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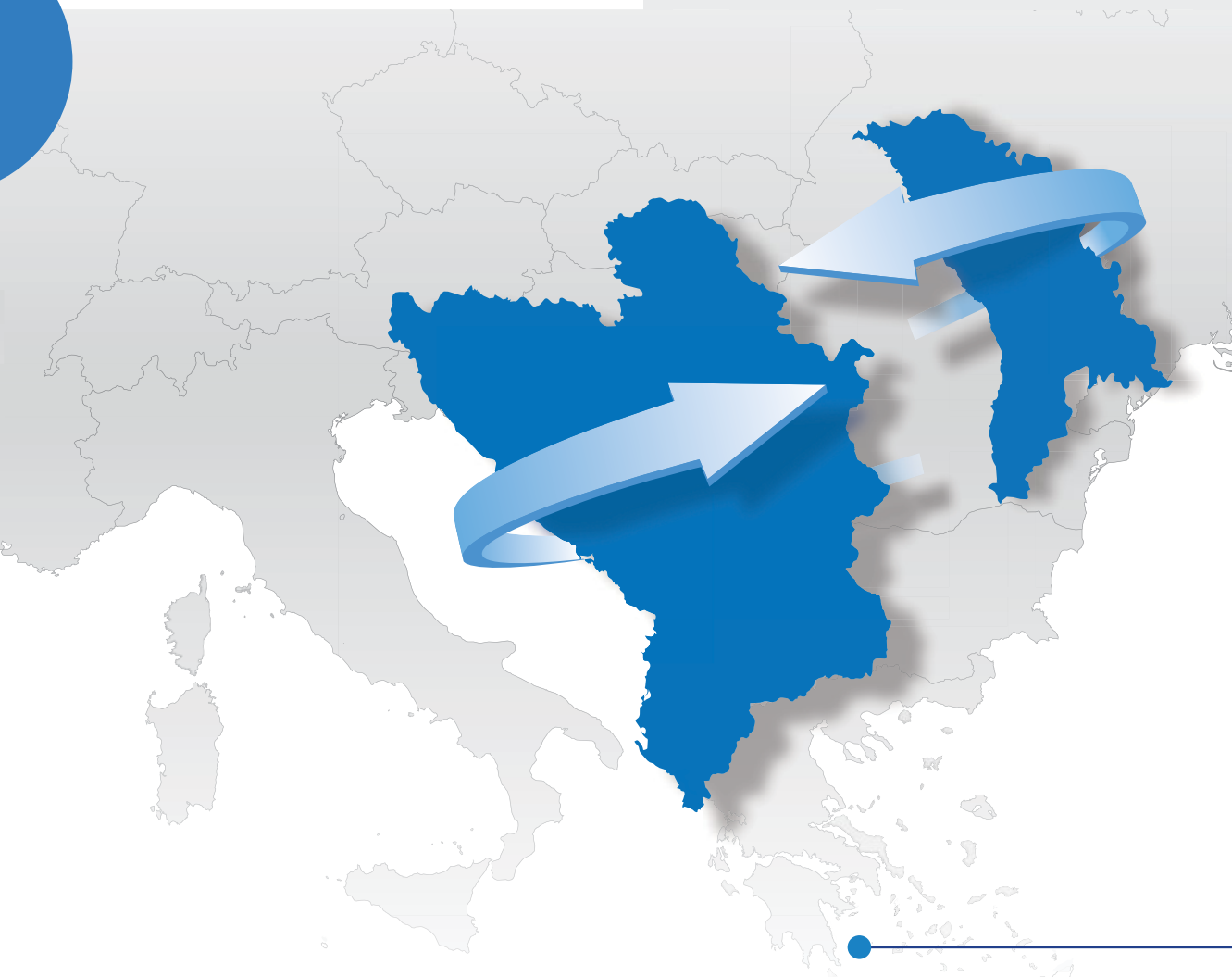
DEUTSCHE ZUSAMMENARBEIT

Guidelines for machinery products

Implementation of Machinery Directive (2006/42/EC)



Implemented by

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1. Acronyms and abbreviations

Acronym/ abbreviation	Explanation
ATEX	Directive on Equipment to be used in potentially explosive atmosphere
CAB	Conformity assessment body
CEFTA	Central European Free Trade Agreement
CEN	Comité Européen de Normalisation / European Committee for Standardisation
CENELEC	Comité Européen de Normalisation Électrotechnique / European Committee for Electrotechnical Standardisation
CNB	Coordination of Notified Bodies
CNB/M	Coordination of Notified Bodies for Machinery
EA	European co-operation for Accreditation
EHSR	Essential Health and Safety Requirement
EX	Explosive atmosphere
EU (EC)	European Union (European Community)
IMS	Integrated Manufacturing System
MD	Machinery Directive 2006/42/EC
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
NLF	New Legislative Framework
NOISE	Noise Emission of Outdoor Equipment Directive
PED	Pressure Equipment Directive
PL	Performance Level
PPE	Personal Protective Equipment
QI	Quality Infrastructure
TCF	Technical Construction File

