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בטיחות מכונות: הערכת סיכונים - עקרונות

Safety of machinery: Risk assessment - Principles

מכון התקנים הישראלי

The Standards Institution of Israel

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תקן ישראלי זה זהה לתקן הבין-לאומי

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הודעה על רוויזיה

תקן ישראלי זה בא במקום

התקן הישראלי ת"י 4484 מדצמבר 2003

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עדכניות התקן

התקנים הישראליים עומדים לבדיקה מזמן לזמן, ולפחות אחת לחמש שנים, כדי להתאימם להתפתחות המדע והטכנולוגיה.

המשתמשים בתקנים יוודאו שבידיהם המהדורה המעודכנת של התקן על גיליונות התיקון שלו.

מסמך המתפרסם ברשומות כגיליון תיקון, יכול להיות גיליון תיקון נפרד או תיקון המשולב בתקן.

תוקף התקן

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יש לבדוק אם התקן רשמי או אם חלקים ממנו רשמיים. תקן רשמי או גיליון תיקון רשמי (במלואם או בחלקם) נכנסים לתוקף 60 יום מפרסום ההודעה ברשומות, אלא אם בהודעה נקבע מועד מאוחר יותר לכניסה לתוקף.

סימון בתו תקן

כל המייצר מוצר, המתאים לדרישות התקנים הישראליים החלים עליו, רשאי, לפי היתר ממכון התקנים הישראלי, לסמנו בתו תקן:

הקדמה לתקן הישראלי

תקן ישראלי זה הוא התקן של הארגון הבין-לאומי לתקינה ISO 14121-1 (מהדורה ראשונה) מספטמבר 2007, שאושר כלשונו כתקן ישראלי.

התקן כולל, בסדר המפורט להלן, רכיבים אלה:

- תרגום סעיף חלות התקן הבין-לאומי (בעברית)
- התקן הבין-לאומי (כלשונו)

חלות התקן (תרגום סעיף 1 של התקן הבין-לאומי)

תקן זה קובע עקרונות כלליים המיועדים לשמש בהשגת מטרות הקטנת סיכונים (risk reduction) הנקובות בתקן הבין-לאומי ISO 12100-1:2003, סעיף 5. עקרונות אלה של הערכת סיכונים מבוססים על הידע והניסיון שנרכשו בנושאי התכן של מכונות והשימוש בהן, ובכל הנוגע לאירועים (incidents), לתאונות (accidents) ולחבלות (harm) הקשורים במכונות, ומטרתם לאפשר הערכה של הסיכונים הטמונים בשלבים הרלוונטיים של מחזור החיים של מכונה.

תקן זה מספק הדרכה לגבי המידע הנדרש לשם ביצוע הערכת סיכונים. התקן מתאר נהלים לזיהוי גורמי סיכון וכן לאֲמִידַת (estimating) סיכונים ולהערכתם (evaluating).

התקן גם מספק הדרכה לגבי קבלת החלטות הנוגעות לבטיחות של מכונות ולגבי סוג התיעוד לשם אימות הערכת הסיכונים הנערכת.

תקן זה אינו ישים לגבי סיכונים הנשקפים לחיות מחמד, לנכסים חומריים או לסביבה.

ICS 13.110

Price based on 28 pages

Bibliography

[1] ISO/TR 14121-2[1)] , *Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods*

1) Under preparation.

Table A.4 (*continued*)

Origin related to	Hazardous event	Subclause(s) of ISO 12100-2:2003 (useful references)
Electrical equipment	— Direct contact — Disruptive discharge — Electric arc — Fire — Indirect contact — Short-circuit	4.4 a) 4.9, 4.12 5.2, 5.3, 5.5.4 6.4, 6.5
Control system	— Dropping or ejection of a moving part of the machine or of a workpiece clamped by the machine — Failure to stop moving parts — Machine action resulting from inhibition (defeating or failure) of protective devices — Uncontrolled movements (including speed change) — Unintended/unexpected start-up — Other hazardous events due to failure(s) or poor design of the control system	4.5 4.11 to 4.13 5.5.2 to 5.5.4 6.3 to 6.5
Materials and substances or with physical factors (temperature, noise, vibration, radiation and environment)	— Contact with objects with high or low temperature — Emission of a substance that can be hazardous — Emission of a level of noise that can be hazardous — Emission of a level of noise that can interfere with a speech communication or with acoustic signals — Emission of a level of vibration that can be hazardous — Emission of radiation fields that can be hazardous — Harsh environmental conditions	4.2.2 4.3 c) 4.4 5.1 5.3.2 5.4 6.3 to 6.5
Workstation and/or work process design	— Excessive effort — Human errors / misbehaviour (unintentional and/or deliberately induced by the design) — Loss of direct visibility of the working area — Painful and tiring postures — Repetitive handling at high frequency	4.2.1 4.7, 4.8 4.11.8 5.5.5, 5.5.6 6.3 to 6.6

A.4 Examples of hazardous events

Table A.4 gives examples of hazardous events that can occur in relation to machinery.

A hazardous event can have different causes. For example, contact with moving parts due to an unexpected start-up can be caused by the unintentional actuation of a control device or by a fault in the control system.

Any cause can, in turn, be the result of another event or combination of events (chain of events).

Table A.4

Origin related to	Hazardous event	Subclause(s) of ISO 12100-2:2003 (useful references)
Shape and/or superficial finishing of accessible parts of the machine	— Contact with rough surfaces — Contact with sharp edges and corners, protruding parts	4.2.1
Moving parts of the machine	— Contact with moving parts — Contact with rotating open ends	4.2, 4.14, 4.15 5.1 to 5.3 5.5.2 to 5.5.4 6.3 to 6.5
Kinetic energy and/or potential energy (gravity) of the machine, parts of the machine, tools and materials used, processed, handled	— Falling or ejection of objects	4.3, 4.5 4.10 to 4.12 5.2.1, 5.2.2, 5.2.7 5.3 5.5.2, 5.5.4, 5.5.5 6.4, 6.5
Stability of the machine and/or parts of the machine	— Loss of stability	4.3 a) and b) 4.6 5.2.6, 5.2.7 6.3 to 6.5
Mechanical strength of parts of the machine, tools etc.	— Break-up during operation	4.3 a) and b) 4.11, 4.13 5.2, 5.2.7 5.3.1 to 5.3.3 5.5.2, 6.4, 6.5
Pneumatic, hydraulic equipment	— Displacement of moving elements — Projection of high pressure fluids — Uncontrolled movements	4.3 a) and b) 4.10, 4.13 5.2.7 5.3.1 to 5.3.3 5.5.4, 6.4, 6.5

Table A.3 (*continued*)

Phases of machine life cycle	Examples of tasks
Fault finding/Troubleshooting	— Adjustments — Dismantling/removal of parts, components, devices of the machine — Faultfinding — Isolation and energy dissipation — Recovering from control and protective devices failure — Recovering from jam — Repairing — Replacement of parts, components, devices of the machine — Rescue of trapped persons — Resetting — Verification of parts, components, devices of the machine
Decommissioning **Dismantling**	— Disconnection and energy dissipation — Dismantling — Lifting — Loading — Packing — Transportation — Unloading
NOTE These tasks can be applied to the machine or parts of it.	

