

~~DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL~~
~~of 17 May 2006~~
~~on machinery, and amending Directive 95/16/EC (recast)~~
Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on machinery products

注) 欧州機械規則 (提案) は、欧州機械指令を廃止しこれに代わるものとして提案されているものです。2021 年 5 月現在、この提案は最終提案段階であり、まだ正式に発行されたものではありません。

本紙は、機械指令 2006/42/EC (2009/127/EC によって修正) をベースに、機械規則の最終提案版 COM(2021) 202 final, 2021/0105(COD) による変更点を赤色で示したものです。付属書Ⅲチャプター 1 (現行の機械指令では、付属書 I チャプター 1 に相当) を抜粋しています。

ANNEX Ⅲ**ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY PRODUCTS****1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS****1.1. GENERAL REMARKS****1.1.1. Definitions**

For the purpose of this Annex:

- (a) 'hazard' means a potential source of injury or damage to health;
- (b) 'danger zone' means any zone within and/or around a machinery product in which a person is subject to a risk to his or her health or safety;
- (c) 'exposed person' means any person wholly or partially in a danger zone;
- (d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving a machinery product;
- (e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;
- (f) 'guard' means a part of the a machinery product used specifically to provide protection by means of a physical barrier;
- (g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;
- (h) 'intended use' means the use of a machinery product in accordance with the information provided in the instructions for use;
- (i) 'reasonably foreseeable misuse' means the use of a machinery product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

1.1.2. Principles of safety integration

- (a) A machinery ~~product must~~ shall be designed and constructed so that it is ~~fitted~~ for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of ~~protective~~ measures ~~taken must~~ shall be to eliminate any risk throughout the foreseeable lifetime of the machinery ~~product~~ including the phases of transport, assembly, dismantling, disabling and scrapping.
- (b) In selecting the most appropriate methods, the manufacturer or his ~~or her~~ authorised representative ~~must shall~~ apply the following principles, in the order given:
- eliminate or reduce risks as far as possible (inherently safe machinery ~~product~~ design and construction),
 - take the necessary protective measures in relation to risks that cannot be eliminated,
 - inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.
- (c) When designing and constructing ~~a~~ machinery ~~product~~ and when drafting the instructions, the manufacturer or his ~~or her~~ authorised representative ~~must shall~~ envisage not only the intended use of the machinery ~~product~~ but also any reasonably foreseeable misuse thereof.
The machinery ~~product must shall~~ be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions ~~must shall~~ draw the user's attention to ways — which experience has shown might occur — in which the machinery ~~product~~ should not be used.
- (d) A machinery ~~product must shall~~ be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.
- (e) ~~A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product must shall~~ be supplied with all the special equipment and accessories, ~~and where appropriate, with the description of specific functional test procedures,~~ essential to enable it to be ~~tested,~~ adjusted, maintained and used safely.

1.1.3. Materials and products

The materials used to construct ~~a~~ machinery ~~product,~~ or products used or created during its use, ~~must shall~~ not endanger persons' safety or health. In particular, where fluids are used, machinery ~~products must shall~~ be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. Lighting

A machinery ~~product must shall~~ be supplied with integral lighting suitable for the operations concerned, where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

A machinery ~~must~~ **shall** be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas ~~must~~ **shall** be provided with appropriate lighting.

1.1.5. Design of a machinery **product** to facilitate its handling

A machinery **product**, or each component part thereof, ~~must~~ **shall**:

- (a) be capable of being handled and transported safely;
- (b) be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery **product** and/or its component parts, there ~~must~~ **shall** be no possibility of sudden movements or of hazards due to instability as long as the machinery **product** and/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of a machinery **product** or its various component parts prevents **it or** them from being moved by hand, the machinery **product** or each component part ~~must~~ **shall**:

- (a) either be fitted with attachments for lifting gear, or
- (b) be designed so that it can be fitted with such attachments, or
- (c) be shaped in such a way that standard lifting gear can easily be attached.

Where a machinery **product** or one of its component parts is to be moved by hand, it ~~must~~ **shall either**:

- (a) ~~either~~ be easily moveable, or
- (b) be equipped for picking up and moving safely.

Special arrangements ~~must~~ **shall** be made for the handling of tools and/or machinery **product** parts, which, even if lightweight, could be hazardous.

