use of muting is according to IEC 62046:2018.									X	
5.8.8	When provided, overriding a protective device is according to 5.7.2.4 and IEC 62046:2018.					X	X		X		
5.8.8	When provided, overriding means provide the same level of risk reduction as the SPE.					X	X				
5.8.9.1	The minimum distance for protective devices providing a trip function is in accordance with ISO 13855:2010.			X					X	X	
5.8.9.2	When protective devices solely provide a presence-sensing function to prevent starting or restart, detection capability requirements stated in the related formula of ISO 13855:2010 are applied.			X			X	X		X	
5.8.9.3	When protective devices provide a trip function to provide protection against lack of clearance, the separation distance is calculated using ISO 13855:2010 with the robot application speed as the approach speed (i.e. K is the robot system speed).			X			X	X		X	
5.8.9.3	When protective devices provide a presence-sensing function to prevent unexpected start due to a lack of clearance, detection capability requirements stated in the related formula of ISO 13855:2010 are applied.			X			X	X		X	
5.8.10	From each control station the visibility, to all the locations within the safeguarded space(s) where operators can be, is ensured.	X	X						X		
5.8.10	Where visibility is not practicable, presence sensing is provided to detect any person throughout the safeguarded space.	X	X			X			X		
5.8.10	Where presence sensing is not practicable, sequenced time-limited reset devices located inside the safeguarded space are provided.	X	X						X		

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5.8.10	The final reset device is located outside the safeguarded space and is not within reach by any person within the safeguarded space.	X	X				X	X			
5.8.10	Where presence sensing and sequenced time-limited reset devices are not practicable, a restart is prevented by one of the following: multiple means for the isolation and lockout of the hazardous equipment located within the safeguarded space; measures to lock a guard in the open position; or measures to lock an obstruction with the detection zone of an AOPD used to detect entry into the hazard zone; or trapped key interlock systems.	X	X						X		
5.8.10	If a start/restart interlock in conjunction with presence sensing is provided, the presence-sensing device meets the requirements of Type 2 from IEC 61496-1:2020.	X	X				X	X			
5.8.10	Protection from unexpected start-up is according to 5.5.7.		X			X	X		X	X	
5.8.10	Safety-related manual control devices are located at a sufficient distance to prevent actuation from inside the safeguarded space according to ISO 13857:2019.	X	X				X	X		X	X
5.9	**End-effectors**										
5.9.1	**End-effectors are designed, selected and integrated to fulfil the following:**										
5.9.1 a)	a) conform with 5.1 and 5.2 as applicable.									X	
5.9.1 b)	b) have a means for manual movement or release, for use without power, to free entrapped fingers or other body parts.	X	X			X	X			X	
5.9.1 c)	c) have safety functions to interlock or monitor functions such as gripper closing and opening with information on the positioning of the end-effector to prevent inadvertent release of the load in a hazardous position.		X				X			X	
5.9.1 d) 1)	d) 1) when operators can be within proximity of the end-effector during the gripping of workpieces, gripping forces are minimized to achieve adequate grasping of an object instead of maximum force available.	X	X	X			X			X	
5.9.1 d) 2)	d) 2) when operators can be within proximity of the end-effector during the gripping of workpieces, contact between gripper/ grasped workpieces and an operator are according to 5.14.6.	X	X	X			X	X		X	
5.9.1 d) 3)	d) 3) when operators can be within proximity of the end-effector during the gripping of workpieces, application design measures are provided by which crush hazards are eliminated.	X	X	X	X			X		X	
5.9.1 e)	e) when operators are exposed to risks of an end-effector or a tool attached to an end-effector, risks are reduced.	X	X		X	X	X	X	X	X	X
5.9.1 f)	f) safety functions used to control risks conform with 5.5 and Annex C.		X				X	X		X	
5.9.1 g)	g) the static and dynamic forces created by the load and the end-effectors together are within the load capacity and dynamic (motion control system) response of the robot.	X		X	X			X		X	
5.9.1 h)	h) align with the mechanical interface.	X	X		X					X	
5.9.1 i)	i) detachable tools are securely attached while in use.	X	X		X					X	

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5.9.1 j)	j) the release of detachable tools only occurs in designated locations or under specific, controlled conditions, if the release could result in a hazardous situation.	X	X		X					X	
5.9.1 k)	k) the end-effector withstands the anticipated forces for its expected life, in accordance with 5.2.2.			X						X	
5.9.1	End-effectors are selected or designed such that loss or restoration of energy supply does not cause a hazardous situation, or other safety measures are provided.	X	X		X					X	
5.9.2	**Additional risk reduction measures include, as applicable, 5.9.2 (a) through (i):**										
5.9.2 a)	a) contain the hazards.	X	X	X	X	X		X	X	X	X
5.9.2 b)	b) locate hazards so not accessible by the operator.	X	X	X	X	X		X	X	X	X
5.9.2 c)	c) use a disable function that depends on the orientation of the end-effector.	X	X		X			X		X	
5.9.2 d)	d) reduce collaborative task zones when hazards exist.	X	X	X	X	X		X	X	X	X
5.9.2 e)	e) identify hazard zones where unexpected hazardous processes can occur.	X	X	X	X	X		X	X	X	X
5.9.2 f)	f) use of warnings before and during the hazardous process, which includes residual time after the process has ended.	X	X		X			X		X	
5.9.2 g)	g) use of sequencing based on conditions instead of times.		X				X			X	
5.9.2 h)	h) use of inspection tools to reduce interventions by operators.	X	X		X			X		X	
5.9.2 i)	i) warnings of hot surfaces.	X	X	X				X		X	
5.9.3	End-effector and fixture are designed with reduced sharp edges to reduce human contact forces or pressures.	X		X	X						
5.9.3	Motion is prevented, or operators safeguarded where edges can result in unacceptable contact force(s) or pressure(s).	X	X	X				X		X	
5.9.4	When operators are exposed to risks of an end-effector or a tool attached to an end-effector, risks are reduced by one or more of the following: force sensing according to 5.14.6, end-effector orientation, grip force, speed monitoring, presence sensing, compliant link, or safety functions.		X	X				X			
5.9.4	Where the maximum grip force of the end-effector exceeds the acceptable limits, the grip force applied by the end-effector is reduced and monitored not to exceed acceptable levels in accordance with 5.14.6.			X						X	
5.9.4	The robot speed for which the gripper is intended to be used is considered in the design of the end-effector so that the end-effector and any workpiece(s) are retained.		X	X							
5.9.4	If the end-effector movement is controlled separately from the robot, the stop monitoring is considered in addition to the robot application stopping.		X			X		X		X	
5.9.4	To reduce risks to operators during a collaborative application, end-effector actuation is prevented when the operator is contacted or within a detection zone around the end-effector.	X			X			X		X	

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5.9.4	Presence sensing devices conform with the relevant parts of IEC 61496:2020.									X	
5.9.4	For power and force limiting (PFL) applications, the effective force for initiating a protective stop is in accordance with 5.14.6.			X						X	
5.9.5	**To reduce risks due to end-effectors and workpieces, 5.9.5 (a) through 5.9.5 (c) are provided:**										
5.9.5 a)	a) There are clearances between end-effector/ fixture/ workpiece and any obstructions in accordance with ISO 13857:2019 and ISO 13854:2017 or protection from hazardous situations due to a lack of clearance with between end-effector/ fixture/ workpiece and any obstructions (e.g. support posts, building columns) in accordance with IEC 62046:2018 and ISO 13855:2010. .		X			X	X	X			X
5.9.5 b)	b) Protection is provided from hazardous situations due to stationary obstacles and moving objects in accordance with ISO 13857:2019 and ISO 13854:2017 .			X	X	X		X	X		X
5.9.5 c)	c) There is space to access are entry/exit locations and paths provided to perform expected tasks in accordance with ISO 14122:2016 series, ISO 15534-1:2000 and ISO 15534-2:2000.			X	X	X		X	X		X
5.9.6	End-effector exchange systems have been selected or designed such that loss or restoration of energy supply does not lead to a hazard.		X			X		X		X	
5.9.6	If designing end-effector exchange systems such that loss or restoration of energy supply does not lead to a hazard is not practicable, other safety measures are provided to mitigate against any hazards.		X			X		X		X	
5.9.6	End-effector exchange system design does not lead to a hazardous situation.	X	X			X		X		X	
5.9.6	Release or disconnection of the end-effector(s), using the end-effector exchange function, is prevented at positions where release would lead to a hazard.		X					X	X	X	
5.9.6	End-effectors exchange system withstands the expected static and dynamic requirements.		X	X				X		X	
5.9.6	The integrator ensures that the tool setting, including TCP value, for each individual end-effector has been entered.	X	X		X						
5.9.6	The integrator designs the system to that it selects the proper TCP for the end-effectors that are being changed.		X		X	X	X	X		X	
5.9.6	If motion can be initiated without the end-effector attached, then protective measures are applied to reduce the associated risk.		X		X	X	X	X	X	X	X
5.9.6	Where several robots use the same type of end-effector exchange system, only intentional combinations of robots and end-effectors are permitted.	X	X	X	X					X	
5.9.6	The possibility of incorrect end-effector selection is considered and, where practicable, the robot application detects such a scenario and prevents continued operation until the correct selection occurs.	X	X		X					X	

