If an end-effector exchange system is used, then the end-effector exchange system design shall ensure that misuse does 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.

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 into the robot controls.

In addition, the integrator shall design the system so that it selects the proper TCP for the end-effectors that are being changed.

If a robot system can initiate motion without the end-effector attached, then the risk assessment considers this scenario. The likelihood of movement without the end-effector attached shall not lead to unacceptable risk.

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 (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.

NOTE 2: Scissor systems are also regarded as rigid guidance.

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, in particular while it is being loaded or unloaded.

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 3: For guidance see EN 619:2002+A1:2010, Annex E.

5.10.2 Prevention of the hazards of falling

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

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:

— when safeguarding is not practicable;

— 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 in such a way as to prevent any hazardous exposure to laser radiation. The requirements of IEC 60825-1 apply.

Optical equipment for the observation or adjustment of laser equipment shall be such that no hazardous situations arises from the 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 load/unload station (for example, crushing, shearing, entanglement hazards).

When a perimeter safeguarding is established, allowable gaps and openings shall be in accordance with 5.8.4.2. Manual stations shall be designed to ensure that the operator cannot access hazards within the perimeter safeguarding. [See also a), b), c) below.]

NOTE 1: Requirements for collaborative applications are given in 5.13.

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;

c) When a robot system 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 can be fulfilled using a protective device to trigger a monitored-standstill according to 5.6.3.2. This shall

   1) detect entry of the operator into the hazard zone which is occupied by any part of the robot system and bring the hazards to a safe state before they can be accessed and;

   2) prevent any part of a robot system from entering a hazard zone occupied by an operator or bringing the robot system to a safe state before it can reach the operator.

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.

5.12.2.2 Moving manual stations

Moving manual stations (e.g., rotating turntables, sliding jigs) can themselves be hazardous. Measures shall be provided to prevent the operator accessing these hazards or bring these hazards to a safe state before they can be accessed.

Whether the workpiece is in position or not, the gap between the moving station and any fixed elements (e.g. machine parts, guards), including additional protective measures, shall not exceed 120 mm.

Additional measures could be necessary to prevent shearing and trapping hazards created by those mechanical parts (e.g. guards) provided to comply 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, a restart interlock shall be provided. Other measures shall be provided to prevent inadvertent resetting of the restart interlock, so preventing the robot system 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 shall be applied, for example, time-limited additional reset control inside the safeguarded space.

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 access, without creating additional hazards. Access to a hazard shall be prevented or the access detected. Hazards shall be brought to a safe state before they can be accessed.

NOTE: See ISO 13857 for partial body entry.

Openings in guards to allow material entry and exit shall be 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, the ESPE shall allow the passage of materials either by one of the following functions, and access to the safeguarded space shall be prevented by the material itself, or by other means according to IEC 62046:

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 observed according to IEC 62046.

The performance level of the muting and blanking functions shall not adversely affect the performance level of the safety function for the ESPE.

5.12.4 Adjacent robot cells

Safeguarding shall be provided to

— ensure that operators in a cell are not exposed to hazards from adjacent cells;

— reduce risks to operators due to the transfer of materials into and out of adjoining cells;

— either prevent operator access to adjacent cells from within a robot cell, or to bring hazards within adjacent cells to a safe state before operators would be exposed to hazards in or caused by adjacent cells.

NOTE 1: See the requirements in 5.8.4 for when guards are used.

NOTE 2: See 5.3 for other machines and integration,

5.13 Collaborative applications

5.13.1 Description of collaborative applications

If one or more operator(s) are within the safeguarded space during automatic operation, the following shall be fulfilled:

— all required safeguards are active; and

— robots shall meet the specific requirements regarding robots for collaborative applications according to 5.12 of Part 1.

— collaborative applications shall be designed to operate in automatic mode (5.7.2.2).

NOTE 1: See requirements in 5.7.2.1 for general mode requirements and 5.7.2.4 for mode selection.

Robot applications may consist of collaborative and non-collaborative tasks within common safeguarded spaces.

NOTE 3: See the requirements in 5.13.4 for changing between collaborative and non-collaborative tasks.

5.13.2 General

Operators shall be protected from injury due to contact from moving parts of the robot application to the operator. Protective devices and/or safety functions shall be provided for safety of the operator(s) in the event of such contact or stop the robot application motion and other hazards before contact occurs.

Robots used for integration into a collaborative application shall comply the requirements for collaborative applications in ISO/DIS 10218-1:2020, 5.14.

Robot applications that include collaborative tasks should have a visual indication for when collaborative tasks may be performed.

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). 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.

NOTE: 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.

NOTE: See ISO 10218-1 for requirements of safety functions for robots intended to be used in collaborative applications.

Any detected failure or fault of safety functions shall result in a stop in accordance with 5.5.4. Automatic operation shall not be resumed after such a stop until reset by a deliberate restart action outside the safeguarded space according to 5.5.7.