1.1.6. Ergonomics

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator ~~must~~ **shall** be reduced to the minimum possible, taking into account ergonomic principles such as:

- (a) allowing for the variability of the operator's physical dimensions, strength and stamina;
- (b) providing enough space for movements of the parts of the operator's body;
- (c) avoiding a machine-determined work rate;
- (d) avoiding monitoring that requires lengthy concentration,
- (e) adapting the human-machinery **product** interface to the foreseeable characteristics of the operators, **including with respect to a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy;**
- (f) **adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (verbally through words and non-verbally through gestures, facial expressions or body**

movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.

1.1.7. Operating positions

The operating position ~~must~~ shall be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery **product** is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery **product** itself gives rise to a hazardous environment, adequate means ~~must~~ shall be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position ~~must~~ shall be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit ~~must~~ shall allow rapid evacuation. Moreover, when applicable, an emergency exit ~~must~~ shall be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery **product** ~~must~~ shall be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery **product**, the seat ~~must~~ shall be provided with the machinery **product**.

The operator's seat ~~must~~ shall enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices ~~must~~ shall be capable of being adapted to the operator.

If the machinery **product** is subject to vibrations, the seat ~~must~~ shall be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings ~~must~~ shall withstand all stresses to which they can be subjected.

Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material ~~must~~ shall be provided.

1.1.9. Protection against corruption

The machinery **product** shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery **product** does not lead to a hazardous situation.

A hardware component for connection that is critical for the compliance of the machinery **product** with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery **product** shall collect evidence of a legitimate or illegitimate intervention in the hardware component.

Software and data that are critical for the compliance of the machinery **product** with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.

The machinery product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.

The machinery product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration.

1.2. CONTROL SYSTEMS

1.2.1. Safety and reliability of control systems

Control systems ~~must~~ shall be designed and constructed in such a way as to prevent hazardous situations from arising.

~~Above all, they~~ Control systems ~~must~~ shall be designed and constructed in such a way that:

- (a) they can withstand, ~~where appropriate to the circumstances and the risks,~~ the intended operating stresses and ~~intended and unintended~~ external influences, ~~including malicious attempts from third parties to create a hazardous situation;~~
- (b) a fault in the hardware or the ~~software~~ logic of the control system ~~does~~ shall not lead to hazardous situations;
- (c) errors in the control system logic ~~do~~ shall not lead to hazardous situations;
- (d) the safety functions cannot be changed beyond the limits defined by the manufacturer in the machinery product risk assessment. The establishment of the limits of the safety functions shall be part of the risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also the learning phase, which cannot go beyond the limits addressed in the risk assessment;
- (e) reasonably foreseeable human errors during operation ~~does~~ shall not lead to hazardous situations;
- (f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority;
- (g) recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority.

Control systems of machinery products with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:

- (a) they shall not cause the machinery product to perform actions beyond its defined task and movement space;
- (b) it shall be possible at all times to correct the machinery product in order to maintain its inherent safety.

Particular attention ~~must~~ shall be given to the following points:

- (a) the machinery ~~product~~ ~~must~~ shall not start unexpectedly;

- (b) the parameters of the machinery ~~product must shall~~ not change in an uncontrolled way, where such change may lead to hazardous situations;
- (c) modifications to the settings or rules, generated by the machinery product or by operators covering also the learning phase, shall be prevented, where such modifications may lead to hazardous situations;
- (d) the machinery ~~product must shall~~ not be prevented from stopping if the stop command has already been given;
- (e) no moving part of the machinery product or piece held by the machinery ~~product must shall~~ fall or be ejected;
- (f) automatic or manual stopping of the moving parts, whatever they may be, ~~must shall~~ be unimpeded;
- (g) the protective devices ~~must shall~~ remain fully effective or give a stop command;
- (h) the safety-related parts of the control system ~~must shall~~ apply in a coherent way to the whole of an assembly of a machinery product ~~and/or partly completed machinery~~.

For ~~cablewire-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication~~ a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.

For autonomous mobile machinery products, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.

1.2.2. Control devices

Control devices ~~must shall~~ be:

- (a) clearly visible and identifiable, using pictograms where appropriate;
- (b) positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity;
- (c) designed in such a way that the movement of the control device is consistent with its effect;
- (d) located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant;
- (e) positioned in such a way that their operation cannot cause additional risk;
- (f) designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action;
- (g) made in such a way as to withstand foreseeable forces, ~~paying particular attention must be paid~~ to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence, the action to be performed ~~must shall~~ be clearly displayed and subject to confirmation, where necessary.