Note: This guideline has been prepared for a better understanding of the application of the Machinery Directive among economic operators but also other stakeholders of QI. Chapters 1 and 2 are intended predominantly for manufacturers, while Chapters 3 and 4 are intended for CABs operating in machinery sector.

2. How to Design-In the Compliance of the Machinery (three-step method)?

2.1 General

Machinery Directive requires that applicable Essential Health and Safety Requirements (EHSRs) related to the machine in question have to be met in a three-step hierarchy of measures for risk reduction. The requirements are written in plain and legal language without giving any technically specific guidance on how to meet the requirements. This brings on a legitimate question on how to approach these requirements and what the relations are between EHSRs, hazards and risks and measures from harmonized standards.

Safe handling in all life-cycles of machinery (transport, assembly, start-up, use, maintenance and disassembly) can be assured when applying the principles of design of safe machinery as described in standard EN ISO 12100 – Safety of machinery – General principles for design — Risk assessment and risk reduction.

These questions typically arise for the designer:

01. how can I approach the design of a machine in an organized manner so that I don't miss meeting every single EHSR?

02. how can I assess when the risks due to present hazard or hazardous situations have to be mitigated by the safety measures?

03. how can I be sure that the applied safety measures in the form of inherently safe design or safeguarding are correct and sufficient?

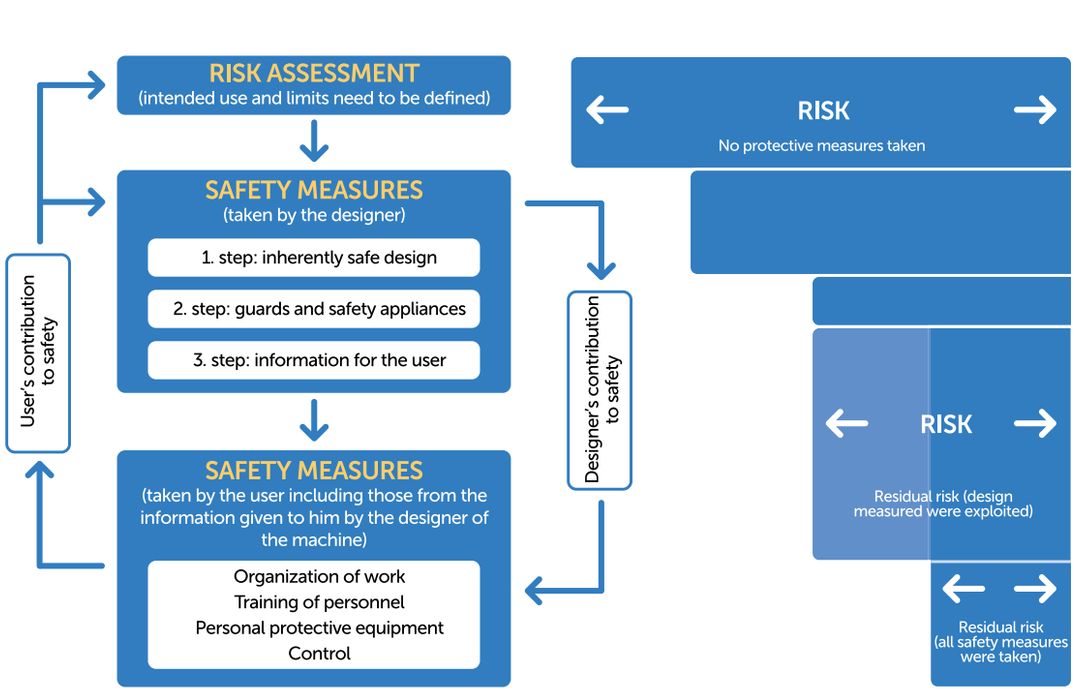
There are basically two similar ways to comprehensively take the EHSRs into account in the design process. One is to follow the list of requirements from Annex I step by step, while the other (more often used and transparent) is a process of conveying the requirements through identification of hazards and their risk assessment and applying risk mitigation measures in a three-step way. When risk mitigation measures follow the (solutions from) harmonized standards, they automatically give presumption of conformity with the Machinery Directive.