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5.9.6	Unintended release of the end-effector is prevented.	X	X		X					X	
5.9.6	Release of the end-effector is only in a specific and safe configuration.		X					X	X	X	
5.10	**Vertical transfer components**										
5.10.1	The movement of the carrier of vertical transfer components serving fixed landings is rigidly guided to and at the landings.			X					X	X	
5.10.1	Where operators have access to the carrier, the vertical transfer is designed and constructed in such a way as to ensure that the carrier remains stationary during access.		X		X			X	X	X	
5.10.1	The vertical transfer is designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.		X						X	X	
5.10.1	The vertical transfer is designed and constructed to prevent the risk of load falling off the carrier.		X							X	
5.10.1	Rope carriers, tractors or tractor carriers are held by counterweights or fitted with a device for permanent control of tension.	X								X	
5.10.2	Where there are lifting (vertical transfer) components and there is a risk due to persons falling when the carrier is not present at the landings, guards are fitted to prevent this risk.	X	X					X	X		
5.10.2	Guards do not open in the direction of the hazard zone.	X	X						X		
5.10.2	Guards are fitted with an interlocking device with guard locking that prevents movements of the carrier until the guards are closed and locked and opening of a guard until the carrier has stopped at the corresponding landing.		X							X	
5.10.3	Risk of crushing between the moving parts and the landings is prevented by safeguarding according to 5.8.		X					X			
5.10.3	Sufficient free space is provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier under all the following conditions: it is necessary to access the movement zone; and there is a risk that persons situated under or above the carrier can be crushed between the carrier and any fixed parts.	X	X					X	X		
5.10.4	The carrier automatically stops at the intended positions, or where this is not practicable, movement is only possible with the actuation of a hold-to-run control device.	X	X								
5.11	**Lasers and laser equipment**										
5.11	Where used, laser equipment is designed and integrated to prevent any hazardous exposure to laser radiation.		X			X	X		X	X	
5.11	Where laser equipment is used, the requirements of IEC 60825-1:2014 are applied.		X			X	X		X	X	
5.11	Optical equipment used for observation or adjustment of laser equipment are such that no hazardous situations arise from their use.		X						X	X	
5.12	**Material handling, manual load / unload stations, material flow, and adjacent cells**										

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5.12.1	Operators are safeguarded from hazards associated with material handling.	X	X						X		X
5.12.2.1	Measures are provided to prevent operator exposure to hazards of the manual stations.	X	X						X		X
5.12.2.1	When a perimeter safeguarding is established, allowable gaps and openings are in accordance with 5.8.5.2.			X					X		X
5.12.2.1	Manual stations are designed to prevent access to hazards within the perimeter safeguarding.		X						X		
5.12.2.1	When used to reduce risk by preventing operator and robot from occupying the hazard zone at the same time, monitored-standstill according to 5.5.8 detects entry of the operator into the hazard zone which is occupied by any part of the robot application and brings the hazards to a safe state before they can be accessed.		X			X	X		X		
5.12.2.1	When used to reduce risk by preventing operator and robot from occupying the hazard zone at the same time, monitored-standstill according to 5.5.8 prevents any part of the robot application from entering a hazard zone occupied by an operator or brings the hazard to a safe state before it reaches the operator.		X			X	X		X		
5.12.2.2	Safeguarding is provided in accordance with 5.8.					X	X		X		
5.12.2.2	Gaps between a moving station and any fixed element complies with ISO 13854:2017, Table 1, to prevent crushing.		X								
5.12.2.3	When presence sensing is used to detect the operator in the safeguarded space, the detection zone of presence-sensing devices includes the entire hazard zone.	X	X	X	X				X		X
5.12.2.3	When presence sensing is not practicable and an operator can pass through the detection field of the SPE and access a hazard zone, the SPE initiates a protective stop according to 5.8.5.2.		X		X	X					
5.12.2.3	When presence sensing is not practicable and an operator can pass through the detection field of the SPE and access a hazard zone, a start/restart interlock is provided according to 5.5.7.1.		X		X	X					
5.12.2.3	Other measures are provided to prevent inadvertent resetting of the start/restart interlock, thereby preventing the robot application from moving into the hazard zone while the operator remains in the hazard zone.		X		X	X					
5.12.2.3	When manual reset is provided, the whole of the safeguarded space is visible from the reset device unless further measures in accordance with 5.8.7 are applied.	X	X	X	X	X			X		
5.12.3	Where materials enter or exit the safeguarded space, safeguarding prevents operator from coming into contact with hazards or brings hazards to a safe state before they can be accessed, without creating additional hazards.	X	X		X	X			X		X
5.12.3	Access to a hazard is prevented or the access detected.	X	X		X	X			X		X
5.12.3	Hazards are brought to a safe state before they can be accessed.	X	X		X	X			X		X
5.12.3	The dimensions of openings in guards to allow material entry and exit are the minimum dimensions necessary for passage.	X	X	X	X				X		

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5.12.3	Possible crushing/shearing hazards between the material and the sides of the opening are eliminated by design and/or additional safeguarding.		X	X	X	X			X		
5.12.3	Where openings for material entry and exit are safeguarded using ESPE, access to the safeguarded space is prevented by the material itself, or by other means according to IEC 62046:2018.		X	X		X			X		
5.12.3	Where openings for material entry and exit are safeguarded using ESPE, the ESPE allows passage of materials by either: a muting function; or a change in protection (e.g. blanking).		X			X	X		X		
5.12.3	Where openings for material entry and exit are safeguarded using ESPE, and the ESPE allows passage of materials by change in protection area (e.g. blanking), the minimum distance indicated by the ESPE manufacturer is applied according to IEC 62046:2018.		X	X		X			X		
5.12.3	The performance levels of muting and blanking safety functions do not adversely affect the performance level of the safety function of the ESPE.		X			X	X				
5.13	Safeguarding is provided to prevent exposure to hazards from adjacent robot cells.		X	X		X			X		X
5.13	Safeguarding is provided to reduce risk due to material transfer into and out of adjoining robot cells.		X	X		X			X		X
5.13	Safeguarding is provided either to prevent operator access to adjacent robot cells from within a robot cell, or to bring hazards within adjacent robot cells to a safe state.		X	X		X			X		X
5.14	**Collaborative applications**										
5.14.1	Operator(s) performing a collaborative task within a safeguarded space are protected from injury due to contact from moving parts of the robot application.		X			X	X		X		
5.14.1	Protective measures are provided for the safety of operator(s) in the event of contact or stop the robot application motion and other hazards before contact occurs.		X			X			X		X
5.14.1	As determined in the application risk assessment, protective measures address quasi-static and transient contact hazards to the operator.		X	X		X	X		X		
5.14.1	Contact exposure to sensitive body regions is avoided according to 5.14.6.3, or if this is not practicable, guards and/or protective devices are applied.	X	X	X		X		X	X		
5.14.1	If one or more operator(s) are within the safeguarded space during robot application motion in automatic operation, all required safeguards are active.		X			X	X		X		
5.14.1	Robots used for integration into a collaborative application conform with the relevant requirements in ISO 10218-1:2025, 5.10.		X			X	X		X	X	
5.14.1	Sharp edges are rounded and softened as far as practicable to reduce human contact forces or pressures.	X	X	X						X	
5.14.1	Motion is prevented, or operators safeguarded where edges can result in unacceptable contact force(s) or pressure(s).	X	X	X			X			X	

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.14.1	As determined by the application risk assessment, application of protective measures addresses the expected exposure of the operator.	X	X	X			X	X			
5.14.1	The collaborative application shall be provided with a means for extrication from trapping situations.		X				X	X	X		
5.14.2	Safeguarded space is designed so that the operator can perform all intended tasks and be protected from hazards.	X	X						X	X	X
5.14.2	Additional hazards are not introduced due to layout and location of equipment and machinery.		X	X					X	X	
5.14.2	Robot application is controlled to prevent hazardous contact and clearance risks.		X	X		X			X	X	
5.14.2	Safeguarded space where operator(s) can interact directly with the robot application is clearly defined.	X		X					X	X	
5.14.3	Operators are protected from hazardous situations during transitions.		X			X	X		X	X	
5.14.3	If the transition is from collaborative to non-collaborative task, start of non-collaborative task is prevented until the operator is outside the safeguarded space.		X			X	X		X	X	X
5.14.4	**Hand-guided control (HGC)**										
5.14.4.1	For HGC use, the robot application is designed to allow direct control of the robot application movement by the operator.		X		X	X	X	X		X	
5.14.4.1	HGC robot application has the following: monitored-speed safety function according to 5.5.6.2; stop category 2 (IEC 60204-1:2016+AMD1:2021) protective stop according to 5.6.3; and monitored-standstill safety function according to 5.5.8.		X			X	X			X	
5.14.4.1	The risk assessment was used to determine the monitored-speed limit value.			X			X	X		X	
5.14.4.1	If operator safety is dependent on limiting the range of robot motion, the robot has software-based limiting safety functions in accordance with ISO 10218-1:2025, 5.7.4.		X	X		X	X		X	X	
5.14.4.1	Hand-guided controls (HGC) conform with ISO 10218-1:2025, 5.14.3.		X			X			X	X	
5.14.4.1	When the operator actuates the HGC hold-to-run control, the monitored-standstill is released, and the operator performs the hand-guided collaborative task.		X			X			X		
5.14.4.1	While using HGC, operator has clear visibility of the hazard zone while hand-guiding the robot application to the intended position(s).		X			X			X		
5.14.4.1	When operator releases the HGC hold-to-run control, a monitored-standstill safety function in accordance with 5.5.8 is triggered unless one or both of the following provides acceptable risk reduction: power and force limiting (PFL) according to 5.14.6; and/or speed and separation monitoring (SSM) according to 5.14.5.		X			X			X		