Control devices ~~must shall~~ be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery products ~~must~~ shall be fitted with indicators as required for safe operation. The operator ~~must~~ shall be able to read them from the control position.

From each control position, the operator ~~must~~ shall be able to ensure that no one is in the danger zones, or the control system ~~must~~ shall be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery product starts, an acoustic and/or visual warning signal ~~must~~ shall be given. The exposed persons ~~must~~ shall have time to leave the danger zone or prevent the machinery starting up.

If necessary, means ~~must~~ shall be provided to ensure that the machinery product can be controlled only from control positions located in one or more predetermined zones or locations.

Where there is more than one control position, the control system ~~must~~ shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When the machinery product has two or more operating positions, each position ~~must~~ shall be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.

1.2.3. Starting

It ~~must~~ shall be possible to start the machinery product only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

- (a) when restarting the machinery product after a stoppage, whatever the cause,
- (b) when effecting a significant change in the operating conditions.

However, the restarting of the machinery product or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For the machinery product functioning in automatic mode, the starting of the machinery product, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where the machinery product has several starting control devices and the operators can therefore put each other in danger, additional devices ~~must~~ shall be fitted to rule out such risks. If safety requires that starting and/or stopping ~~must~~ shall be performed in a specific sequence, there ~~must~~ shall be devices which ensure that these operations are performed in the correct order.

1.2.4. Stopping

1.2.4.1. Normal stop

The machinery product ~~must~~ shall be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation ~~must~~ shall be fitted with a control device to stop some or all of the functions of the machinery ~~product~~, depending on the existing hazards, so that the machinery ~~product~~ is rendered safe. The machinery ~~product~~'s stop control ~~must~~ shall have priority over the start controls. Once the machinery ~~product~~ or its hazardous functions have stopped, the energy supply to the actuators concerned ~~must~~ shall be cut off.

1.2.4.2. Operational stop

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition ~~must~~ shall be monitored and maintained.

1.2.4.3. Emergency stop

The machinery ~~product~~ ~~must~~ shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

- (a) the machinery ~~product~~ in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken;
- (b) portable hand-held and/or hand-guided machinery ~~product~~.

The device ~~must~~ shall:

- (a) have clearly identifiable, clearly visible and quickly accessible control devices;
- (b) stop the hazardous process as quickly as possible, without creating additional risks,
- (c) where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop device has ceased following a stop command, that command ~~must~~ shall be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it ~~must~~ shall not be possible to engage the device without triggering a stop command; it ~~must~~ shall be possible to disengage the device only by an appropriate operation, and disengaging the device ~~must~~ shall not restart the machinery ~~product~~ but only permit restarting.

The emergency stop function ~~must~~ shall be available and operational at all times, regardless of the operating mode.

Emergency stop devices ~~must~~ shall be a backup to other safeguarding measures and not a substitute for them.

1.2.4.4. Assembly of machinery ~~products~~

In the case of a machinery ~~product~~ or parts of a machinery ~~product~~ designed to work together, the machinery ~~must~~ shall be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery ~~product~~ itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. Selection of control or operating modes

The control or operating mode selected ~~must~~ shall override all other control or operating modes, with the exception of the emergency stop.

If the machinery product has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it ~~must~~ shall be fitted with a mode selector, which can be locked in each position. Each position of the selector ~~must~~ shall be clearly identifiable and ~~must~~ shall correspond to a single operating or control mode.

The selector may be replaced by another selection method, which restricts the use of certain functions of the machinery product to certain categories of operator.

If, for certain operations, the machinery ~~must~~ shall be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector ~~must~~ shall simultaneously:

- (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 on the machine's product's sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector ~~must~~ shall activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator ~~must~~ shall be able to control the operation of the parts he or she is working on from the adjustment point.

1.2.6. Failure of the power supply or communication network connection

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery product ~~must~~ shall not lead to dangerous hazardous situations.

Particular attention ~~must~~ shall be given to the following points:

- (a) the machinery ~~must~~ shall not start unexpectedly;
- (b) the parameters of the machinery ~~must~~ shall not change in an uncontrolled way when such change can lead to hazardous situations;
- (c) the machinery product ~~must~~ shall not be prevented from stopping if the stop command has already been given;
- (d) no moving part of the machinery product or piece held by the machinery product ~~must~~ shall fall or be ejected,
- (e) automatic or manual stopping of the moving parts, whatever they may be, ~~must~~ shall be unimpeded,
- (f) the protective devices ~~must~~ shall remain fully effective or give a stop command.