5.13.3 Safeguarded spaces

The safeguarded space where the operator(s) can interact directly with the robot system shall be clearly defined (e.g. floor marking, signs).

The design of the safeguarded space shall be such that the operator can perform all intended tasks safely. The location of equipment and machinery shall not introduce additional hazards.

The robot application shall either be

a) controlled to prevent any clearance risks; or

b) controlled to prevent any hazardous contact.

NOTE: See Annex M for guidance on contact limits.

If there is coordinated or synchronized motion (e.g. line tracking), special considerations could be needed.

NOTE: See ISO 13854 for guidance.

5.13.4 Change between non-collaborative task and collaborative task

Transitions during collaborative task are particularly critical parts of a collaborative application.

The types of transitions are:

a) between methods of collaborative tasks;

b) from collaborative tasks to non-collaborative tasks; and

c) from non-collaborative tasks to collaborative tasks.

These shall be designed such that the robot system shall not create a hazardous situation for the operator 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.

5.13.5 Hand-guided controls (HGC)

5.13.5.1 General

The robot system shall have a monitored-speed safety function according to 5.5.6.2 and a monitored-standstill safety function according to 5.6.3.2. A risk assessment shall be used to determine the monitored-speed limit value. If operator safety is dependent on limiting the range of motion of the robot, the robot shall have soft axis and space limiting safety functions in accordance with ISO/DIS 10218-1:2020, 5.9.4.

NOTE 1: See the requirements in 5.4.7.3 for non-mechanical limiting devices.

NOTE 2: For guidance, also see ISO/DIS 10218-1:2020, 5.4.3 and 5.5.2.

Hand-guided collaborative applications shall fulfil the following requirements:

a) when the robot system reaches the pre-determined position the hand-guiding controls (HGC) becomes active, a monitored-standstill shall be active unless power and force limiting (PFL) or speed and separation monitoring (SSM) provides acceptable risk reduction;

b) the hand-guiding controls (HGC) complies with ISO/DIS 10218-1:2020, 5.14.3;

c) when the operator actuates the HGC hold-to-run control, the monitored-standstill is released, and the operator performs the hand-guiding collaborative task;

d) the operator shall have clear visibility of the portion of the safeguarded space used while hand-guiding the robot system/ robot application to the intended position;

e) when the operator releases the guiding device, a monitored-standstill safety function in accordance with 5.6.3.2 is triggered unless one or both of the following provides acceptable risk reduction:

   — power and force limiting (PFL) according to 5.13.7;

   — speed and separation monitoring (SSM) according to 5.13.6.

5.13.5.2 Location or positioning of HGC

The HGC shall be located to fulfil the following:

a) proximity of operator to robot to be able to directly observe robot system and workpiece motion and any hazards that might arise from this motion (e.g. controls mounted on end-effector);

b) operator position and posture shall not lead to additional hazards (e.g. operator not under heavy loads or under manipulator arm);

c) operator position shall provide unobstructed view of entire hand-guided task zone (e.g. additional persons entering).

The mapping between the motion axes of the hand guiding device and the motion shall be clearly presented and easily understood. The direction of motion of the robot and end-effector shall be understandable and easily controllable from the HGC.

Specific risks associated with hand-guiding collaborative applications are the exposure to the moving robot system and workpieces, exposure to hanging loads and the possibility of non-ergonomic postures and associated physical strain. The location and the functionality of the hand-guiding control (HGC) device shall include, as applicable:

— choosing the optimal location considering the need for a full view of the application, minimizing exposure to moving workpieces, and an ergonomically favourable posture for the operator which can include mounting on the end-effector structure, mounting at a fixed station, or providing as a mobile device carried by the operator;

— end-effector safety functions shall be provided to prevent inadvertent release of a workpiece which causes a hazardous situation according to 5.9;

— safety functions to limit speed, acceleration, deceleration of the moving parts of the robot system and the workpiece;

— safety functions to limit forces and torques in the moving parts of the robot system and workpiece;

— comply with 5.2.9 to ensure that loss or change of power shall not lead to loss of load, unexpected motion, or other hazards.

The presentation of the controls on the hand-guiding device and their implementation as part of the robot application are key to the realization of risk reduction measures for hand-guided type of collaborative applications.

5.13.6 Speed and separation monitoring (SSM)

5.13.6.1 General

Robot applications designed to maintain a protective separation distance between the operator and the robot application in a dynamic manner shall use robots that comply with the requirements of ISO 10218-1. The speed and separation monitoring capabilities can be integral to the robot, provided by an external protective device, or a mixture of both. There can be some shared functionality.

With speed and separation monitoring, risk reduction is achieved by maintaining at least the protective separation distance between operator and robot application, end-effector and workpiece during robot application motion.

When the protective separation distance decreases to a value below the minimum allowed protective separation distance, a stop of the robot application shall occur in accordance with 5.5.4. 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 protective separation distance shall be maintained, even during detection zone transitions. The time for the robot application to decelerate shall be considered.