Table A.3 (*continued*)

Phases of machine life cycle	Examples of tasks
Setting **Teaching/programming and/or process changeover**	— Adjustment and setting of protective devices and other components — Adjustment and setting or verification of functional parameters of the machine (e.g. speed, pressure, force, travelling limits) — Clamping/fastening the workpiece — Feeding, filling, loading of raw material — Functional test, trials — Mounting or changing tools, tool-setting — Programming verification — Verification of the final product
Operation	— Clamping/fastening the workpiece — Control/inspection — Driving the machine — Feeding, filling, loading of raw material — Manual loading/unloading — Minor adjustments and setting of functional parameters of the machine (e.g. speed, pressure, force, travel limits) — Minor interventions during operation (e.g. removing waste material, eliminating jams, local cleaning) — Operating manual controls — Restarting the machine after stopping / interruption — Supervision — Verification of the final product
Cleaning **Maintenance**	— Adjustments — Cleaning, disinfection — Dismantling/removal of parts, components, devices of the machine — Housekeeping — Isolation and energy dissipation — Lubrication — Replacement of tools — Replacement of worn parts — Resetting — Restoring fluid levels — Verification of parts, components, devices of the machine

A.3 Examples of hazardous situations

Hazardous situations are those circumstances in which a person is exposed to at least one hazard. The exposure of a person is often the consequence of performing a task on the machine.

Some examples of hazardous situations are:

a) work near moving parts;

b) exposure to ejection of parts;

c) work underneath a load;

d) work near objects or materials at extreme temperatures;

e) exposure of the worker to hazards generated by noise.

In practice, hazardous situations are often described in terms of tasks or operation of tasks (manual loading and/or unloading of work-pieces in a press, trouble-shooting under voltage, etc.).

When describing a hazardous situation, it should be ensured that the analysed situation is clearly defined using the information available (task performed, hazard, hazardous zone).

Table A.3 includes a list of tasks which can result in a hazardous situation in case of exposure to one or more of the hazards given in Table A.1.

Table A.3

Phases of machine life cycle	Examples of tasks
Transport	— Lifting — Loading — Packing — Transportation — Unloading — Unpacking
Assembly and installation **Commissioning**	— Adjustments of the machine and its components — Assembly of the machine — Connecting to disposal system (e.g. exhaust system, waste water installation) — Connecting to power supply (e.g. electric power supply, compressed air) — Demonstration — Feeding, filling, loading of ancillary fluids (e.g. lubricant, grease, glue) — Fencing — Fixing, anchoring — Preparations for the installation (e.g. foundations, vibration isolators) — Running the machine without load — Testing — Trials with load or maximum load

Table A.2 (*continued*)

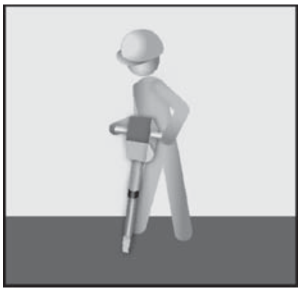
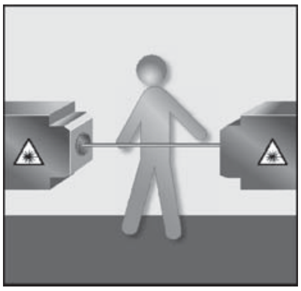
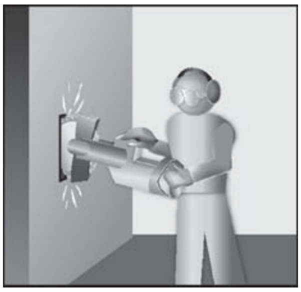
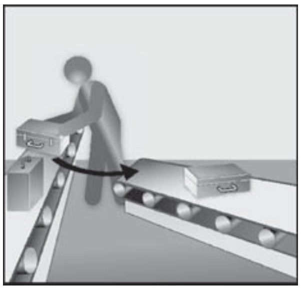
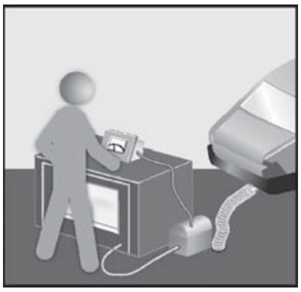
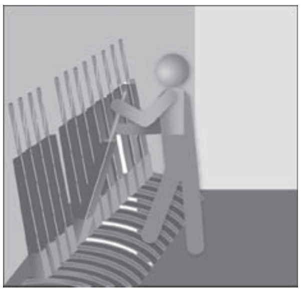
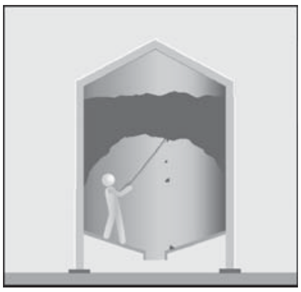
Hazard		Hazard	
	**Origin** vibrating equipment **Potential consequences** — osteo-articular disorder — vascular disorder		**Origin** noisy manufacturing process **Potential consequences** — fatigue — hearing impairment — loss of awareness — stress
	**Origin** laser beam **Potential consequences** — burn — damage to eyes and skin		**Origin** dust (emissions) **Potential consequences** — breathing difficulties — explosion — loss of sight
	**Origin** posture **Potential consequences** — discomfort — fatigue — musculoskeletal disorder		**Origin** fumes **Potential consequences** — breathing difficulties — irritation — poisoning
	**Origin** location of control devices **Potential consequences** — any as a consequence of a human error — stress		**Origin** gravity (bulk material solidified) **Potential consequences** — collapse, falling — crushing — slumping/sagging — suffocation — wedging/jamming

Table A.2 is a subset of Table A.1 and contains some examples of typical hazards. Each origin has been related to potential significant consequences. The order of potential consequences is not associated with any priority.