1.3. PROTECTION AGAINST MECHANICAL HAZARDS RISKS

1.3.1. Risk of loss of stability

The machinery **product** and its components and fittings **must shall** be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery **product**.

If the shape of the machinery **product** itself or its intended installation does not offer sufficient stability, appropriate means of anchorage **must shall** be incorporated and indicated in the instructions.

1.3.2. Risk of break-up during operation

The various parts of machinery **product** and their linkages **must shall** be able to withstand the stresses to which they are subject when used.

The durability of the materials used **must shall** be adequate for the nature of the working environment foreseen by the manufacturer or his **or her** authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The instructions **must shall** indicate the type and frequency of inspections and maintenance required for safety reasons. They **must shall**, where appropriate, indicate the parts subject to wear and the criteria for replacement.

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

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, **must shall** be able to withstand the foreseen internal and external stresses and **must shall** be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions **must shall** be fulfilled to avoid risks to persons:

- (a) when the work piece comes into contact with the tool, the latter **must shall** have attained its normal working condition,
- (b) when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement **must shall** be coordinated.

1.3.3. Risks due to falling or ejected objects

Precautions **must shall** be taken to prevent risks from falling or ejected objects.

1.3.4. Risks due to surfaces, edges or angles

Insofar as their purpose allows, accessible parts of the machinery **must shall** have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. Risks related to a combined machinery **product**

Where the machinery **product** is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery **product**), it ~~must~~ **shall** be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For this purpose, it ~~must~~ **shall** be possible to start and stop separately any elements that are not protected.

1.3.6. Risks related to variations in operating conditions

Where the machinery **product** performs operations under different conditions of use, it ~~must~~ **shall** be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. Risks related to moving parts **and psychological stress**

The moving parts of **the machinery product** ~~must~~ **shall** be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or ~~must~~ **shall**, where risks persist, be fitted with guards or protective devices.

All necessary steps ~~must~~ **shall** be taken to prevent accidental blockage of moving parts ~~involved in the work~~. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools ~~must~~ **shall**, when appropriate, be provided to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery **product** shall identify these specific protective devices and how they are to be used.

The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to:

- (a) human-machine coexistence in a shared space without direct collaboration;**
- (b) human-machine interaction.**

The machinery product with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be adapted to respond to people adequately and appropriately (verbally through words or nonverbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.

1.3.8. Choice of protection against risks arising from moving parts

Guards or protective devices designed to protect against risks arising from moving parts ~~must~~ **shall** be selected on the basis of the type of risk. The following guidelines ~~must~~ **shall** be used to help to make the choice.

1.3.8.1. Moving transmission parts

Guards designed to protect persons against the hazards generated by moving transmission parts ~~must~~ shall be:

- (a) either fixed guards as referred to in section 1.4.2.1, or
- (b) interlocking movable guards as referred to in section 1.4.2.2.

Interlocking movable guards ~~should~~ shall be used where frequent access is envisaged.

1.3.8.2. Moving parts involved in the process

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process ~~must~~ shall be:

- (a) either fixed guards as referred to in section 1.4.2.1, or
- (b) interlocking movable guards as referred to in section 1.4.2.2, or
- (c) protective devices as referred to in section 1.4.3, or
- (d) a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts ~~must~~ shall be fitted with:

- (a) fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and
- (b) adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.

1.3.9. Risks of uncontrolled movements

When a part of the machinery ~~product~~ has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, ~~must~~ shall be prevented or ~~must~~ shall be such that it does not present a ~~hazard~~ risk.

1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

1.4.1. General requirements

Guards and protective devices ~~must~~ shall:

- (a) be of robust construction;
- (b) be securely held in place;
- (c) not give rise to any additional hazard;
- (d) not be easy to by-pass or render non-operational;
- (e) be located at an adequate distance from the danger zone;
- (f) cause minimum obstruction to the view of the production process, and;
- (g) enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition, guards ~~must~~ shall, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery ~~product~~.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards ~~must~~ shall be fixed by systems that can be opened or removed only with tools.

Their fixing systems ~~must~~ shall remain attached to the guards or to the machinery ~~product~~ when the guards are removed.

Where possible, guards ~~must~~ shall be incapable of remaining in place without their fixings.