But what exactly does a three-step way mean to design-in the compliant machine?
It means that the design of a safe machine should follow three consecutive steps:

1st step measures for inherently safe design

2nd step selection and design of appropriate guarding and safety appliances

3rd step instructions for use



Principles of mitigating the risk(s) to an acceptable level by measures taken from designer and user (according to EN ISO 12100).

2.1.1
1st step: Inherently safe design

In the first step, the designer should try to eliminate the hazards as much as possible in view of the intended use of the machine with the limitation of exposure of persons For example: selection and placement of necessary operator's activities and workstations, selection of number of operators as well as their abilities, automation and mechanization of certain machine operations, use of information technology for monitoring, etc. Inherently safe design shall be obtained furthermore by:

01. Consideration of geometrical factors and physical aspects (assuring the visibility of workstations and monitoring of the machine processes without obstacles, accessibility and logic of control system, limitation of masses and velocities of movable elements, reduction of emissions of any kind, avoidance of sharp edges, application of safety distances etc.);

02. Taking into account the general technical knowledge regarding the machine design (design codes and calculation rules for basic elements and structures with respect to predictable stress, fatigue and foreseeable misuse) together with information on materials and incorporated working substances;

03. Choice of an appropriate technology including the supply of energy;

04. Applying the principle of the positive mechanical action of a component on another component;

05. Provisions for stability (geometry of the base, weight distribution, dynamic forces and oscillation, influence of external forces like wind pressure);

06. Provisions for maintainability (accessibility to the machinery parts in need of maintenance, ease of handling, safety precautions);

07. Observing ergonomic principles (adaptation to human anthropometric data and physical stress in work);

08. Preventing electrical hazard (general provisions are set in EN 60204-1);

09. Preventing hazards from hydraulic and pneumatic equipment (limitation of pressures, safety elements for overpressure, etc.);

10. Applying inherently safe design measures to the control system (general provisions are set in EN ISO 13849-1 like prevention of unexpected start-up, restart after power interruption, uncontrolled speed change, failure to stop, hardware and software aspects, etc.);

11. Minimizing risks due to the failure of safety functions (redundancy and monitoring of control circuits;

12. Minimizing the probability of failure of safety functions;

13. Limiting exposure to hazards through mechanisation or automation of (un) loading operations.

2.1.2
2nd step: Guards and safety appliances

When inherently safe design cannot be achieved due to the functionality limitations or nature of working processes, the designer should seek for appropriate safety measures within the second step – guarding and safety appliances. Their selection and performance shall be checked again by risk assessment. As before, the use of harmonised standards is again recommended. More detailed guidance is given further on in this document.

2.1.3
3rd step: Information for use

When, after application of technical measures, residual risks in the machine still exist, the designer has to convey the residual risks through information to warn the users about the residual risks. Available audio-visual communications are:

01. Signals and warning devices,

02. Warnings and pictograms (standardised graphical signs according to ISO 7000),

03. Safety warnings on residual risks in instructions for use (manual, handbook).

The manufacturer shall warn the user on residual risks, define the personal protective equipment (PPE) for safe work with the machine and, where appropriate, train the user for safe work. The user is responsible to use and maintain the machine in compliance with the manufacturer's instructions for use. In no case can the instructions for use substitute the omitted measures for inherently safe design if such measures are later technically possible to realize, because safe design measures give a higher level of safety due to their independency on psychophysical abilities of the user as well as lower possibility to defeat safety measures.

To cross-check whether the risk assessment process has taken into account all safety related issues, a manufacturer can also check whether applicable EHSR from Annex I of the Machinery Directive have been met. This is especially useful for industrial machinery or one-off machines where no product standard exists.

Pictograms are warning the user of residual risks, safe practices and/or use of PPE

2.2 Addressing essential requirements

EHSRs in MD are organised differently and are grouped in six chapters against the nature of the hazards they are covering (taxonomy approach). The first chapter shall be used for any kind of machine, while other chapters cover specific types of machinery. The seven major requirements in the first chapter refer to:

01. general requirements (clause 1.1): sets the terminology and gives guidelines on how to assure safety by using the three-step compliance procedure in order to achieve the goal, i.e. the elimination of hazards by inherently safe design and/or lowering the risk to an acceptable level through the use of safeguarding and information to the users;

02. requirements for control systems (clause 1.2): start-up, stop, emergency stop, mode selection, software;

03. safeguarding against mechanical hazards (clause 1.3): types of guarding, characteristics of guards, interlocking;

04. selection of guards and safety appliances (clause 1.4): types and conditions for selection, characteristics of safety appliances;

05. requirements for other types of hazards (clause 1.5): electrical supply and electrical equipment, fire and explosion protection, noise and vibrations, emission of dangerous substances, etc.;

06. requirements for planning safe maintenance activities on the machine and its safe performance (clause 1.6);

07. marking (clause 1.7): information devices, signals, warnings on residual risks, marking plate, information for use (manual).