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Table H.1 *(continued)*

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.14.4.1	HGC collaborative applications are designed, positioned, and integrated considering the user operation of controlling the robot such that pinching, crushing sharp edges and other "caught-in" or "compressed by objects" injury risks are reduced or eliminated through design.		X			X			X		
5.14.4.2	The location, layout and control of motion through the hand-guided device shall be considered for a hand-guided type of collaborative application.			X					X		
5.14.4.2	The mapping of actuation direction of the HGC to the motion of axes, robot and end-effectors is clearly shown.		X			X	X		X		X
5.14.4.2	The direction of motion of the robot and end-effector is easily controlled by the HGC.		X			X	X		X		X
5.14.4.2	The HGC is located so that the operator has an unobstructed view of entire hand-guided task zone, including workpiece motion, any hazards that might arise from motion and visibility of operators entering the task zone.	X	X						X		
5.14.4.2	The HGC minimizes operator exposure to moving workpieces.		X						X		
5.14.4.2	The HGC is located such that operator positioning and posture does not cause additional hazards.		X								X
5.14.4.2	The HGC provides an ergonomically favourable posture for the operator.	X	X						X		
5.14.4.2	End-effector safety functions are provided to prevent inadvertent release of a workpiece which cause a hazardous situation according to 5.9.		X			X	X		X		
5.14.4.2	Loss or change of power does not lead to loss of load, unexpected motion or other hazards, in accordance with 5.2.10.		X			X					
5.14.5	**Speed and separation monitoring (SSM)**										
5.14.5.1	Speed and separation monitoring (SSM) applies to all people within the safeguarded space.		X		X	X	X		X	X	
5.14.5.1	If the performance of the protective device is limited by the number of people in the safeguarded space and the number has been exceeded, a protective stop occurs.		X			X	X				
5.14.5.1	SSM is implemented in accordance with Annex L, ISO 13855:2010 and IEC 62046:2018.		X			X	X				
5.14.5.1	Collaborative applications using SSM use an SPE that detects entry into the safeguarded space and/or monitors the presence of any person.		X			X	X				
5.14.5.1	When a presence-sensing device (PSD) is used to define detection zones, the size and location of the detection zones are set so that the separation distance is maintained including consideration of deceleration time.		X	X		X	X				X
5.14.5.1	The time from activation of a stop command and for the robot application to decelerate to stop (v_s in Annex L) is included in the separation distance.		X	X							X

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.14.5.1	If stopping performance is not monitored by a safety function, then stopping performance is checked and the SSM application or safety function parameters modified when the stopping performance degrades.			X		X	X				
5.14.5.1	If the distance between the operator(s) and moving parts of the application decreases to a value below the separation distance, a stop of the robot application occurs, in accordance with 5.6.3.		X	X	X	X	X			X	
5.14.5.1	When used with PFL, the transition time for PFL to become active is included in determining the minimum separation distance.		X	X		X	X	X		X	
5.14.5.1	Robots used for SSM with dynamic speed implementation conform with the requirements of ISO 10218-1:2025, 5.10.3, which also requires inclusion of the time for the robot application to decelerate and reliably stop.		X	X		X	X	X		X	
5.14.5.2	The SSM collaborative application has a monitored-speed safety function(s) and a mean for adjusting the parameters of the robot monitor-speed safety function(s) according to 5.5.6.2.		X	X		X	X	X			
5.14.5.2	The SSM collaborative application has a speed and separation monitoring (SSM) safety function to continuously monitor relative distances and speeds of person(s) and the robot application.		X	X		X	X	X			
5.14.5.2	If operator safety is dependent on limiting the range of robot application motion, the robot has software-based limiting safety function(s) in accordance with ISO 10218-1:2025, 5.7.4.		X	X		X	X		X		X
5.14.5.2	Delays in communication to realize SSM are included in the separation distance monitoring safety function.		X	X		X	X				
5.14.5.2	When SSM robot application may resume operation automatically following a protective stop and monitored-standstill according to 5.5.8, the separation distance is maintained, and no people are within the SSM safeguarded space.		X		X	X	X		X		X
5.14.5.3	Monitoring separation distances are provided by safety function(s).			X		X	X				
5.14.6	**Power and force limiting (PFL)**										
5.14.6.1	PFL application uses robot that complies with the requirements of ISO 10218-1:2025, 5.10.4.									X	
5.14.6.1	PFL application is designed to adequately reduce risks of injury by not exceeding applicable threshold limits for contact events.		X	X	X	X	X	X	X		
5.14.6.1	Pressure and force contact parameters are verified of the identified contact event(s).		X	X							
5.14.6.1	Safety functions are used and configured for the robot application such that the risk of injury is lessened to an acceptable level.			X							
5.14.6.2	Contact from moving parts of the robot application to body regions are categorized as either quasi-static contact or transient contact.		X						X		X
5.14.6.3	The severity and probability of occurrence of contact events from the moving parts of the robot application to an operator(s) are reduced.		X	X		X		X	X		X

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.14.6.3	Hazards associated with contact to the face, skull and forehead are considered in the risk assessment.	X	X		X			X	X	X	X
5.14.6.3	**Severity and probability of occurrence of contact events are reduced, by fulfilling as necessary for risk reduction 5.14.6.3 a) through 5.14.6.3 h):**										
5.14.6.3 a)	a) Severity and probability of occurrence of contact events are reduced, by layout design (5.4), robot application design (5.4.3), use of safety functions according to 5.5 and Annex C.		X	X		X	X	X	X		X
5.14.6.3 b)	b) Severity and probability of occurrence of contact events are reduced, by end-effector design, selection and implementation in accordance with 5.9.		X	X		X	X	X	X		X
5.14.6.3 c)	c) Severity and probability of occurrence of contact events are reduced, by end-effector exchange systems, if provided, design, selection and implementation in accordance with 5.9.6.		X	X		X	X	X	X		X
5.14.6.3 d)	d) Severity and probability of occurrence of contact events are reduced, by one of more of the following: — reducing speed by: speed limiting safety function, according to 5.5.6; — trigger a lower speed value for the speed limiting safety function when approaching a potential clamping contact event; — using a protective device that either triggers the speed reduction when an operator is detected, or the protective devices triggers a protective stop to prevent contact from occurring.		X	X		X	X	X	X		X
5.14.6.3 e)	e) Severity and probability of occurrence of contact events are reduced, by implementing the PFL collaborative application to avoid potential contact(s) by keeping the tool direction away from operator(s), which can be implemented with a safety function for pose limiting or orientation limiting.		X	X		X	X	X	X		X
5.14.6.3 f)	f) Severity and probability of occurrence of contact events are reduced, by reducing the effective mass of moving parts of the robot application by selection of robot, end-effector and other payload influences.		X	X		X	X	X	X		X
5.14.6.3 g)	g) Severity and probability of occurrence of contact events are reduced, by keeping movements away from the operator by implementation of limiting devices according to 5.4.7.		X	X		X	X	X	X		X
5.14.6.3 h)	h) Severity and probability of occurrence of contact events are reduced, by the use of guards and/or protective devices to protect sensitive body regions, including the skull, forehead, larynx, eyes, ears, or face.		X	X		X	X	X	X		X
5.14.6.3	Risks due to contact with the face, skull and forehead (Annex M, Table M.3, Body Regions 1, 2 and 3) in a PFL application are reduced.		X	X		X	X		X		X
5.14.6.3	PFL applications avoid foreseeable contacts with sensitive parts of the body including the skull, forehead, larynx, eyes, ears, or face.		X	X		X			X		X

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.14.6.3	Preventive measures reduce risk of contact with sensitive body parts due to unintentional or reasonably foreseeable misuse.		X	X		X			X		
5.15	**Assembly, installation and commissioning**										
5.15.1.1	Commissioning plan includes information for protective measures for operators during commissioning.	X						X	X		
5.15.1.2	Interim safeguards protect against hazards identified in risk assessment.	X	X					X	X		
5.15.1.2	Appropriate safeguarding means are in place prior to initiating power-on start-up testing and verification.	X	X					X	X		
5.15.1.2	Awareness means are installed to indicate the boundary of the restricted space.	X							X		
5.15.1.3	Initial start-up procedure plan is established and includes items listed in 5.15.1.3 as a minimum.									X	
5.15.1.3	Before applying power, the following have been installed as intended: mechanical mounting and stability; electrical connections; utility connections; communications connections; peripheral equipment and systems; limiting devices for reducing the range of motion to a subset of the maximum space.	X			X	X		X	X	X	
5.15.1.3	Instructions are provided that all operators exit the safeguarded space prior to applying drive power.									X	
5.15.1.3	After power is applied, the items listed in 5.15.1.3 c) are verified.		X	X		X	X		X		X
5.15.2	Environmental conditions like surrounding temperature, humidity, electro-magnetic disturbances, surrounding lighting, etc., are considered in the design and protective measures.		X						X		
5.15.2	Components can withstand the expected use and environmental conditions.		X	X					X	X	
5.15.3	All sources of robot application and other equipment power meet the requirements specified by the machine and component manufacturers.					X				X	
5.15.3	Electrical installations meet the requirements of IEC 60204-1:2016+AMD1:2021.					X				X	
5.15.3	Hydraulic power installations meet the requirements of ISO 4413:2010.					X				X	
5.15.3	Pneumatic power installations meet the requirements of ISO 4414:2010.					X				X	
5.15.4	Indoor lighting meets the requirements of ISO 8995-1:2002.		X	X							
5.15.4	Outdoor lighting meets the requirements of ISO/CIE 8995-3:2018.		X	X							
5.15.4	Adequate lighting is provided in areas of frequent inspection, adjustment or maintenance.	X	X	X	X			X			
5.15.4	Additional lighting results in an illumination intensity of 500 lx.			X							
5.15.5	Controls are labelled to clearly indicate their function, according to IEC 60204-1:2016+AMD1:2021, IEC 61310-1:2007 and IEC 61310-2:2007.	X								X	
5.16	**Maintenance**										