1.4.2.2. Interlocking movable guards

Interlocking movable guards ~~must~~ shall:

- (a) as far as possible remain attached to the machinery ~~product~~ when open,
- (b) be designed and constructed in such a way that they can be adjusted only by means of an intentional action.

Interlocking movable guards ~~must~~ shall be associated with an interlocking device that:

- (a) prevents the start of hazardous machinery ~~product~~ functions until they are closed and
- (b) gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery ~~product~~ functions has ceased, movable guards ~~must~~ shall be associated with a guard locking device in addition to an interlocking device that:

- (a) prevents the start of hazardous machinery ~~product~~ functions until the guard is closed and locked, and
- (b) keeps the guard closed and locked until the risk of injury from the hazardous machinery ~~product~~ functions has ceased.

Interlocking movable guards ~~must~~ shall be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery ~~product~~ functions.

1.4.2.3. Adjustable guards restricting access

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work ~~must~~ shall be:

- (a) adjustable manually or automatically, depending on the type of work involved, and
- (b) readily adjustable without the use of tools.

1.4.3. Special requirements for protective devices

Protective devices ~~must~~ shall be designed and incorporated into the control system in such a way that:

- (a) moving parts cannot start up while they are within the operator's reach,
- (b) persons cannot reach moving parts while the parts are moving, and

(c) the absence or failure of one of their components prevents starting or stops the moving parts. Protective devices ~~must~~ shall be adjustable only by means of an intentional action.

1.5. RISKS DUE TO OTHER ~~HAZARDS~~ CAUSES

1.5.1. Electricity supply

Where a machinery product has an electricity supply, it ~~must~~ shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive ~~73/23/EEC~~ 2014/35/EU shall apply to a machinery product. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of a machinery product with regard to electrical ~~hazards~~ risks are governed solely by this ~~Directive~~ Regulation.

1.5.2. Static electricity

A machinery product ~~must~~ shall be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. Energy supply other than electricity

Where a machinery product is powered by source of energy other than electricity, it ~~must~~ shall be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. Errors of fitting

Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, ~~must~~ shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information ~~must~~ shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions ~~must~~ shall give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections ~~must~~ shall be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5. Extreme temperatures

Steps ~~must~~ shall be taken to eliminate any risk of injury arising from contact with or proximity to machinery product parts or materials at high or very low temperatures.

The necessary steps ~~must~~ shall also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6. Fire

A machinery ~~product must~~ shall be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery ~~product~~ itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery ~~product~~.

1.5.7. Explosion

A machinery ~~product must~~ shall be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery ~~product~~ itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery ~~product~~.

A machinery ~~product must~~ shall comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific ~~Community Directives Union~~ harmonisation legislation.

1.5.8. Noise

A machinery ~~product must~~ shall be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery ~~product~~.

1.5.9. Vibrations

A machinery ~~product must~~ shall be designed and constructed in such a way that risks resulting from vibrations produced by the machinery ~~product~~ are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery ~~products~~.

1.5.10. Radiation

Undesirable radiation emissions from the machinery ~~product must~~ shall be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions ~~must~~ shall be limited to the lowest level, which is sufficient for the proper functioning of the machinery ~~product~~ during setting, operation and cleaning. Where a risk exists, the necessary protective measures ~~must~~ shall be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning ~~must~~ shall be limited to levels that do not have adverse effects on persons.

1.5.11. External radiation

A machinery ~~product must~~ shall be designed and constructed in such a way that external radiation does not interfere with its operation.

1.5.12. Laser radiation

Where laser equipment is used, the following ~~should~~ shall be taken into account:

- (a) laser equipment on a machinery ~~product must~~ shall be designed and constructed in such a way as to prevent any accidental radiation;
- (b) laser equipment on a machinery ~~product must~~ shall be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health;
- (c) optical equipment for the observation or adjustment of laser equipment on a machinery ~~product must~~ shall be such that no health risk is created by laser radiation.

1.5.13. Emissions of hazardous materials and substances

A machinery ~~product must~~ shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a ~~hazard risk~~ cannot be eliminated, the machinery ~~product must~~ shall be so equipped that hazardous materials and substances can be contained, ~~captured~~, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery ~~product~~, the devices for containment ~~and/or or capture, filtration or separation and~~ evacuation ~~must~~ shall be situated in such a way as to have the maximum effect.