Table A.2

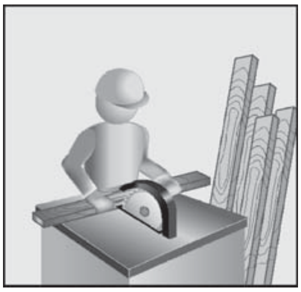
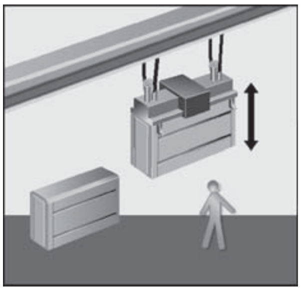
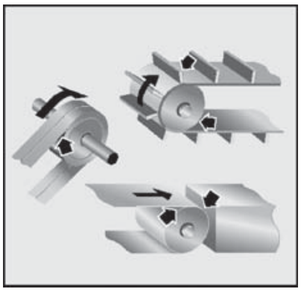
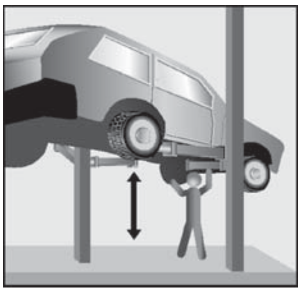
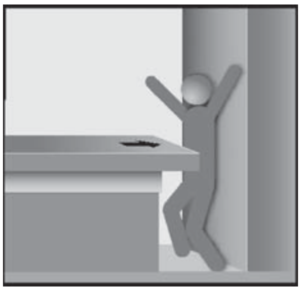
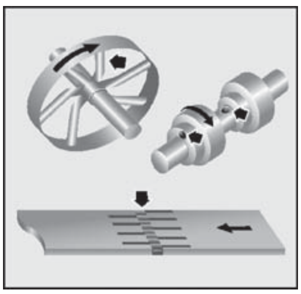
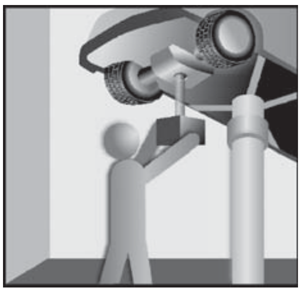
Hazard		Hazard	
	**Origin** cutting parts **Potential consequences** — cutting — severing		**Origin** falling objects **Potential consequences** — crushing — impact
	Origin moving elements **Potential consequences** — crushing — impact — shearing		Origin moving elements (three examples) **Potential consequences** — drawing-in — friction, abrasion — impact
	**Origin** gravity, stability **Potential consequences** — crushing — trapping		**Origin** approach of a moving element to a fixed part **Potential consequences** — crushing — impact
	**Origin** rotating or moving elements (three examples) **Potential consequences** — severing — entanglement		**Origin** moving elements **Potential consequences** — crushing — friction, abrasion — impact — severing
	**Origin** live electrical parts **Potential consequences** — electric shock — burn — puncture — scald		**Origin** objects or materials with a high or low temperature **Potential consequences** — burn

Table A.1 (*continued*)

No.	Type or group	Examples of hazards		Subclause of ISO 12100-1:2003 or ISO 12100-2:2003	
		Origin[a]	Potential consequences[b]	ISO 12100-1	ISO 12100-2
9	**Hazards associated with environment in which the machine is used**	— Dust and fog — Electromagnetic disturbance — Lightning — Moisture — Pollution — Snow — Temperature — Water — Wind — Lack of oxygen	— Burn — Slight disease — Slipping, falling — Suffocation — Any other as a consequence of the effect caused by the sources of the hazards on the machine or parts of the machine	4.12	4.6 4.11.11 5.2.1 6.5.1 b)
10	**Combination of hazards**	— E.g. repetitive activity + effort + high environmental temperature	— E.g. dehydration, loss of awareness, heat stroke	4.11	—

[a] One origin of hazards can have several potential consequences.

[b] For each type or group of hazard, some potential consequences can be related with several origins of hazards.

Table A.1 (*continued*)

No.	Type or group	Examples of hazards		Subclause of ISO 12100-1:2003 or ISO 12100-2:2003	
		Origin[a]	Potential consequences[b]	ISO 12100-1	ISO 12100-2
7	**Material/ substance hazards**	— Aerosol — Biological and microbiological (viral or bacterial) agent — Combustible — Dust — Explosive — Fibre — Flammable — Fluid — Fume — Gas — Mist — Oxidizer	— Breathing difficulties, suffocation — Cancer — Corrosion — Effects on reproductive capability — Explosion — Fire — Infection — Mutation — Poisoning — Sensitization	4.8	4.2.2 4.3 b) 4.3 c) 4.4 a) 4.4 b) 5.1 5.3.2.1 5.4.4 6.5.1 c) 6.5.1 g)
8	**Ergonomic hazards**	— Access — Design or location of indicators and visual displays units — Design, location or identification of control devices — Effort — Flicker, dazzling, shadow, stroboscopic effect — Local lighting — Mental overload/underload — Posture — Repetitive activity — Visibility	— Discomfort — Fatigue — Musculoskeletal disorder — Stress — Any other (e.g. mechanical, electrical) as a consequence of human error	4.9	4.2.1 4.7 4.8 4.11.8 5.2.1 5.3.2.1

Table A.1 (*continued*)

No.	Type or group	Examples of hazards		Subclause of ISO 12100-1:2003 or ISO 12100-2:2003	
		Origin[a]	Potential consequences[b]	ISO 12100-1	ISO 12100-2
4	**Noise hazards**	— Cavitation phenomena — Exhausting system — Gas leaking at high speed — Manufacturing process (stamping, cutting, etc.) — Moving parts — Scraping surfaces — Unbalanced rotating parts — Whistling pneumatics — Worn parts	— Discomfort — Loss of awareness — Loss of balance — Permanent hearing loss — Stress — Tinnitus — Tiredness — Any other (e.g. mechanical, electrical) as a consequence of an interference with speech communication or with acoustic signals	4.5	4.2.2 4.3 c) 4.4 c) 4.8.4 5.1 5.3.2.1 5.4.2 6.3 6.5.1 c)
5	**Vibration hazards**	— Cavitation phenomena — Misalignment of moving parts — Mobile equipment — Scraping surfaces — Unbalanced rotating parts — Vibrating equipment — Worn parts	— Discomfort — Low-back morbidity — Neurological disorder — Osteo-articular disorder — Trauma of the spine — Vascular disorder	4.6	4.2.2 4.3 c) 4.8.4 5.3.2.1 5.4.3 6.5.1 c)
6	**Radiation hazards**	— Ionising radiation source — Low frequency electromagnetic radiation — Optical radiation (infrared, visible and ultraviolet), including laser — Radio frequency electromagnetic radiation	— Burn — Damage to eyes and skin — Effects on reproductive capability — Genetic mutation — Headache, insomnia, etc.	4.7	4.2.2 4.3 c) 5.3.2.1 5.4.5 6.5.1 c)