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		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
5.16.1	As far as practicable, adjustment, maintenance, repair, cleaning and servicing task are possible while the robot application is at a safe state.		X			X	X		X		
5.16.1	Robot cell is designed and constructed to allow safe access to where intervention is necessary during maintenance.	X							X		
5.16.1	When it is necessary to perform maintenance within the safeguarded space, the system has local means of controlling and isolating hazardous energy.	X				X			X		
5.16.1	When it is necessary to perform maintenance within the safeguarded space and these tasks are anticipated and integral to production and the tasks need to be performed without energy isolation, effective alternative protective measures are provided.		X			X	X				
5.16.1	When effective alternative protective measures are provided, the protective measures for the control of hazardous energy or for position monitoring includes one or more of 5.16 c) 1 through 4.										
5.16.2	If the application requires movement without drive power capability, the integration fulfils this requirement.	X	X			X		X		X	
5.16.2	When movement without drive power is used, the implementation complies with the instructions for use.	X				X				X	
5.16.2	When movement without drive power is used, warnings and information are updated.	X								X	
5.16.2	Means to actuate the end-effector in a hazardous situation have been integrated.		X				X			X	

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Annex I
(informative)

End-effectors

I.1 Gripper end-effectors

I.1.1 General

End-effectors often include gripping mechanisms designed to hold workpieces. In general, there are two gripping principles with advantages and disadvantages, namely mechanical actuation (e.g. grasping or clamping) and non-mechanical actuation (e.g. vacuum cups and magnetic grippers). The choice of principle and the mechanical design can be selected to be suitable for the specific application.

When selecting or designing a gripper for a specific application, the features and functions of the end-effector can be a part of the risk-reduction measure(s). These gripper features and functions include the following:

a) manual move or release function for use without power, to free entrapped fingers or other body parts;

NOTE Power includes, but is not limited to, electrical, pneumatic, hydraulic, kinetic, or stored energies.

b) persistent gripping function under loss of power, to prevent a heavy workpiece from falling out;

c) minimization of gripping forces needed to achieve adequate grasping of an object instead of maximum force available;

d) application design measures in which crush hazards are eliminated (e.g. force limiting safety function(s) while the robot is positioning the gripper, inhibiting gripper closure if the gripper is not in the grip location, sufficient clearance for an operator's fingers not to be crushed when the gripper closes).

End-effectors can be designed, constructed and selected such that risks associated with airborne noise are reduced, particularly at the source of emission. If noise emission is relevant, then reproducible noise emission data can be provided with the end-effector.

I.1.2 Grasp-type grippers

Workpieces can be secured in grasp-type grippers, typically either by a form closure grasp or by force closure grasp. In the former case, the grasping surfaces geometrically trap the workpiece in place. The latter case holds the workpiece through friction generated by the grasping force between the workpiece and grasping surfaces.

NOTE See ISO 14539:2000, 3.2.1.2 and 3.2.1.3 for definitions of "form closure grasp" and "force closure grasp".

Some grippers can have a physical capability of actuating with forces that are significantly higher than the forces they are normally configured to provide. Systems that control gripping forces can have either a fixed or adjustable force setting. If a fault in the gripper control system can result in an unacceptable risk in the robot application, then a safety-related function prevents forces from exceeding the limit value threshold.

If forces are adjustable, the interface is designed such that setting and adjusting can be performed to consistent values. Verification of settings (e.g. by use of a checksum indication) and protection against unauthorized changes (e.g. by use of password) can be necessary, according to 5.5.

With the use of pin grippers for grasping of workpiece by penetrating the surface with pins, needles and hooks, the sharpness of the penetrators is a consideration.

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I.1.3 Vacuum grippers

Loss of the workpiece is a concern with vacuum grippers.

If the loss of vacuum can result in a hazard, the following can be considered to reduce risks:

a) redundant or diverse vacuum systems (each branch capable of holding the workpiece in place);

b) safety-related control and generation of vacuum with an appropriate performance level;

c) warning signals (audio/visual) when power is lost and vacuum holding of a workpiece is only maintained for a limited time.

I.1.4 Magnet grippers

Loss or release of the workpiece(s) due to a loss of power or a change of the magnetic field can be a concern with magnet grippers. The influences of the magnetic fields are considerations in the selection and use of magnet grippers.

If the loss of or release of the workpiece(s) can result in a hazard, the following can be considered to reduce risks:

a) diverse or redundant magnetic systems (each branch capable of holding the workpiece in place);

b) safety-related control and generation of magnetic field with an appropriate performance level;

c) warning signals (audio/visual) when power is lost and holding a workpiece is only maintained for a limited time.

The activation/deactivation of the magnet gripper can be safely monitored in accordance with 5.5 and Annex C.

I.2 Application specific end-effectors

I.2.1 General

There are application specific end-effectors where the end-effector performs a work on a workpiece or to its environment and does not manipulate by grasping. When an operator is exposed to hazards created by the end-effector's applications, the end-effector is designed so the hazardous attributes of its operations are reduced to an adequate level.

I.2.2 Application examples

Application examples include:

a) joining/assembly/adhesive/inspection (e.g. welding, laser, sensing, measuring, pressure, gluing, sealing, riveting);

b) fastening (e.g. torque gun);

c) material removal/cutting/trimming/grinding/polishing/deburring/sanding (e.g. laser, blade, water-jet, drilling);

d) dispensing/spraying/coating (e.g. hot glue, paint, mould injection, foundry);

e) use of technologies with emissions (e.g. laser, water cutting, radiation, ultrasonic).

I.2.3 Weld applications

End-effectors for any welding applications are designed such that the welding wire feeders do not unintentionally forward the welding wire with the risk of hitting the eyes of an operator. Examples of ways

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to achieve such a design include using a disable function that depends on the orientation of the end-effector or using orientation safety functions of the robot.

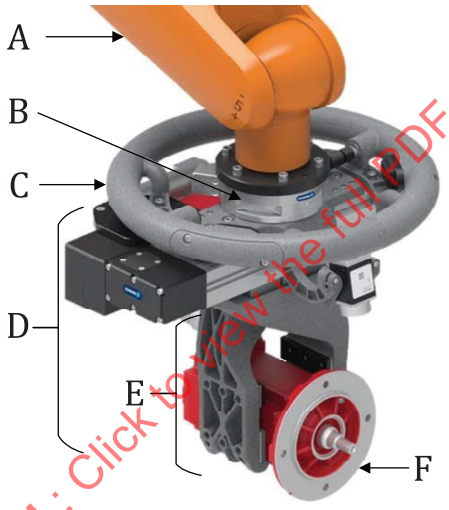
NOTE Welding applications typically strongly encourage either personal protective equipment (PPE) and/ or weld curtains to protect the operator against welding light and splatters as a complementary means of protection for residual risks.

I.3 Examples for collaborative applications

I.3.1 HGC integrated into the end-effector

HGC is intended to provide direct operator input to effect robot motion in accordance with 5.14.4. If the hand-guided application involves moving loads in a gripper, the HGC could provide the means to open and close the gripper.

Figure I.1 shows an application example of hand-guided control integrated into an end-effector for a collaborative application. The gripper grasps the workpiece in an area where the gripper is separated from a person. The operator uses the HGC to guide the gripper while pressing hold-to-run controls on the HGC, which uses a hand-guided wheel, for the collaborative task.



Key

A	manipulator	D	end-effector
B	force-torque sensor	E	gripper “fingers”
C	hand-guiding wheel, with hold-to-run controls	F	workpiece

Figure I.1 — HGC integrated into the end-effector example

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I.3.2 Power and force limited (PFL) end-effector

Figure I.2 shows an application where the workpiece or end-effector can contact a person. This example is solely about PFL of the end-effector. The example does not show or reflect risk reduction that can be required of the robot. Figure I.2 is not to scale.

If the forces and pressures could be higher than acceptable limits, the end-effector gripping force is limited by a safety function. For guidance, see Annex M.

The performance level required (PL_r) of any end-effector safety functions are in accordance with 5.5.