1.5.14. Risk of being trapped in a machine

A machinery ~~product must~~ shall be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15. Risk of slipping, tripping or falling

Parts of the machinery ~~product~~ where persons are liable to move about or stand ~~must~~ shall be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

Where appropriate, these parts ~~must~~ shall be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16. Lightning

A machinery ~~product~~ in need of protection against the effects of lightning while being used ~~must~~ shall be fitted with a system for conducting the resultant electrical charge to earth.

1.6. MAINTENANCE

1.6.1. Machinery ~~product~~ maintenance

Adjustment and maintenance points ~~must~~ shall be located outside danger zones. It ~~must~~ shall be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while the machinery ~~product~~ is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures ~~must~~ shall be taken to ensure that these operations can be carried out safely (see section 1.2.5).

In the case of automated machinery and, where necessary, other machinery ~~product~~, a connecting device for mounting diagnostic fault-finding equipment ~~must~~ shall be provided.

Automated machinery components, which have to be changed frequently, ~~must~~ shall be capable of being removed and replaced easily and safely. Access to the components ~~must~~ shall enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2. Access to operating positions and servicing points

Machinery ~~must~~ shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, ~~and~~ maintenance ~~and~~ cleaning of the machinery.

~~In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed.~~

1.6.3. Isolation of energy sources

A machinery ~~product~~ ~~must~~ shall be fitted with means to isolate it from all energy sources. Such isolators ~~must~~ shall be clearly identified. They ~~must~~ shall be capable of being locked if reconnection could endanger persons. Isolators ~~must~~ shall also be capable of being locked where an operator is unable, from any of the points to which he ~~or she~~ has access, to check that the energy is still cut off.

In the case of machinery ~~products~~ capable of being plugged into an electricity supply, removal of the plug is sufficient, ~~provided that~~ if the operator can check from any of the points to which he ~~or she~~ has access that the plug remains removed.

After the energy is cut off, it ~~must~~ shall be possible to dissipate normally any energy remaining or stored in the circuits of the machinery ~~product~~ without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps ~~must~~ shall be taken to ensure operator safety.

1.6.4. Operator intervention

The machinery ~~product~~ ~~must~~ shall be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it ~~must~~ shall be possible to carry it out easily and safely.

1.6.5. Cleaning of internal parts

The machinery ~~must shall~~ be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or preparations without entering them; any necessary unblocking ~~must shall~~ also be possible from the outside. If it is impossible to avoid entering the machinery, it ~~must shall~~ be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1. Information and warnings on the machinery product

Information and warnings on the machinery product ~~should shall~~ preferably be provided in the form of readily understandable symbols or pictograms. ~~Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.~~

1.7.1.1. Information and information devices

The information needed to control a machinery product ~~must shall~~ be provided in a form that is unambiguous and easily understood. It ~~must shall~~ not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the ~~machine machinery product must shall~~ be easily understood and easy to use.

1.7.1.2. Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of an unsupervised machinery product, the machinery product ~~must shall~~ be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where a machinery product is equipped with warning devices, these ~~must shall~~ be unambiguous and easily perceived. The operator ~~must shall~~ have facilities to check the operation of such warning devices at all times.

The requirements of the specific ~~Community Directives Union legislation~~ concerning colours and safety signals ~~must shall~~ be complied with.

1.7.2. Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, ~~must shall~~ be provided.

1.7.3. Marking of a machinery product

All machinery ~~products must shall~~ be marked visibly, legibly and indelibly with the following minimum particulars:

- (a) the business name and full address of the manufacturer and, where applicable, his ~~or her~~ authorised representative;
- (b) designation of the machinery ~~product~~;
- (c) the CE marking ~~(see Annex III)~~;
- (d) designation of series or type;
- (e) serial number, if any,
- (f) the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery ~~product~~ when affixing the CE marking.

Furthermore, a machinery ~~product~~ designed and constructed for use in a potentially explosive atmosphere ~~must shall~~ be marked accordingly.

A machinery ~~product must shall~~ also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

Where a machine ~~product part must shall~~ be handled during use with lifting equipment, its mass ~~must shall~~ be indicated legibly, indelibly and unambiguously.

1.7.4. Instructions

~~All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.~~

The instructions accompanying the machinery ~~product must shall~~ be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation ~~must shall~~ be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his ~~or her~~ authorised representative may be supplied in only one ~~Community official language of the Union~~ which the specialised personnel understand.