Table A.1

No.	Type or group	Examples of hazards		Subclause of ISO 12100-1:2003 or ISO 12100-2:2003	
		Origin[a]	Potential consequences[b]	ISO 12100-1	ISO 12100-2
1	**Mechanical hazards**	— Acceleration, deceleration (kinetic energy) — Angular parts — Approach of a moving element to a fixed part — Cutting parts — Elastic elements — Falling objects — Gravity (stored energy) — Height from the ground — High pressure — Machinery mobility — Moving elements — Rotating elements — Rough, slippery surface — Sharp edges — Stability — Vacuum	— Being run over — Being thrown — Crushing — Cutting or severing — Drawing-in or trapping — Entanglement — Friction or abrasion — Impact — Injection — Shearing — Slipping, tripping and falling — Stabbing or puncture — Suffocation	4.2.1 4.2.2 4.10	4.2.1 4.2.2 4.3 a) 4.3 b) 4.6 4.10 5.1 5.2 5.3 5.5.2 5.5.4 5.5.5 5.5.6 6.1 6.3 6.4 6.5
2	**Electrical hazards**	— Arc — Electromagnetic phenomena — Electrostatic phenomena — Live parts — Not enough distance to live parts under high voltage — Overload — Parts which have become live under fault conditions — Short-circuit — Thermal radiation	— Burn — Chemical effects — Effects on medical implants — Electrocution — Falling, being thrown — Fire — Projection of molten particles — Shock	4.3	4.9 5.2 5.3.2 5.5.4 6.4 6.5
3	**Thermal hazards**	— Explosion — Flame — Objects or materials with a high or low temperature — Radiation from heat sources	— Burn — Dehydration — Discomfort — Frostbite — Injuries by the radiation of heat sources — Scald	4.4	4.4 b) 4.8.4 5.2.7 5.3.2.1 5.4.5

Annex A
(informative)

Examples of hazards, hazardous situations and hazardous events

A.1 General

This annex gives, in separate tables, examples of hazards (see Tables A.1 and A.2), hazardous situations (see Table A.3), and hazardous events (see Table A.4), in order to clarify those concepts and assist persons performing a risk assessment to identify them (see Clause 6).

The lists of hazards, hazardous situations and hazardous events given in this annex are not exhaustive, nor are they prioritized. Therefore, the designer should also identify and document any other hazard, hazardous situation or hazardous event existing in the machine.

Table A.1 also provides cross-referencing to ISO 12100-1 and/or ISO 12100-2 for each hazard type or group.

A.2 Examples of hazards

In Table A.1, hazards have been grouped according to their type (mechanical hazards, electrical hazards, and so on). In order to offer more detailed information on the type of hazards, two additional columns have been included, corresponding to the origin of the hazard and potential consequences.

The use of one or more of the columns presented in Table A.1 depends on the degree of detail needed for describing an identified hazard. In some cases, it is sufficient to use only one of the columns presented in Table A.1, particularly when hazards are in the same hazard zone and can be grouped together in terms of protective measures. Which of the columns is or are used depends on whether the origin of the hazard or nature of the consequences is most useful when choosing an appropriate protective measure. However, all hazards should be documented, even if the risk associated with them appears to have been sufficiently reduced by a protective measure suggested for reducing the risk associated with another hazard. Otherwise, the undocumented hazard, the risk of which was sufficiently reduced by the mitigation of another hazard, could be neglected.

Where, for describing a hazard, more than one of the columns presented in Table A.1 are used, these should not be read line by line. Appropriate words should be selected and combined to describe the hazard in the most convenient way. For example:

— crushing due to moving elements;

— crushing due to a lack of stability of the machine or part of the machine;

— electrical shock or electrocution due to electrical equipment parts which become live under fault conditions;

— permanent hearing loss due to prolonged exposure to noise caused by stamping of parts;

— respiratory disease due to inhalation of toxic substances;

— musculoskeletal disorder due to bad postures and repetitive activity;

— burn due to contact with material at high temperature;

— dermatitis due to skin contact (dermal exposure) to toxic substances.

8.3 Comparison of risks

As part of the process of risk evaluation, the risks associated with the machinery or parts of the machinery can be compared with those of similar machinery or machine parts, provided the following criteria apply:

— the similar machinery is in accordance with relevant standards;

— the intended use, reasonably foreseeable misuse and the design and construction of both machines are comparable;

— the hazards and the elements of risk are comparable;

— the technical specifications are comparable;

— the conditions for use are comparable.

The application of this comparison method does not eliminate the need to follow the risk assessment process according to this part of ISO 14121 for the specific conditions of use (e.g. when a band saw used for cutting meat is compared with a band saw used for cutting wood, the risks associated with the different material shall be assessed).

9 Documentation

Documentation of risk assessment shall demonstrate the procedure that has been followed and the results that have been achieved. This documentation includes the following, as applicable:

a) the machinery for which the assessment has been made (e.g. specifications, limits, intended use);

b) any relevant assumptions that have been made (e.g. loads, strengths, safety factors);

c) the hazards and hazardous situations identified and the hazardous events considered in the assessment (see Clause 6);

d) the information on which risk assessment was based (see 4.2);

   1) the data used and the sources (e.g. accident histories, experience gained from risk reduction applied to similar machinery);

   2) the uncertainty associated with the data used and its impact on the risk assessment;

e) the risk reduction objectives to be achieved by protective measures, for the selection of which, the standards or other specifications used should be referenced,

f) the protective measures implemented to eliminate identified hazards or to reduce risk;

g) residual risks associated with the machinery;

h) the result of the risk assessment (see Figure 1);

i) any forms completed during the risk assessment.

NOTE There is no requirement in this part of ISO 14121 to deliver the risk assessment documentation together with the machine.

The achievement of adequate risk reduction (see 8.2) and a favourable outcome of risk comparison (see 8.3), applied when practicable, gives confidence that risk has been adequately reduced.