In the following section, basic approaches to these essential groups of safety measures are given:

Further requirements refer to different types of machinery or specific hazards:

01. machinery for agri-food stuffs, portable hand-held and/or hand-guided machinery, machinery for working wood and analogous materials, portable fixing and impact machinery, pesticide application machinery,

02. mobile machinery,

03. lifting operation machinery,

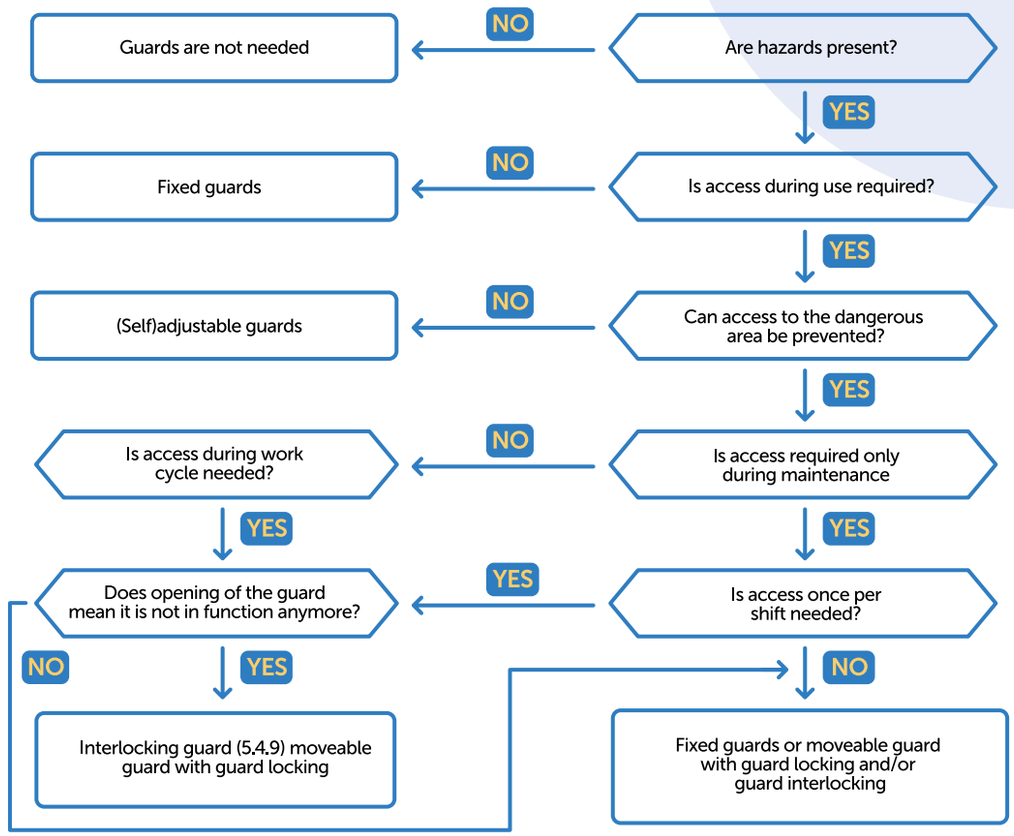
04. underground work machinery,

05. machinery for lifting or moving persons.

06. General guidelines for implementation of guarding and safety appliances.

2.3 Guards and safety appliances

Guards should prevent users from the mechanical hazards arising in the machine. Guards should be selected according to the nature of their use (EN ISO 14120) and designed with respect to maintain its safety function (safety distances according to EN ISO 13854 and EN ISO 13857).



Guideline for selection of guard against movable parts (EN ISO 14120)

2.4 Control system

The logic of the control system of the machine and its safety aspect is also standardized. Main requirements (like necessary actuators and their function) are described in some of the EHSRs. However, general rules on design and verification of safety related parts of the control system are (when not defined in C-type standard) set in EN ISO 13849-1 and EN ISO 13849-2.

Namely, failure of one of the control system components can cause irregular operation of machine causing a possible harmful event likely to happen. In this matter, control systems shall be carefully designed and checked to work properly. Evolving from the risk assessment, five basic performance levels of control systems exist requiring control system architecture and reliability characteristics. In practice, if the risk assessment regarding the control system shows high risk for the user, the designer should choose a more sophisticated system where its proper function can be under diagnostic coverage in the regular intervals or shall have redundant wiring.