~~The instructions must be drafted in accordance with the principles set out below.~~

~~The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge.~~

~~When the instructions are provided in digital format, the manufacturer shall:~~

- ~~(a) mark on the machinery product and in an accompanying paper how to access the digital instructions;~~
- ~~(b) clearly describe which version of the instructions corresponds to the machinery product model;~~
- ~~(c) be presented in a format that makes it is possible for the end user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product.~~

1.7.4.1. General principles for the drafting of instructions

- (a) The instructions ~~must~~ shall be drafted in one or more official ~~Community~~ languages of the Union. The words 'Original instructions' ~~must~~ shall appear on the language version(s) verified by the manufacturer or his or her authorised representative;
- (b) Where no 'Original instructions' exist in the official language~~(s)~~ or languages of the ~~country~~ Member State where the machinery product is to be used, a translation into that/those language(s) ~~must~~ shall be provided by the manufacturer or his or her authorised representative or by the person bringing the machinery product into the language area in question. The translations ~~must~~ shall bear the words 'Translation of the original instructions';
- (c) The contents of the instructions ~~must~~ shall cover not only the intended use of the machinery product but also take into account any reasonably foreseeable misuse thereof.
- (d) In the case of a machinery product intended for use by non-professional operators, the wording and layout of the instructions for use ~~must~~ shall take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2. Contents of the instructions

1. Each instruction manual ~~must~~ shall contain, where applicable, at least the following information:
- (a) the business name and full address of the manufacturer and, where applicable, of his or her authorised representative;
- (b) the designation of the machinery product as marked on the machinery product itself, except for the serial number (see section 1.7.3);
- (c) the ~~EE~~ EU declaration of conformity, or a document setting out the contents of the ~~EE~~ EU declaration of conformity, showing the particulars of the machinery product, not necessarily including the serial number and the signature, or the internet address where the EU declaration of conformity can be accessed;
- (d) a general description of the machinery product;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery product and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery product;
- (h) warnings concerning ways in which the machinery product ~~must~~ shall not be used that experience has shown might occur;
- (i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery product is to be mounted;
- (j) instructions relating to installation and assembly for reducing noise or vibration;
- (k) instructions for the putting into service and use of the machinery product and, if necessary, instructions for the training of operators;

- (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
- (m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;
- (n) the essential characteristics of tools, which may be fitted to the machinery product;
- (o) the conditions in which the machinery product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- (p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery product and of its various parts where these are regularly to be transported separately;
- (q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
- (r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the design and the use of the machinery product;
- (s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- (t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
- (u) the following information on airborne noise emissions:
 - i. the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact ~~must~~ shall be indicated;
 - ii. the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa);
 - iii. the A-weighted sound power level emitted by the machinery product, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values ~~must~~ shall be either those actually measured for the machinery product in question or those established on the basis of measurements taken for a technically comparable machinery product, which is representative of the machinery product to be produced.

In the case of a very large machinery product, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery product may be indicated.

Where the harmonised standards or technical specifications adopted by the Commission in accordance with article 17(3) ~~are not~~ cannot be applied, sound levels ~~must~~ shall be measured using the most appropriate method for the machinery product. Whenever sound emission values are indicated, the uncertainties surrounding these values ~~must~~ shall be specified. The operating conditions of the machinery product during measurement and the measuring methods used ~~must~~ shall be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels ~~must~~ shall be measured at a distance of 1 metre from the surface of the machinery product and at a height

of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure ~~must~~ shall be indicated.

With respect to noise reduction machinery products, the instructions shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).

Where specific Community Directives lays down other requirements for the measurement of sound pressure levels or sound power levels, those ~~Directives legal acts~~ must shall be applied and the corresponding provisions of this section shall not apply;

(v) where a machinery product is likely to emit non-ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.

(w) where the machinery product design allows emissions of hazardous substances from the machinery product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery product, and any of the following:

- i. the flow rate for the emission of hazardous materials and substances from the machinery product,
- ii. the concentration of hazardous materials or substances around the machinery product coming from the machinery product or from materials or substances used with the machinery product,
- iii. the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.

The values referred to in the first subparagraph shall either be actually measured for the machinery product in question or established based on measurements in respect of a technically comparable machinery product, which is representative of the state of the art.

1.7.4.3. Sales literature

Sales literature describing the machinery product ~~must~~ shall not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery products ~~must~~ shall contain the same information on emissions as is contained in the instructions.