8.2 Achievement of adequate risk reduction

8.2.1 Three-step method

The following steps, taken in the given priority will signify that the method according to ISO 12100-1:2003, definition 5.4 has been carried out.

a) The hazard has been eliminated or the risk reduced by design or by the substitution through less hazardous materials and substances or by application of ergonomic principles. (The requirements for inherently safe design measures are given in ISO 12100-2:2003, Clause 4.)

b) The risk has been reduced by the application of safeguarding and complementary protective measures of a type that adequately reduces risk for the intended use and reasonably foreseeable misuse, and which are appropriate for the application. (The requirements for safeguarding and complementary protective measures are given in ISO 12100-2:2003, Clause 5.)

c) When the application of safeguarding or complementary protective measures (see ISO 12100-2:2003, 5.5) is not practicable or does not reduce the risk adequately, the information for use shall also include notice of any residual risk. This information shall include but not be limited to

    1) operating procedures for the use of the machinery consistent with the expected ability of personnel who use the machinery or other persons who can be exposed to the hazards associated with the machinery,

    2) the recommended safe working practices for the use of the machinery and the related training requirements adequately described,

    3) sufficient information, including warning about residual risks for the different phases of the life of the machinery, and

    4) the description of any recommended personal protective equipment, including details as to the need for it, as well as of the training needed for its use.

8.2.2 Presumptions of adequate risk reduction

Adequate risk reduction is achieved when

— all operating conditions and all intervention procedures have been considered,

— the hazards have been eliminated or risks reduced to the lowest practicable level,

— any new hazards introduced by the protective measures have been properly addressed,

— users are sufficiently informed and warned about the residual risks,

— protective measures are compatible with one another,

— sufficient consideration has been given to the consequences that can arise from the use of a machine designed for professional/industrial use when it is used in a non-professional/non-industrial context, and

— the protective measures do not adversely effect the operator's working conditions or the usability of the machine.

Those components and systems identified as immediately increasing the risk in case of failure (see ISO 12100-1:2003, definition 3.28) need special attention when estimating risk.

When protective measures include work organization, correct behaviour, attention, application of personal protective equipment, skill or training, the relatively low reliability of such measures compared with proven technical protective measures shall be taken into account in the risk estimation.

7.3.6 Possibility of defeating or circumventing protective measures

Risk estimation shall take account of the possibility that protective measures can be defeated or circumvented. The estimation shall also take account of the incentive to defeat or circumvent protective measures, for example,

a) where the protective measure slows down production, or interferes with any other activities or preferences of the user,

b) where the protective measure is difficult to use;

c) when persons other than the operator are involved;

d) when the protective measure is not recognized by the user or is not accepted as suitable for its function.

The possibility of defeating a protective measure depends on both the type of protective measure (e.g. adjustable guard, programmable trip device) and its design details.

The use of programmable electronic systems introduces an additional possibility of defeat or circumvention, if access to safety-related software is not properly designed and monitored. Risk estimation shall identify cases in which safety-related functions are not separated from other machine functions and shall determine the extent to which access is possible. This is particularly important when remote access for diagnostic or process correction purposes is required.

7.3.7 Ability to maintain protective measures

Risk estimation shall consider whether the protective measures can be maintained in the condition necessary to provide the required level of protection.

NOTE If the protective measure cannot easily be maintained in correct working order, this can encourage the defeat or circumvention of the protective measure in order to allow continued use of the machinery.

7.3.8 Information for use

Risk estimation shall take into account the information for use, as available.

NOTE For information for use, see ISO 12100-2:2003, Clause 6.

8 Risk evaluation

8.1 General

Following risk estimation (see Clause 7), risk evaluation shall be carried out to determine if risk reduction is required. If risk reduction is required, then appropriate protective measures shall be selected and applied, and the procedure repeated (see Figure 1). As part of this iterative process, the designer shall check whether additional hazards are introduced or other risks increased when new protective measures are applied. If additional hazards do occur, they shall be added to the list of identified hazards and appropriate protective measures will be required to address them.

7.3 Aspects to be considered during risk estimation

7.3.1 Persons exposed

Risk estimation shall take into account all persons (operators and other persons) who could reasonably be foreseen as being exposed to the hazard.

7.3.2 Type, frequency and duration of exposure

The estimation of the exposure to the hazard under consideration (including long-term damage to health) requires analysis of, and shall account for, all modes of operation of the machinery and methods of working. In particular, the analysis shall account for the needs for access during setting, teaching, process changeover or correction, cleaning, fault-finding and maintenance.

The risk estimation shall also take into account tasks for which it is necessary to suspend protective measures.

7.3.3 Relationship between exposure and effects

The relationship between exposure to a hazard and its effects shall be taken into account for each hazardous situation considered. The effects of accumulated exposure and synergistic effects shall also be considered. Risk estimation as a result of considering these effects shall, as far as practicable, be based on appropriate recognized data.

NOTE Accident data can be available to indicate the probability and severity of injury associated with the use of a particular type of machinery with a particular type of protective measure.

7.3.4 Human factors

Human factors can affect risk and shall be taken into account in the risk estimation. This includes, for example,

a) interaction of person(s) with the machinery, including correction of malfunction,

b) interaction between persons,

c) stress-related aspects,

d) ergonomic aspects,

e) awareness of risks by persons in a given situation, depending on their training, experience and ability,

f) fatigue aspects.

Training, experience and ability can affect the risk, but none of these factors shall be used as a substitute for hazard elimination, risk reduction by design or safeguarding where the aforementioned protective measures can be practicably implemented.

Aspects of limited abilities (e.g. due to disability, age) should also be considered in this context.

7.3.5 Suitability of protective measures

Risk estimation shall take into account the suitability of protective measures and shall

a) identify the circumstances which can result in harm,

b) when appropriate, use quantitative methods to compare alternative protective measures, and

c) provide information allowing the selection of appropriate protective measure.

d) number of persons requiring access;

e) frequency of access.

7.2.3.3 Occurrence of hazardous events

The occurrence of a hazardous event influences the probability of the occurrence of harm. Factors to be taken into account when estimating the occurrence of a hazardous event are, among others:

a) reliability and other statistical data;

b) accident history;

c) history of damage to health;

d) risk comparison (see 8.3).

NOTE The occurrence of a hazardous event can be of technical or human origin.

7.2.3.4 Possibilities of avoiding or limiting harm

The possibility of avoiding or limiting harm influences the probability of the occurrence of harm. Factors to be taken into account when estimating the possibility of avoiding or limiting harm are, among others:

a) the different persons who can be exposed to the hazard(s), for example,

   — skilled, or

   — unskilled;

b) how quickly the hazardous situation could lead to harm, for example,

   — suddenly,

   — quickly, or

   — slowly;

c) any awareness of risk, for example,

   — by general information, in particular, information for use,

   — by direct observation, or

   — through warning signs and indicating devices, in particular, on the machinery;

d) the human ability of avoiding or limiting harm (e.g. reflex, agility, possibility of escape);

e) practical experience and knowledge, for example,

   — of the machinery,

   — of similar machinery, or

   — absence of experience.