Safety appliances shall be positioned with respect to the velocity of approaching moving parts according to EN ISO 13855. Safety distances shall be calculated and appropriate equipment selected as follows:

S = (v x t) + C

S...minimum distance from body to point of actuation of safety appliance

v...velocity of approaching (to parts of human body)

t...total stopping time

C...additional distance

Widely known safety appliances are (to list a few of them):

01. emergency stop (g),

02. two-hand control device (f),

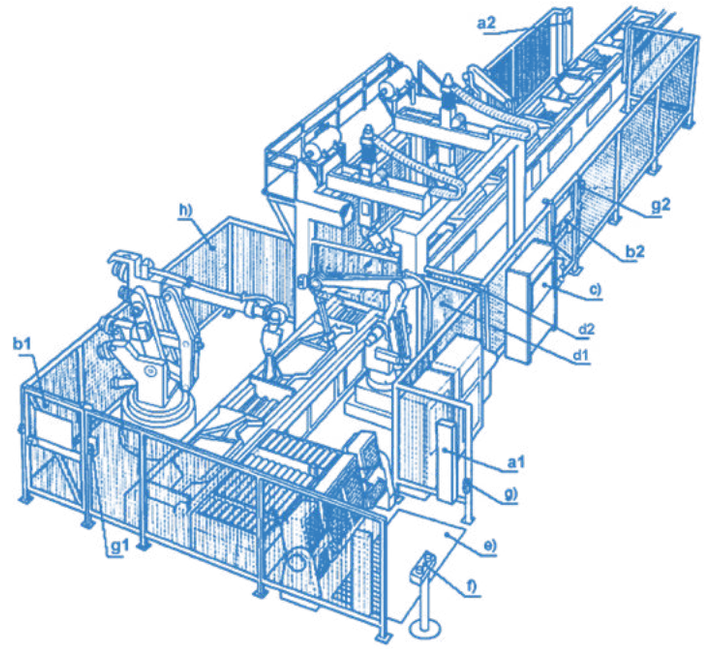
03. interlocking guard with guard locking (b),

04. time delay (c),

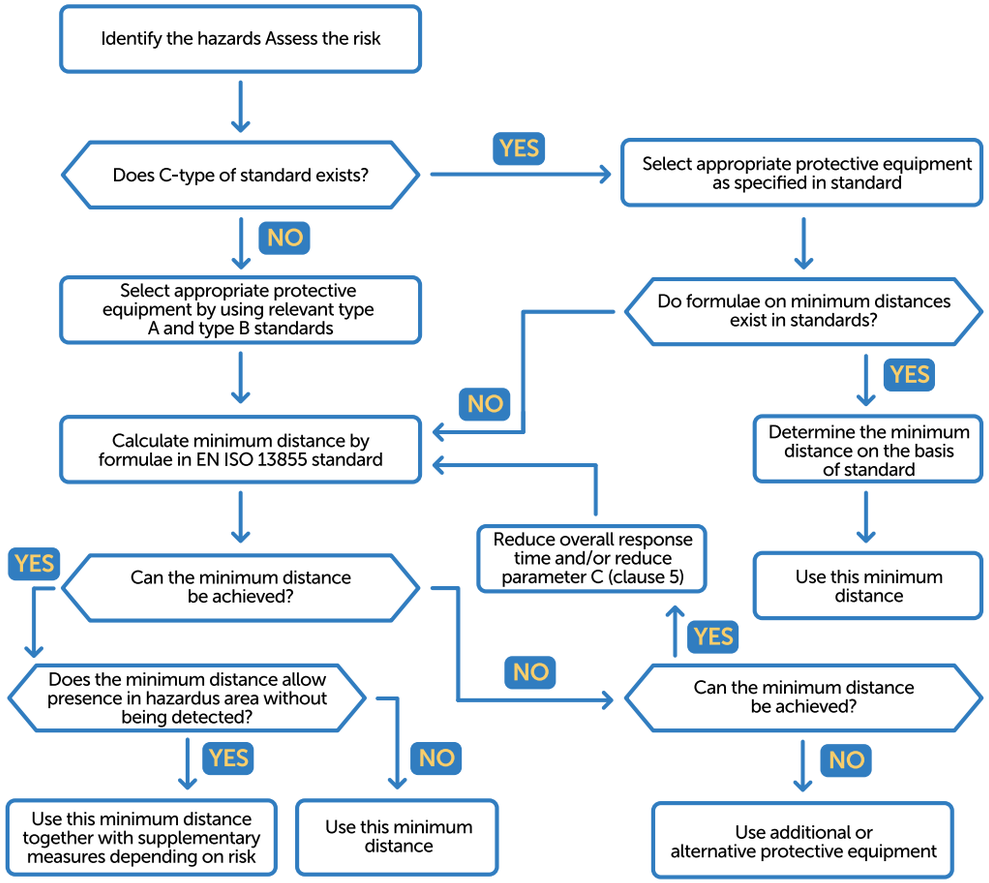
05. electrooptical sensitive equipment (a),

06. pressure mats (e),

07. limit switches (h).