Speed and separation monitoring may be used in conjunction with power and force limited (PFL) functionality. With PFL according to Part 1, 5.12.4, the protective separation distance can be reduced to zero (0) when contact to an operator is within acceptable biomechanical limits. The transition time for PFL to become active shall be included in the minimum separation distance.

5.13.6.2 Enabling SSM

The collaborative application using SSM shall have a protective stop according to 5.6.3 that stops all hazardous robot application motion.

The collaborative application using SSM shall have the following:

- a monitored-speed safety function according to 5.5.6.2; and
- protective separation distance for SSM in accordance with Annex L.

The collaborative application using SSM should have the following:

- a speed limiting safety function for setting/adjusting the robot speed according to Part 1, 5.5.2;
- safety communications of real-time position, speed or acceleration of the robot and stopping distance in the current configuration of the joints.

NOTE 2: Dynamic speed implementation, with adjustable speed or path before coming to a protective stop can be provided by safety function(s).

Protective separation distance requires the measurement or estimation of the position of both the robot application and the operator.

Speed and separation monitoring shall apply to all operators within the safeguarded space. If the performance of the protective device is limited by the number of operators in the safeguarded space, the maximum number of operators shall be stated in the information for use. If that maximum value is exceeded, a protective stop shall occur.

When the operator(s) moves away from the robot application after a protective stop has occurred, the robot application may resume operation automatically, according to the requirements of this clause, while maintaining the required protective separation distance. When the robot application reduces its speed, the protective separation distance may decrease correspondingly.

If operator safety is dependent on limiting the range of motion of the robot application, the robot shall be equipped with soft axis and space limiting safety function(s) according to 5.4.7.3.

5.13.6.3 Protective separation distance for speed and separation monitoring

5.13.6.3.1 Constant and variable speed and separation values

The maximum permissible speeds and the minimum protective separation distances in an application can be either variable or constant. For variable values, the maximum permissible speeds and the protective separation distances may be adjusted continuously based on the relative speeds and distances of the robot applications and the operator. For constant values, the maximum permissible speed and the protective separation distance shall be determined using the worst case of the application.

The means for monitoring the relative speeds and distances of the operator and robot applications shall be by safety function(s).

5.13.6.3.2 Maintaining the protective separation distance

If the implementation of speed and separation monitoring is dependent on limiting the range of motion of the robot application, the robot shall have soft axis and space limiting safety function(s) in accordance with ISO/DIS 10218-1:2020, 5.9.4. Other robot safety functions can also facilitate the implementation of speed and separation monitoring.

The protective separation distance can be provided by the following:

— speed reduction, which may transition to a monitored-standstill according to 5.6.3.2;

— execution of an alternative path which complies with the required protective separation distance.

NOTE: The protective separation distance can be calculated based on the concepts used to create the minimum distance formula in ISO 13855, modified to consider the following hazards associated with speed and separation monitoring. This is described in Annex L.

The robot application shall be designed to account for the speed of the robot application during stopping ($\boldsymbol{v}_{\mathbf{S}}$ in Annex L), from the activation of the stop command until the robot has halted.

Alternative implementations may be used if they comply with the requirements of 5.5.

5.13.7 Power and force limiting (PFL)

5.13.7.1 General

Power and force limited collaborative robot applications shall comply with the requirements of power and force limiting in accordance with ISO/DIS 10218-1:2020, 5.14.5.

The robot application shall be designed to adequately reduce risks to an operator by not exceeding the applicable threshold limits for contact events. Contact events between moving parts of a robot application and operator(s) are identified during the risk assessment. Contact parameters of pressure and force shall be verified following the identification of contact event(s).

NOTE 1: See Annex M for guidance on threshold limit values and Annex N for guidance on measuring forces and/or pressures.

NOTE 2: 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.

If robot application motion can result in clamping or pinning a body region between a part of the robot and another item in the robot cell, a speed limiting safety function shall be used to enable the robot application to be configured to comply with the biomechanical limits associated with the exposed body region, as shown in Annex M.

NOTE 3: For verification and validation requirements, see Clause 6 and Annex H.

NOTE 4: 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 5: 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.

5.13.7.2 Contact situations

When using power and force limiting, contact events to the operator could occur in several ways:

— intended 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 between moving parts of the robot application to body regions shall be categorized one of following:

a) quasi-static contact; or

NOTE 1: This 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.

b) transient contact.

NOTE 2: This is 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 arm, 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.

5.13.7.3 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.

In particular, the hazards associated with contact to the face, skull and forehead (Annex M, Table M.3, body regions 1, 2 and 3) shall be considered in the risk assessment. Risks resulting in contacts to the forehead (1), temple (2) and face (3) can occur when the moving parts of the robot application contact these three specific body regions. The contact from the moving parts of the robot application can happen because the operator is in