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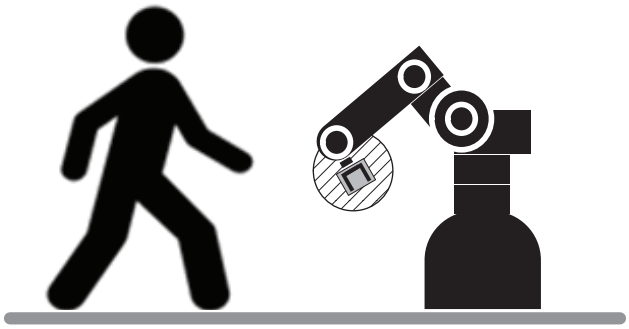


Figure I.2 — Force and pressure limiting (PFL) by the gripper example

I.4 Gripper designs and their safety performance

Electric grippers can have an internal or an external controller and motor control. In both cases, forces and pressures higher than Annex M, can be safely limited for a power and force limiting collaborative applications.

Grippers that are capable of forces and pressures higher than acceptable limits, could require the use of a safety function to reduce risks, though other protective measures could achieve the same level of risk reduction. For guidance, see Annex M.

A monitored-standstill is required in accordance with 5.5.8.

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Annex J
(informative)

Safeguarding manual load and unload stations

J.1 Risk assessment

The hazards associated with manual load/unload stations are listed Annex A. Manual load/unload stations bring the operator close to the hazards associated with the load/ unload stations.

The risk assessment for manual load/unload stations addresses the following:

a) possibility of unintentional access to the safeguarded space inside the robot cell;

b) possibility of intentional access to the safeguarded space inside the robot cell (e.g. maintenance or other manual intervention);

c) likelihood of restart of the robot application occurring while an operator is within the safeguarded space (e.g. if another person outside the robot cell restarts the robot cell without being aware that an operator is inside);

d) automatic operation with an operator at a task zone near the manual load/unload station.

J.2 Design

J.2.1 General

Manual load/unload stations require operator interaction with the robot application in the task zone, but not simultaneously for most applications. For PFL collaborative applications, the interaction can be at the same time according to 5.14.6.

There are two main concerns:

a) safeguarding the operator from hazards introduced by the robot application;

b) preventing access to hazard zones beyond the manual load/unload station.

The dimensioning of safeguards and protective structures against access to hazard zones is described in ISO 14120:2015, ISO 13857:2019 and 5.8.

To minimize ergonomic risks, manual load/unload stations can be lower than 1 400 mm. ISO 13857:2019 states that protective structures lower than 1 400 mm should be used with additional protective measures.

Continuous presence sensing by an SPE can be used as a measure to prevent either or both of the following:

— unexpected start-up (5.7.3);

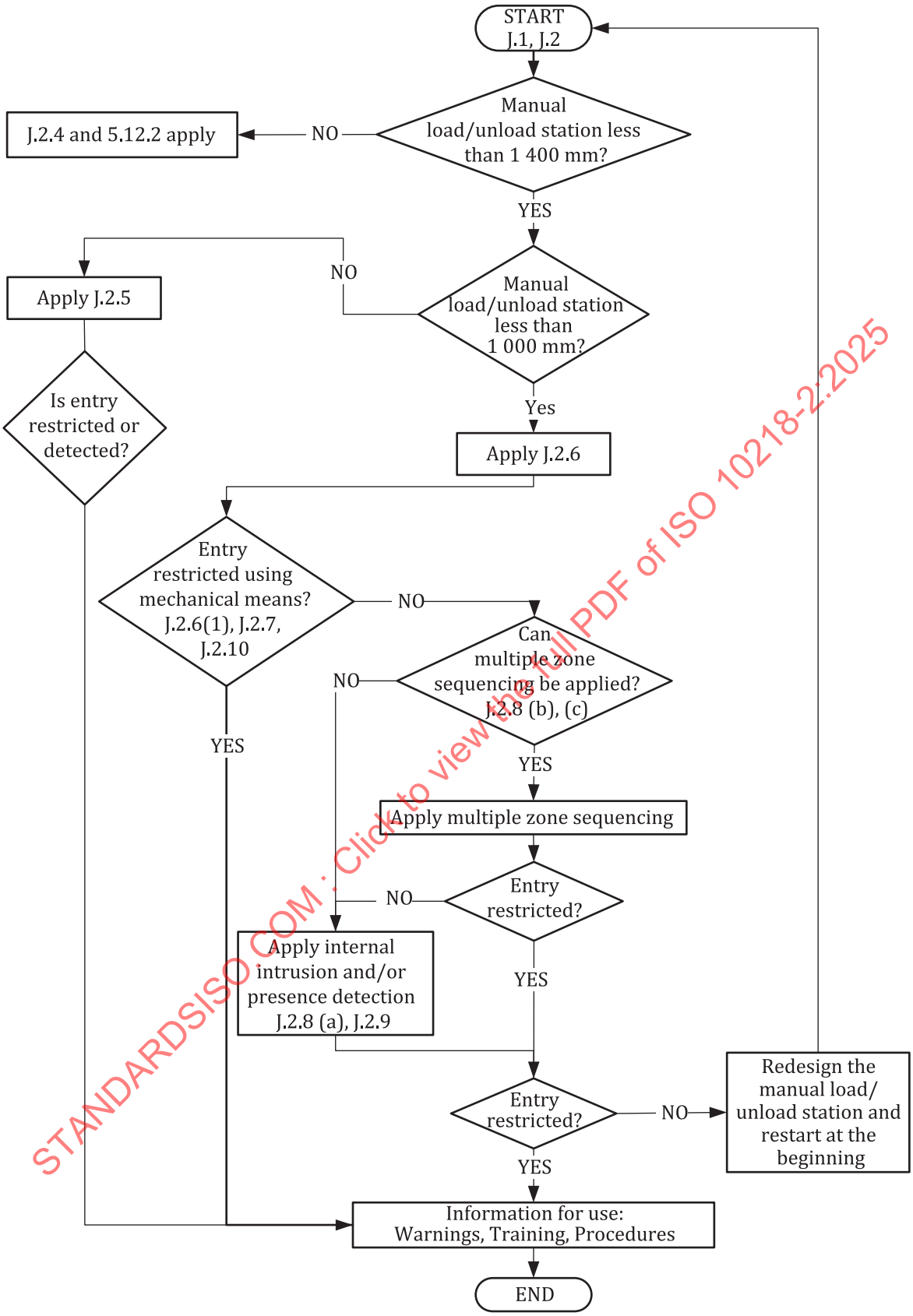
— contact between the operator and robot application.

NOTE An example of ergonomic risk is handling heavy or large workpieces during manual load/unload operations. Inadequate design of the task, machine or robot cell could lead to increased ergonomic risk factors to the operator. Further information regarding ergonomic risk factors is given in ISO 6385:2016, ISO 14738:2002 and Table A.1 ergonomic hazards.

Figure J.1 is a risk reduction flowchart for this Annex.

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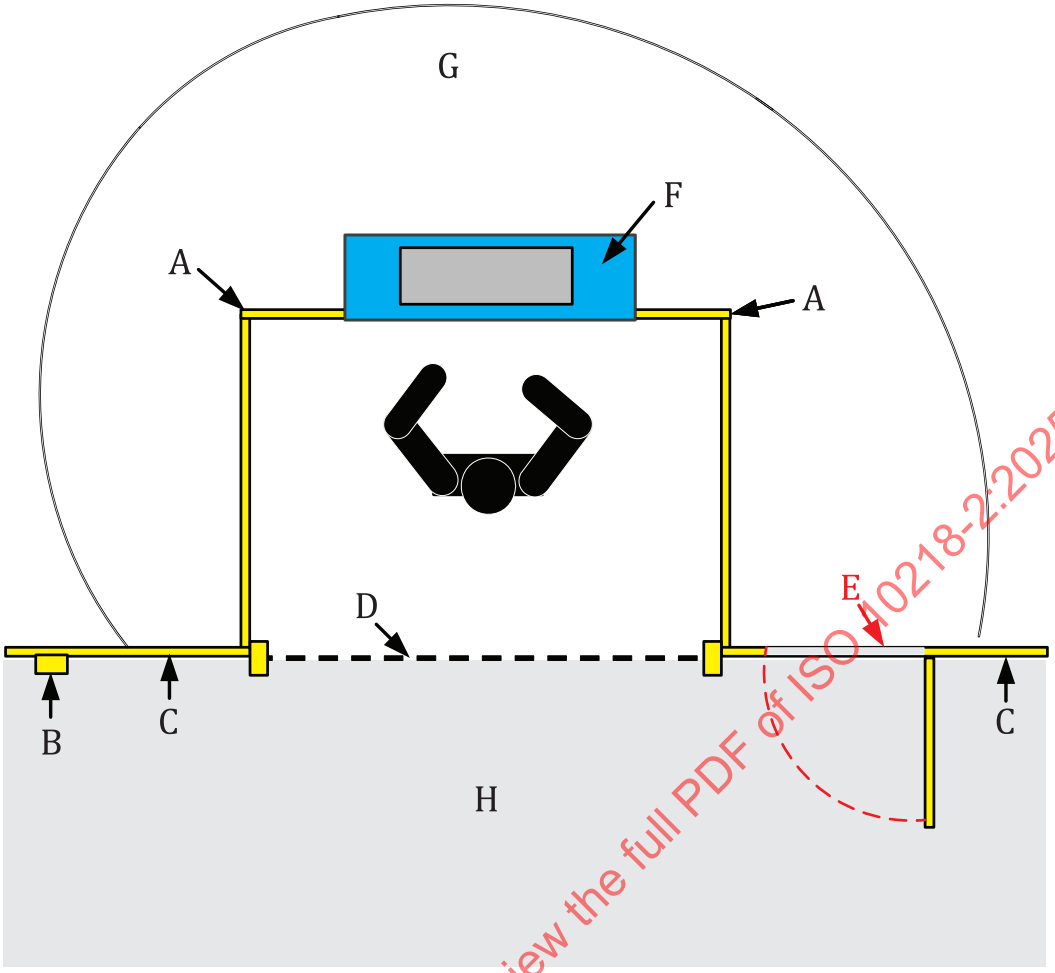


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Figure J.1 — Manual load/unload station risk reduction flowchart

An example layout of a manual load/unload station is illustrated in Figure J.2.