Types of safety appliances (excerpt from former associated standard EN 953)



Guideline for selection and positioning of safety appliances (EN ISO 13855)

2.5 Electrical equipment of machinery

Standard EN 60204-1 gives guidance for design of electrical circuits. It defines requirements for control systems, protection against (in)direct touch of live parts, overcurrent protection, short circuit, overheating, unexpected start-up after restorage of power supply and phase connection failure. It furthermore gives guidelines for selection of electrical equipment and its resistance to external influences (especially ingress protection IP). Prior to putting the machine into operation the following electrical tests shall be conducted (assuring the traceability and repeatability of the tests) and recorded in the TCF:

01. test of continuity of safety circuit,

02. insulation resistance test,

03. dielectric strength test,

04. leakage current,

05. control system performance test.

2.6 Other major safety requirements

2.6.1 Fire and explosion

Machine intended to be used in potentially explosive atmospheres (EX) shall comply with the ATEX directive. This is also the case when the machine does not operate in EX atmosphere but includes one or more components containing explosive atmospheres (for example: paint cabin). The component(s) in question shall be ATEX proved.
Systems for fire protection shall be considered if the machine is used in a fire propagation environment.

2.6.2 Noise and vibration

Low noise emission design and measures at the noise sources are stipulated (use of nonmetals, avoidance of resonance, design of noise silencers, appropriate design of ducts and pipes, etc.). Even though MD does not set any noise limitations, it is clear that low noise emission machinery is healthy for use due to lower mental stress. Users shall be informed on actual noise emission values (in manual), if the noise emission exceeds 70 dB(A). An appropriate PPE for ear protection shall be prescribed for the user.
Low vibration design of (hand-held or riding) machinery is also stipulated. When the level of vibration exceeds 2.5 m/s2, the actual vibration level shall be stated in the manual.

2.6.3 Radiation

Some machinery uses the properties of electromagnetic (EM) fields, X-rays, Y-rays, laser, etc. for their operation. MD requires that emissions of these radiations shall be limited to the functional extent only in order to protect the user from any harmful effects of radiation.

In addition to safety aspects, the compliance with the EMC directive shall be assured. Compliance with the EMC directive means, that the machine in question does not emit harmful EM disturbances as well as being immune to EM disturbances.

2.6.4
Pollution emission

The machinery shall be designed for low pollution as much as possible. Gases, dust or mist shall be extracted from the machine by extraction systems catching the substances in filters.

2.6.5
Maintenance of machinery

Statistics of harmful events show a trend of increased injuries happening during the maintenance activities. Since MD requires measures for all life-cycles, the safe maintenance shall always be in mind of any designer. Setting-up, servicing or repairing, cleaning and maintenance shall be possible under conditions of stand-still or controlled low speed only and not while the machine is running normally.

Further requirements refer to different types of machinery or specific hazards:

01. machinery for agri-food stuffs, portable hand-held and/or hand-guided machinery, machinery for working wood and analogous materials, portable fixing and impact machinery, pesticide application machinery

02. mobile machinery,

03. lifting operation machinery,

04. underground work machinery,

05. machinery for lifting or moving persons.

06. General guidelines for implementation of guarding and safety appliances

2.6.6
Mobile machinery

Mobile machinery (like construction machinery, agricultural machinery, etc.) has to fulfil the additional requirements against the harmful events caused by moving machinery:

01. ergonomics at workstations,

02. control system for manoeuvring,

03. protection against mechanical hazards,

04. protections against other hazards,

05. indicators,

06. marking.

2.6.7
Lifting equipment

Additional requirements bring provisions for:

01. stability,

02. manoeuvring,

03. mechanical strength,

04. ropes, chains and webbings,

05. auxiliary lifting equipment,

06. controls,

07. marking.

The dynamic and static load tests have to be performed.