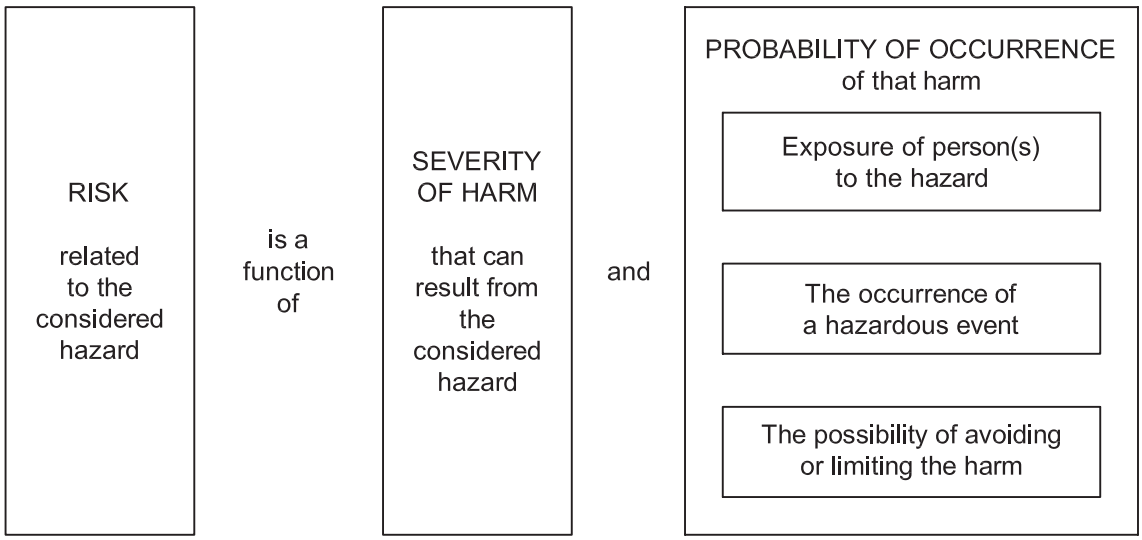


Figure 2 — Elements of risk

7.2.2 Severity of harm

The severity can be estimated by taking into account:

a) the severity of injuries or damage to health, for example,

- slight,
- serious, or
- death;

b) the extent of harm, for example,

- one person,
- several persons.

7.2.3 Probability of occurrence of harm

7.2.3.1 General

The probability of the occurrence of harm can be estimated by taking into account 7.2.3.2 to 7.2.3.4.

7.2.3.2 Exposure of persons to hazards

Exposure of a person to a hazard influences the probability of the occurrence of harm. Factors to be taken into account when estimating the exposure are, among others:

a) need for access to the hazard zone (e.g. for normal operation, correction of malfunction, maintenance or repair);

b) nature of access (e.g. manual feeding of materials);

c) time spent in the hazard zone;

— recovery of operation from jam;

— re-start after unscheduled stop;

— faultfinding/trouble-shooting (operator intervention);

— cleaning and housekeeping;

— preventive maintenance;

— corrective maintenance.

All reasonably foreseeable hazards, hazardous situations or hazardous events associated with the various tasks shall then be identified. Annex A gives examples of hazards, hazardous situations and hazardous events to assist in this process. Several methods are available for the systematic identification of hazards.

In addition, reasonably foreseeable hazards, hazardous situations or hazardous events not directly related to tasks shall be identified (e.g. seismic events, lightning, excessive snow loads, noise, break-up of machinery, hydraulic hose burst).

NOTE Examination of the available design documentation can be a useful means of identifying hazards on the machinery, particularly those associated with moving elements (e.g. motors, hydraulic cylinders).

7 Risk estimation

7.1 General

After hazard identification (see Clause 6), risk estimation shall be carried out for each hazardous situation by determining the elements of risk given in 7.2. When determining those elements, it is necessary to take into account the aspects specified in 7.3.

7.2 Elements of risk

7.2.1 General

The risk associated with a particular hazardous situation depends on the following elements:

a) the severity of harm;

b) the probability of occurrence of that harm, which is a function of

   1) the exposure of person(s) to the hazard,

   2) the occurrence of a hazardous event,

   3) the technical and human possibilities of avoiding or limiting the harm.

The elements of risk are shown in Figure 2. Additional details are given in 7.2.2, 7.2.3 and 7.3.

5.5 Other limits

Examples of other limits:

a) environmental — recommended minimum and maximum temperatures, whether the machine can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.;

b) housekeeping — level of cleanliness required;

c) properties of the material(s) to be processed.

6 Hazard identification

Following the determination of the limits of the machinery (see Clause 5), the essential step in any machine risk assessment is the systematic identification of reasonably foreseeable hazards, hazardous situations and/or hazardous events during all phases of the machine life cycle, i.e.:

a) transport, assembly and installation;

b) commissioning;

c) use;

d) de-commissioning, dismantling and disposal.

It is assumed that, when present on machinery, a hazard will sooner or later lead to harm if measures are not taken to eliminate or provide protective measures.

Only when hazards have been identified can steps be taken to eliminate them or reduce risks. To accomplish this hazard identification, it is necessary to identify the operations to be performed by the machinery and the tasks to be performed by persons who interact with it, taking into account the different parts, mechanisms or functions of the machine, the materials to be processed, if any, and the environment in which the machine can be used.

Task identification should consider all those tasks associated with all the phases of the machine life cycle listed above. Task identification should also take into account, but not be limited to, the following task categories:

- setting;
- testing;
- teaching/programming;
- process/tool changeover;
- start-up;
- all modes of operation;
- feeding machine;
- removal of product from machine;
- stopping the machine;
- stopping the machine in an emergency;

5.2 Use limits

Use limits includes the intended use and the reasonably foreseeable misuse. Aspects to be taken into account include the following:

a) the different machine operating modes and the different intervention procedures for the users (including interventions required by malfunctions of the machine use);

b) the use of the machinery (e.g. industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (e.g. visual or hearing impairment, size, strength) — if specific information is not available, the manufacturer should take into account general information about the intended user population (e. g. appropriate anthropometric data);

c) the anticipated levels of training, experience or ability of users such as

   1) operators,

   2) maintenance personnel or technicians,

   3) trainees and apprentices, and

   4) the general public;

d) exposure of other persons to the hazards associated with the machinery where it can be reasonably foreseen, including

   1) operators working in the vicinity, e.g. operators of adjacent machinery (i.e. persons likely to have a good awareness of the specific hazards),

   2) non-operator employees in the vicinity, e.g. administration staff (i.e. persons with little awareness of specific hazards but likely to have a good awareness of site safety procedures, authorized routes etc.), and

   3) non-employees in the vicinity, e.g. visitors (i.e. persons likely to have very little awareness of the machine hazards or the site safety procedures), members of the public including children, where applicable.