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Key

A guard
B reset
C perimeter guard
D protective device (sensitive protective equipment) or interlocked guard
E maintenance access (shown as interlocked guard)
F manual load/unload station
G hazard zone within the safeguarded space
H area outside the safeguarded space (non-hazard zones)

NOTE Surrounding safeguarding is not shown in the Figure for simplicity of the illustration.

Figure J.2 — Example layout of a manual load/unload station with a reset interlock

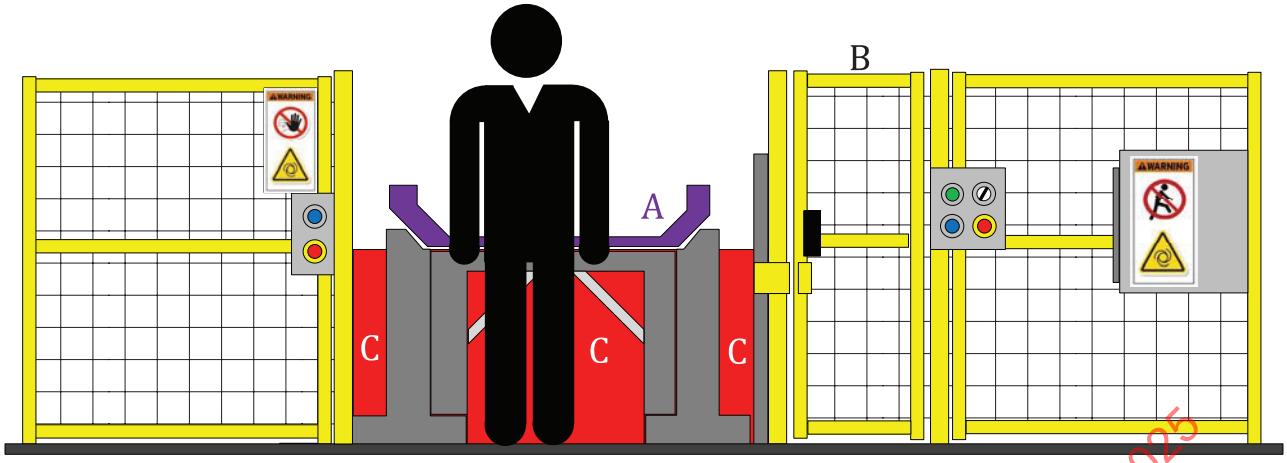
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J.2.2 Example safeguarding of a manual load/unload station with an adjacent interlocked guard

Subclauses 5.12, 5.13 and 5.16 specify requirements for means for the safe access of the operator to the robot application or robot cell for material handling, manual loading/unloading, material flow, other manual stations and maintenance. The means of access is shown near the manual load/unload stations in Figure J.3. Figure J.3 shows general principles without details. For simplicity of viewing, surrounding safeguarding and the openings (C) under the workpiece (A) are shown without the guarding that is required to prevent access.

NOTE 1 See 5.12.2 for the requirements of manual load/unload stations and other manual stations. ISO 13857:2019 provides guidance on preventing access through an opening in any fixture or part of a manual load/unload station.

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Key

A workpiece

B interlocked guard

C openings that require obstruction to prevent access

NOTE Surrounding perimeter safeguarding and guards to prevent access below the workpiece (A) are not shown in the Figure to simplify the example. See Figure J.9. SPE could be used instead of obstructions for "C".

Figure J.3 — Interlocked guard allowing access

Safeguarding against operators reaching from the manual load/unload station into hazard zones is ensured by means of guards according to ISO 14120:2015, with distances according to ISO 13857:2019, Table 2 and functional safety according to 5.5. The robot application is prevented from reaching any operator using limiting devices according to 5.4.7.

The integration needs to account for the stopping angle/ distance when establishing the restricted space(s), which can change dynamically according to 5.4.7.4.

NOTE 2 The robot application stopping distance can initially be determined by simulation, but the actual stopping distance is later verified and validated for the application according to Clause 6 and Annex H. The stopping distance could be limited by a safety function.

J.2.3 Example safeguarding separation distances of manual load/unload station

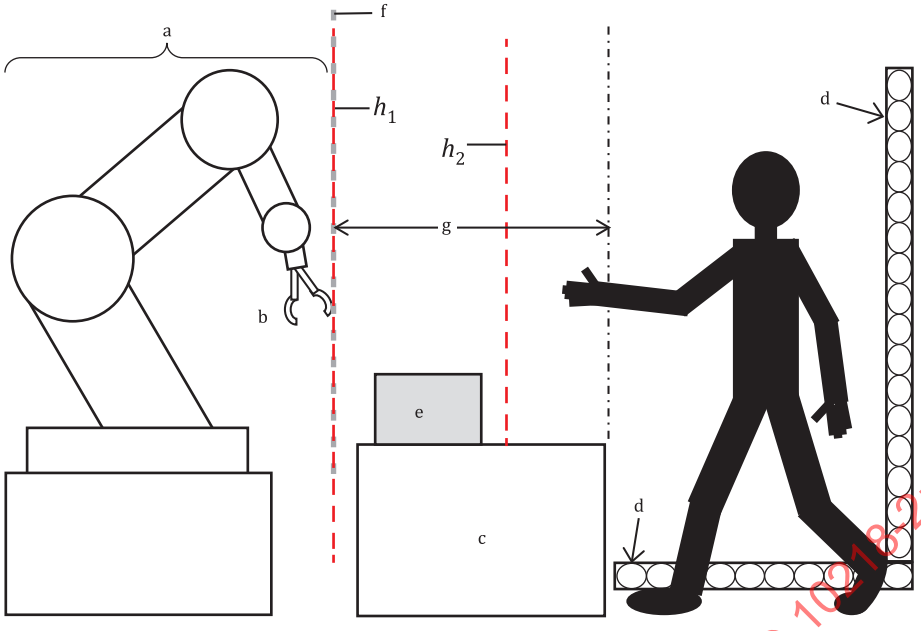
Safeguarding against hazards that the operator could reach while standing near the manual load/unload station is fulfilled by sensitive protective equipment (SPE), guards and interlocked guards, which are installed according to ISO 14119:2024, ISO 14120:2015, ISO 13857:2019, ISO 13855:2010 and 5.12.

NOTE See Figure J.4, Figure J.5 which show a manual load/unload station using dynamic limiting, however not all the required safeguarding is shown.

Stepping behind and remaining undetected by the protective device at the entry of the manual load/unload station is prevented by design measures (i.e. distance between the entry protective device and perimeter safeguarding) or by additional safeguards (e.g. by using a horizontal AOPD as shown in Figure J.4). The system restarts according to 5.5.7. Figure J.4 and Figure J.5 illustrate the use of dynamic limiting which dynamically changes the restricted space.

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Key

g^{Δ} distance according to ISO 13857:2019 when manual load/unload station is an impeding device

h_1 restricted space (including workpiece) when either of the AOPDs (d) are obstructed

h_2 restricted space (including workpiece) when either AOPD (d) is unobstructed

Δ separation distance “g” from the edge of the impeding device to h_1 is determined by the:

— intrusion is not detected (J.2.8) by “f”, which is the safety-related input to the SRP/CS for dynamic limiting

— operator detected in the manual load/ unload area by horizontal “d”

— dynamically changed restricted space, at either ”h_1"or ”h_2" and

— manual load/ unload station is the impeding device (J.2.7)

ǂ surrounding perimeter safeguarding and prevention or detection of access at the manual load/unload station are not shown in the figures to simplify the example

a Robot with end-effector.

b End-effector.

c Manual load/ unload station.

d Light curtain (AOPD) shown (other SPE can be used) – 1 vertical (J.2.8) and 1 horizontal (J.2.9).