2.6.8
Lifting equipment for persons

Machinery used for lifting of goods can also be used for lifting persons. Similar requirements apply as before with special emphasis on possible fall from height hazard. If the mobility function of the machine is present during the lifting operation, than these two movements shall be coordinated in a manner of safe work.

Machinery used underground shall be designed, manufactured and tested against safe use in possible fire or explosive areas.

2.7 Risk assessment

As argued earlier and due to the fact that the same hazards may arise on various parts of the machine in question or there may be a combination of hazards at one spot, a preferred approach for comprehensive and systematic safety analysis is to use the risk assessment procedure as described in EN ISO 12100.

Another reason for this approach is that risk is by definition a combination of the probability and the severity of the possible injury or damage to health in a hazardous situation. Since general hazards and risks linked with machines are listed in Annex I of MD but have to be estimated to assess the need for safety measures, EN ISO 12100 with a basic methodology on risk evaluation makes a better base for justification of safety measures.

Standard EN ISO 12100 gives basic principles and details on the risk assessment procedure.

It is an essential step of the designer to assure the compliance of the machine with the EHSRs of the MD. It contains:

01. list of hazards and hazardous situations that may appear (Annex B),

02. links between EHSRs from Annex I of MD and types of hazards and hazardous situations as well as links to the basic standard for safe design EN ISO 12100,

03. principles for risk evaluation and assessment of measures taken,

04. principles for preparation of harmonised standards in support of MD.

In other words, risk assessment is a recursive procedure where the designer:

01. clearly defines the scope and boundaries of the risk assessment,

02. systematically identifies hazards or hazardous situations and risks associated with them with regards to the intended use of the machine and who can get hurt (user, property, nature, etc.),

03. evaluates the severity and probability of a harmful event (methodology is not specified but ISO/TR 14121-2: 2012 Safety of machinery — Risk assessment — Part 2: Practical guidance and examples of methods gives a good example of detailed methodology),

04. assesses existing control measures and their (in)sufficiency to achieve acceptable risk (compliance) level,

05. selects and implements safety measures for eliminating or reducing the unacceptable risks in a three-step design process (use of technical solutions from harmonized standards are stipulated),

06. evaluates fulfilment of EHSRs or compliance with MD.

07. documents the identified hazards, risk ratings, and recommended control measures as well as communicating the residual risks with the users,

08. regularly reviews and updates the risk assessment to account for changes in the activity, process, or external factors.

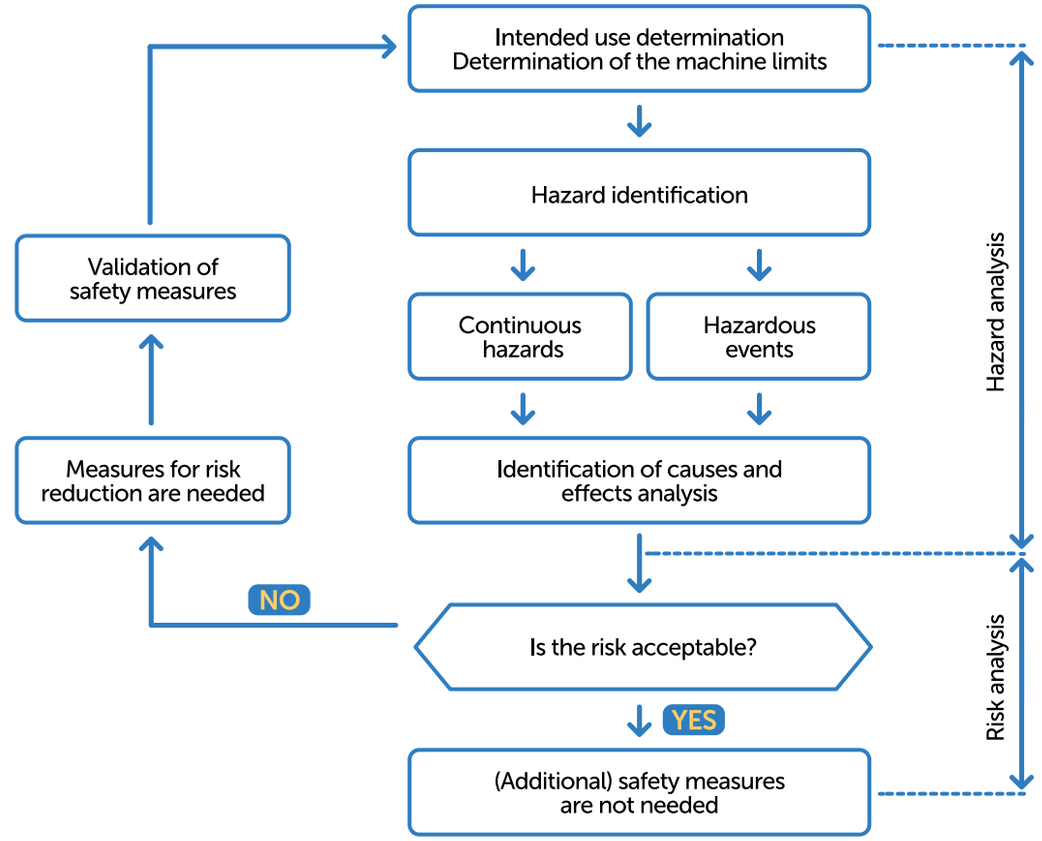
Remember that risk assessment is an iterative process that should be performed at appropriate intervals or when significant changes occur. It requires ongoing monitoring and review to ensure that control measures are effective and risks are managed appropriately.