5.3 Space limits

Aspects to be taken into account include

a) range of movement;

b) space requirements for persons to interact with the machine, e.g. during operation and maintenance;

c) human interaction, e.g. “operator-machine” interface; and

d) “machine-power supply” interface.

5.4 Time limits

Aspects to be taken into account include

a) the “life limit” of the machinery and/or of some of its components (e.g. tooling, parts that can wear, electromechanical components), taking into account its intended use and reasonably foreseeable misuse; and

b) recommended service intervals.

3) documentation on previous designs of similar machinery, if relevant;

4) information for use of the machinery, as available;

b) related to regulations, standards and other applicable documents:

1) applicable regulations;

2) relevant standards;

3) relevant technical specifications;

4) safety data sheets;

c) related to experience of use:

1) any accident, incident or malfunction history of the actual or similar machinery;

2) the history of damage to health resulting, for example, from emissions (noise, vibration, dust, fumes, etc.), chemicals used or materials processed by the machinery.

NOTE An incident that has occurred and resulted in harm can be referred to as an “accident”, whereas an incident that has occurred and that did not result in harm can be referred to as a “near miss” or “dangerous occurrence”.

d) Relevant ergonomic principles (see ISO 12100-2:2003, 4.8).

The information shall be updated as the design develops or when modifications to the machine are required.

Comparisons between similar hazardous situations associated with different types of machinery are often possible, provided that sufficient information about hazards and accident circumstances in those situations is available.

The absence of an accident history, a small number of accidents or low severity of accidents should not be taken as a presumption of a low risk.

For quantitative analysis, data from data bases, handbooks, laboratories or manufacturers’ specifications may be used, provided that there is confidence in the suitability of the data. Uncertainty associated with these data shall be indicated in the documentation (see Clause 9).

5 Determination of limits of machinery

5.1 General

Risk assessment begins with the determination of the limits of the machinery, taking into account all the phases of the machinery life. This means that the characteristics and performances of the machine or a series of machines in an integrated process, and the related people, environment and products, should be identified in terms of the limits of machinery as given in 5.2 to 5.6.

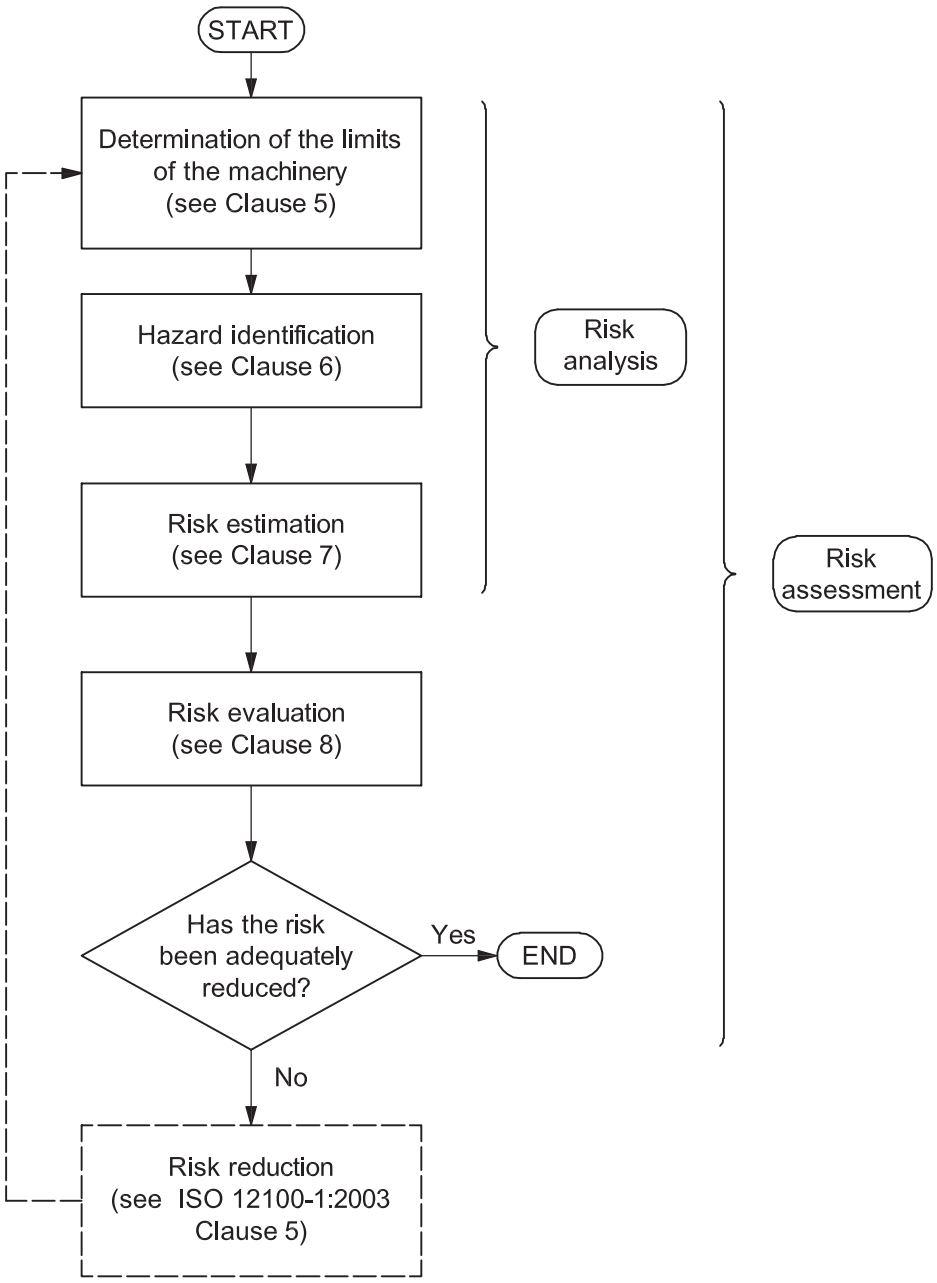


Figure 1 — Iterative process for reducing risk

4.2 Information for risk assessment

The information for risk assessment should include the following:

a) related to machinery description:

   1) user specifications;

   2) anticipated machinery specifications, including

      i) description of the various phases of the whole life cycle of the machinery,

      ii) design drawings or other means of establishing the nature of the machinery, and

      iii) required energy sources and how they are supplied;

3.17
task
specific activity performed by one or more persons on or in the vicinity of the machine during its lifecycle

4 General principles

4.1 Basic concepts

Risk assessment is a series of logical steps to enable, in a systematic way, the analysis and evaluation of the risks associated with machinery. Risk assessment is followed, whenever necessary, by risk reduction as described in ISO 12100-1:2003, Clause 5. Iteration of this process can be necessary to eliminate hazards as far as practicable and to adequately reduce risks by the implementation of protective measures.