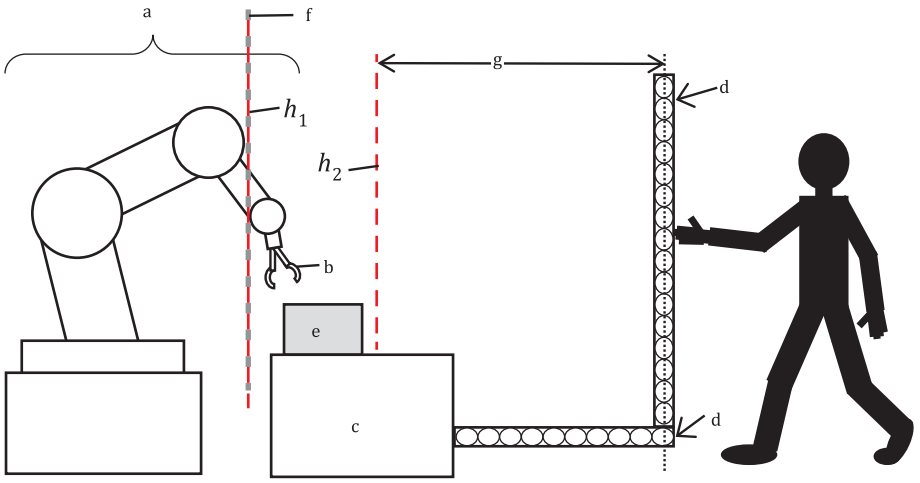
e Workpiece.

f Dynamic limiting (5.4.7.4) safety-related input to the SRP/CS to dynamically change the restricted space.

Figure J.4 — Example of an operator at a manual load/unload station

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Key

g$^{\Delta}$ separation distance according to ISO 13855:2010

h restricted space of robot application (including workpiece)

Δ separation distance "g" from the vertical AOPD (d) to the restricted space h_2 is determined by the:

- robot system (a) intrusion is detected by "f", which is the safety-related input to the SRP/CS for dynamic limiting to make h_2 active as the restricted space
- no intrusion and no presence are detected by either AOPD (d)

ǂ surrounding perimeter safeguarding and prevention or detection of access at the manual load/unload station are not shown in the figures to simplify the example

a Robot with end-effector.

b End-effector.

c Manual load/ unload station.

d Light curtain (AOPD) shown (other SPE can be used) – 1 vertical (J.2.8) and 1 horizontal (J.2.9).

e Workpiece.

f Dynamic limiting (5.4.7.4) safety-related input to the SRP/CS to dynamically change the restricted space.

Figure J.5 — Example of a robot application at a manual load/ unload area

J.2.4 Impeding devices of height greater than or equal to 1 400 mm

See 5.12.2 for the requirements where the height of the impeding device is greater than or equal to 1 400 mm.

J.2.5 Impeding devices of height from 1 000 mm to 1 400 mm

If the impeding device height of 1 400 mm cannot be achieved due to robot cell design, the impeding device height could be reduced to 1 000 mm depending on the protection given by the shape of the impeding device and the results of the risk assessment. The deviation from the height of 1 400 mm is as small as possible. The areas where the height of 1 400 mm is not achieved are kept to a minimum.

When the height of the manual load/unload station is between 1 400 mm and 1 000 mm, the fixture or manual load/unload station can become the impeding device to restrict entry into the robot cell (see ISO 13857:2019). While the fixture or manual load/unload station could be an adequate impeding device, the risk assessment addresses hazards presented by both the robot application and any additional safeguarding needed. For example, forklift pockets can create natural steps for climbing.

If impeding devices are below 1 400 mm in height, they should be provided with additional protective measures according to ISO 13857:2019. These can be a combination of the following:

a) keeping guards and impeding devices at manual load/unload stations as high as practicable;

b) keeping openings and slots as small as practicable;

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c) additional protective devices, e.g. interlocked guards (see ISO 14119:2024) and SPE (see ISO 13855:2010) to safely control hazards within the robot cell.

NOTE See 5.8.5.2 and 5.8.9 for minimum distance requirements.

The following complementary measures can be used to supplement, but not be used instead of safeguarding:

— measures to further reduce the residual risk of circumvention of the impeding device by providing a nearby safe means of entry with the related training to operators;

— warning signs;

— written instructions at the manual load/unload stations.

J.2.6 Impeding devices of height less than 1 000 mm

ISO 13857:2019 specifies that a manual load/unload station that is lower than 1 000 mm is insufficient to restrict entry; it needs an additional protective device.

In such cases, entry is detected using one or more protective devices. The design and construction of the task zone(s) (e.g. manual load/unload station) provides effective measures to prevent entry into the hazard zone(s) within the robot cell, or, if intrusion occurs, that the risks associated with such entry are adequately reduced. To achieve this, the design strategy to prevent, impede or detect entry into the robot cell via the manual load/unload station ensures that the risks associated with such entry are adequately reduced by applying the following protective measures, in the following order:

1) mechanical fixture and the manual load/unload station are designed to be impeding devices, as described in J.2.7;

2) detection of intrusion in hazard zones by multiple zone sequencing to determine if someone is moving through the detection zones and entering the robot cell, as described in J.2.8 and shown in Figures J.7 and J.8;

3) internal intrusion detection is used to detect a person trying to enter beyond the fixture or manual load/unload station, as described in J.2.9 and shown in Figures J.7 and J.8.

Supplemental measures to prevent the reasonably foreseeable circumvention of the safeguards could include, for example, adding angled components to prevent walking that bypasses the ESPE to enter the robot cell. See J.2.7.2 and Figure J.6.

J.2.7 Mechanical deterrent in fixture and manual load/unload station design

J.2.7.1 Whole body access deterrence

The design is such that the operator cannot gain or is deterred from whole body access into the robot cell by crawling/squeezing through an opening within the fixture or over the manual load/unload station. The design applies principles specified in ISO 13857:2019 and ISO 14120:2015, specifically the characteristics and limitations outlined below.

ISO 13857:2019 addresses reaching through guard openings. As specified in the note to ISO 13857:2019, Table 7, slot openings greater than 180 mm and square/round openings greater than 240 mm allow access for the whole body. Openings designed within these limitations prevent access by crawling. A risk assessment can determine if a larger opening is effective in preventing access by crawling, by an analysis of the following:

— existing anthropometric data;

NOTE See the ISO 7250 series for statistical summaries of body measurements from national populations.

— the dimensions needed to provide entry by crawling;

— other physical aspects of the opening that might be an impedance to entry.

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EXAMPLE If the passage through the fixture or manual load/unload station involves a 90° turn by the individual, entry by crawling is highly unlikely.

It is insufficient to post warning labels prohibiting entry by crawling/squeezing through or over openings.

J.2.7.2 Step elimination

According to ISO 14120:2015, the design of guarding and supporting structures shall not include features that could assist in climbing over or circumventing the guard. The vertical surfaces of the frame are designed to eliminate the possibility of climbing over the fixture or manual load/unload station, as follows:

a) there is no step and no portion where the person can climb by gripping something; it is not possible to climb up a slope even if the person grips something (see Figure J.6 and Annex K, K.1); and

b) surroundings to openings in guards or supporting structures do not provide:

- a climbing surface;
- a surface to grasp to climb;
- the ability to wedge a foot for a footstep or pathway.

If a) and b) are not fulfilled, then intrusion by a person needs to be detected by either:

- electro-sensitive protective equipment according to the IEC 61496 series, or
- an interlocked guard according to ISO 14120:2015 and ISO 14119:2024.



Key

H 1 000 mm minimum height

NOTE Surrounding structures and safeguarding are not shown in Figure J.6 to aid in the understanding the sloped surface in the figure. See Annex K Figures K.1, K.2, K.3 and K.4.

Figure J.6 — Example of step elimination by use of sloped surfaces

J.2.8 Detection of intrusion in hazard zones

As stated in IEC 61496-1:2020, IEC 62046:2018, ISO 13855:2010 and the ISO 13856:2013 series, SPEs can be used to detect the intrusion of an operator into the hazard zone. The SPE or a combination of SPEs can be used, taking into consideration the following:

a) the SPE is installed to detect the entry of the operator(s) into the safeguarded space;

b) the SPE is installed to determine the operator's movement (inwards or backwards to the hazard zone) by evaluation of the operator's position at different times or by sensing the operator's movement direction;

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c) the evaluation method of the operator's movement and position provides a reliable estimation if an operator has entered the hazard zone and, in such a case, the protective device initiates a protective stop.

Where there is a risk of more than one operator entering the loading station and one operator remains at the loading station while one or more operators access the hazard zone, the system detects this situation and initiates a protective stop.

The minimum distance requirements are described in 5.8.5.2 for guards and interlocked guards and 5.8.9 for SPE.

J.2.9 Presence sensing

Intrusion detection is used to detect an operator trying to enter beyond the fixture or manual load/ unload station. Presence sensing is the detection of an operator inside the hazard zone. Depending on the results of the risk assessment, continuous presence sensing of the operator inside the safeguarded space could be needed.

The following are means by which to accomplish intrusion detection:

— detection zone inside the safeguarded space using SPE;

NOTE 1 See Figure J.7, item 7, and Figure J.8, item X while not being detected by Z.

— scanners (AOPDDR) under positioners, frames, fixtures and manual load/ unload stations to detect persons crossing from the load/unload side to the inside of the safeguarded space;

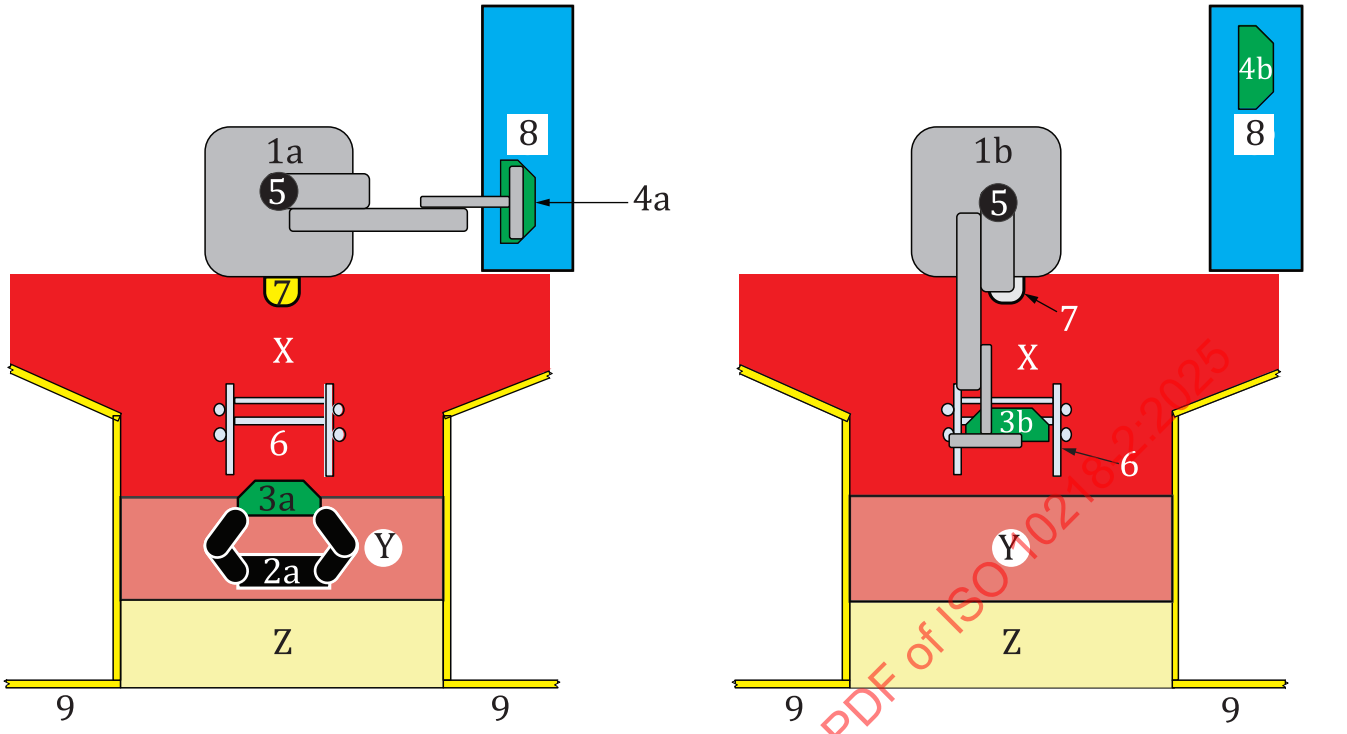
NOTE 2 See Figure J.7, item 7.

— sensitive protective equipment (SPE) installed according to 5.8.6.

Figure J.7 and Figure J.8 illustrate examples of intrusion detection and presence detection with multiple zone sequencing to detect that the operator has left the detection zones. Figure J.7 shows the use of multiple zone sequencing with three detection zones of a laser scanner (AOPDDR) to detect intrusion, presence at the load station, intrusion into the robot cell and the operator leaving the detection zones.

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a) Operator loading workpiece **b) Robot application is processing the workpiece**

Key

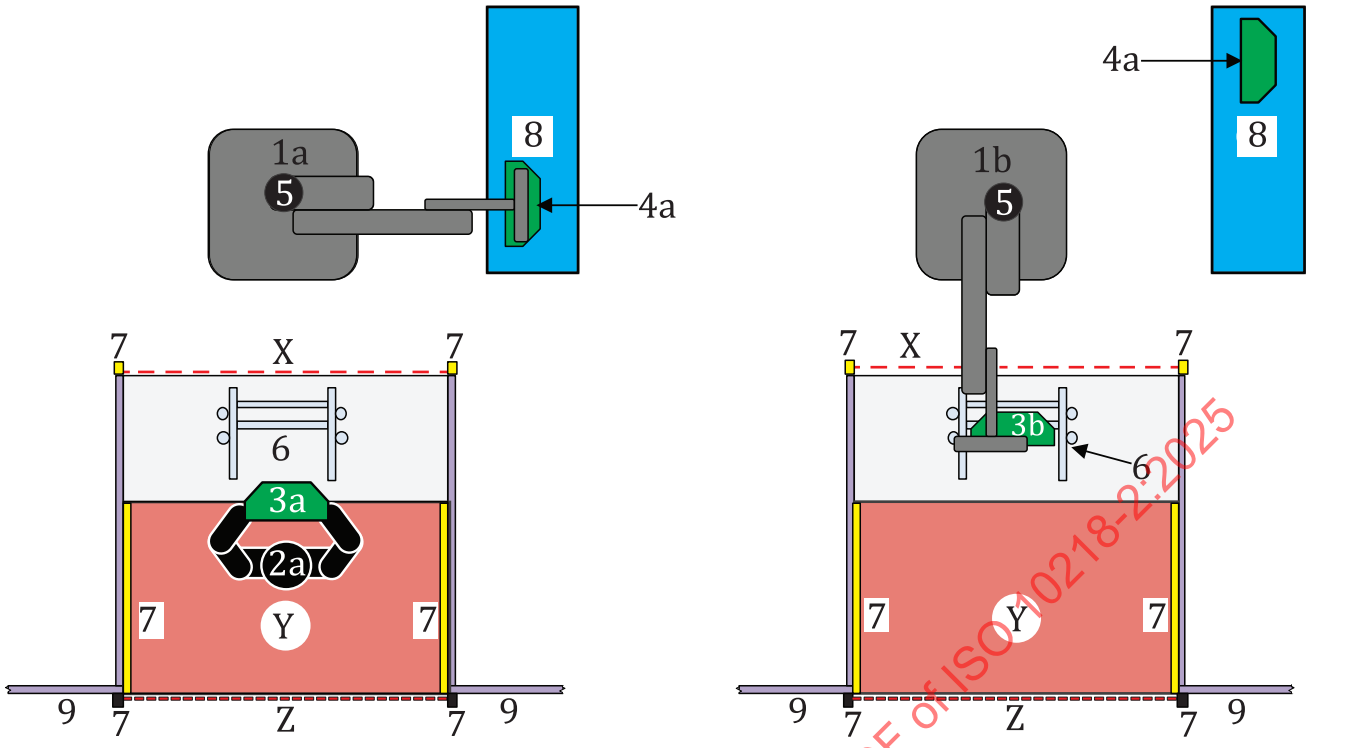
1	industrial robot application transferring to conveyor while an operator is loading a workpiece	industrial robot application processing at fixture or manual load/ unload station while no operator is present
2	operator loading the workpiece into the fixture or manual load/unload station	operator performing other tasks and no longer is within detection zones X, Y or Z
3	workpiece loading	workpiece processing
4	workpiece transferring to the conveyor	workpiece conveying
5	robot with end-effector	
6	manual load station, fixture or location where loading and unloading occurs	
7	laser scanner (AOPDDR)	
8	conveyor	
9	perimeter guard (not all of the guard is shown)	
X	inner detection zone (also under the manual load/unload station)	
Y	loading area detection zone	
Z	entry-exit detection zone	

Figure J.7 — Laser scanner (AOPDDR) with three detection zones

Figure J.8 shows the use of multiple zone sequencing with three light curtains (AOPD). A vertical light curtain detects intrusion (Z) to the manual load station (6) area. A horizontal light curtain detects presence in the fixture or manual load station area (Y). The vertical light curtain (X) has two purposes: detect intrusion by the robot application and detect intrusion by operator into the robot cell. Sequencing is used to determine if the operator leaves the fixture or manual load station area.

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a) Operator loading workpiece **b) Robot application is processing the workpiece**

Key

1	industrial robot application transferring to conveyor while an operator is loading a workpiece	industrial robot application processing at manual load/ unload station while no operator is present
2	operator loading the workpiece into the fixture or manual load/unload station	operator performing other tasks and not detected within detection zones X, Y or Z
3	workpiece loading	workpiece processing
4	workpiece transferring to the conveyor	workpiece conveying
5	robot with end-effector	
6	manual load station, fixture or location where loading and unloading occurs	
7	light curtain (AOPD), 3 total with 2 vertical and 1 horizontal installations	
8	conveyor	
9	perimeter guard (not all the guard is shown)	
X	inner vertical light curtain detection zone	
Y	loading area horizontal light curtain detection zone	
Z	entry-exit vertical light curtain detection zone	

Figure J.8 — Multiple light curtains (AOPD) including one (1) AOPD (“X”) inside a manual load/ unload station

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J.2.10 Example of dimensions of openings for whole body and toehold or footstep access

Figure J.9 shows two illustrations of a manual load/ unload station. The top illustration is before applying guard(s) to prevent access. Both illustrations show a manual load/ unload station that is at an ergonomic height and with an opening width sufficient for operators to have space for their hands to manipulate and position the workpiece.

The bottom illustration shows one example of guarding (D) to prevent whole body access through openings in a structure or manual load/ unload station or fixture. This space is reduced by the guard “E” to minimize the likelihood of that area being used for access. The A and B opening sizes are described in ISO 13857:2019,

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