Risk assessment includes the following (see Figure 1):

a) risk analysis:

   1) determination of the limits of the machinery (see Clause 5);

   2) hazard identification (see Clause 6);

   3) risk estimation (see Clause 7);

b) risk evaluation (see Clause 8).

Risk analysis provides information required for the risk evaluation, which in turn allows judgements to be made about whether or not risk reduction is required.

These judgments shall be supported by a qualitative, or where appropriate, a quantitative, estimate of the risk associated with the hazards present on the machinery

NOTE A quantitative approach can be appropriate when useful data is available. However, a quantitative approach is restricted by the useful data that are available and/or the limited resources of those conducting the risk assessment. Therefore, in many applications, only qualitative risk estimation will be possible.

The risk assessment shall be conducted so that it is possible to document the procedure that has been followed and the results that have been achieved (see Clause 9).

3.9
protective measure
measure intended to achieve risk reduction

NOTE 1 It is implemented:

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

— 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).

NOTE 2 See ISO 12100-1:2003, Figure 1.

[ISO 12100-1:2003, definition 3.18]

3.10
reasonably foreseeable misuse
use of a machine in a way not intended by the designer, but which may result from readily predictable human behaviour

[ISO 12100-1:2003, definition 3.23]

3.11
residual risk
risk remaining after protective measures have been taken

NOTE See ISO 12100-1:2003, Figure 1.

[ISO 12100-1:2003, definition 3.12]

3.12
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO 12100-1:2003, definition 3.11]

3.13
risk analysis
combination of the specification of the limits of the machine, hazard identification and risk estimation

[ISO 12100-1:2003, definition 3.14]

3.14
risk assessment
overall process comprising a risk analysis and a risk evaluation

[ISO 12100-1:2003, definition 3.13]

3.15
risk estimation
definition of likely severity of harm and probability of its occurrence

[ISO 12100-1:2003, definition 3.15]

3.16
risk evaluation
judgement, on the basis of risk analysis, of whether the risk reduction objectives have been achieved

[ISO 12100-1:2003, definition 3.16]

3.2
hazard
potential source of harm

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

NOTE 2 The hazard envisaged in this definition:

— either is permanently present during the intended use of the machine (e.g. motion of hazardous moving elements, electric arc during a welding phase, unhealthy posture, noise emission, high temperature);

— or can appear unexpectedly (e.g. 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)

[ISO 12100-1:2003, definition 3.6]

3.3
hazard zone
danger zone
any space within and/or around machinery in which a person can be exposed to a hazard

[ISO 12100-1:2003, definition 3.10]

3.4
hazardous event
event that can cause harm

NOTE A hazardous event can occur over a short period of time or over an extended period of time.

3.5
hazardous situation
circumstance in which a person is exposed to at least one hazard

NOTE The exposure can result in harm immediately or over a period of time.

[ISO 12100-1:2003, definition 3.9]

3.6
intended use of a machine
use of a machine in accordance with the information provided in the instructions for use

[ISO 12100-1:2003, definition 3.22]

3.7
machinery
machine
assembly of linked parts or components, at least one of which moves, with the appropriate machine actuators, control and power circuits, joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material

NOTE The term “machinery” also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

[ISO 12100-1:2003, definition 3.1]

3.8
malfunction
failure of a machine to perform an intended function

NOTE For examples, see ISO 12100-1:2003, 5.3 b), item 2).

Safety of machinery — Risk assessment —

Part 1: Principles

1 Scope

This part of ISO 14121 establishes general principles intended to be used to meet the risk reduction objectives established in ISO 12100-1:2003, Clause 5. These principles of risk assessment bring together knowledge and experience of the design, use, incidents, accidents and harm related to machinery in order to assess the risks posed during the relevant phases of the life cycle of a machine.

This part of ISO 14121 provides guidance on the information that will be required to enable risk assessment to be carried out. Procedures are described for identifying hazards and estimating and evaluating risk.

It also gives guidance on the making of decisions relating to the safety of machinery and on the type of documentation required to verify the risk assessment carried out.

It is not applicable to risks posed to domestic animals, property or the environment.

2 Normative references

The following referenced documents are indispensable for the application 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 12100-1:2003, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology*

ISO 12100-2:2003, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles and specifications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
harm
physical injury or damage to health

[ISO 12100-1:2003, definition 3.5]

Introduction

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

a) Type-A standards (basic standards) give basic concepts, principles for design, and general aspects that can be applied to machinery.

b) Type-B standards (generic safety standards) deal with one or more safety aspect(s) or one or more type(s) of safeguards that can be used across a wide range of machinery:

   — type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);

   — type-B2 standards on safeguards (e.g. two-hands controls, interlocking devices, pressure sensitive devices, guards).

c) Type-C standards (machine safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This part of ISO 14121 is a type-A standard as stated in ISO 12100-1.

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 according to the provisions of the type-C standard.

The purpose of this type-A standard is to describe principles for a consistent systematic procedure for risk assessment as stated in ISO 12100-1:2003, Clause 5.

This part of ISO 14121 gives guidance for decisions related to the design of machinery and will assist in the preparation of consistent and appropriate type-B and type-C standards, so that machines can be produced that are safe for their intended use in accordance with the methodology given in ISO 12100.

Annex A gives, in separate tables, examples of hazards, hazardous situations and hazardous events, so as to clarify these concepts and assist the designer in the process of hazard identification.

The practical use of a number of methods for each stage of risk assessment is described ISO/TR 14121-2, which also gives some guidance on how the selection of protective measures (in accordance with ISO 12100) can reduce the different elements of risk in relation to Figure 2 of this part of ISO 14121.

This part of ISO 14121 can be incorporated in training courses and manuals where appropriate to give basic instruction on risk assessment.

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14121-1 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

This first edition of ISO 14121-1 cancels and replaces ISO 14121:1999, of which it constitutes a technical revision.

ISO 14121 consists of the following parts, under the general title *Safety of machinery — Risk assessment*:

— *Part 1: Principles*

— *Part 2: Practical guidance and examples of methods* [Technical Report]

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