Generally, risk associated with a specific hazard is a combination of:

01. severity (S),

02. probability of hazardous event.

Both of these factors define the estimated level of risk.



Principle of risk assessment (EN ISO 12100)

2.7.1
Risk estimation

Risk estimation is the process of assessing and quantifying the level of risk associated with a specific hazard or set of hazards. It involves evaluating the likelihood or probability of a hazardous event occurring and the potential consequences or impacts if the event were to happen.

Determination of probability - it can be based on historical data, expert judgment, statistical analysis, or other relevant information. Consider factors such as the frequency of exposure to the hazard, the possibility to detect and avoid it and the reliability of control measures.

Assessing unwanted consequences - evaluate the potential consequences or impacts that could result from the hazardous event. This includes considering the severity of harm to people, property, or the environment. Consequences can range from minor injuries or damage to catastrophic events with significant loss of life or widespread environmental damage. Consider both immediate and long-term consequences.

Qualitative Assessment - conduct a qualitative assessment by assigning qualitative descriptors to the probability and consequences. This can involve using scales such as low, medium, or high to describe the likelihood or severity of harm. This provides a qualitative understanding of the risk level and helps prioritize risk mitigation efforts.

Combine Probability and Consequences - combine the probability and consequences assessments to determine the overall risk level. This can be done through a risk matrix, where the likelihood and severity ratings are plotted on a matrix to determine the risk rating. The matrix can be divided into risk zones (i.e. ''heat maps'') or levels, such as low, medium, high, or using a numerical scale.

Technical report ISO/TR 14121-2, that is often used in the machinery sector, gives examples of qualitative and quantified approach to risk estimation and determination of risk levels.

Risk estimation matrix (ISO/TR 14121-2:2012, Table 1)				
Probablity of occurrence of harm (EN ISO 12100:2010, 5.5.2.3)	Severity of harm			
	Catastrophic	Serious	Moderate	Minor
Very likely	High	High	High	Medium
Likely	High	High	Medium	Low
Unlikely	Medium	Medium	Low	Negligible
Remote	Low	Low	Negligible	Negligible

Risk estimation matrix

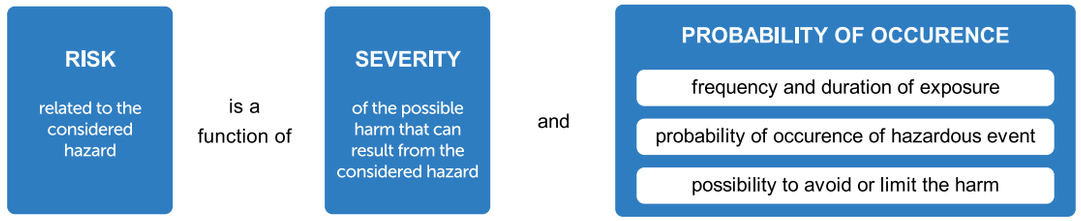
Review and Update – generally, risk estimation is not a one-time activity. It shall be at least performed before and after safety (control) measures are applied to mitigate the risk. Regular review and update risk assessments shall take place as new information becomes available, conditions change or new hazards are identified.

Probability can be further defined as a combination of:

01. frequency and duration of exposure to a hazardous situation or hazard (F),

02. probability of occurrence of a hazard or a hazardous event (P) and

03. possibility to limit or avoid a harmful event (W).



Risk is a function of severity and occurrence probability.

A harmful event can be assessed in the view of the nature of possible damage (users, property, animals, environment), type of injury and extent (one or more persons).

Severity (S):

01. S0- no hazard,

02. S1- light injury (reversible),

03. S2- heavy injury (irreversible),

04. S3- death (or more heavily injured).

Time or frequency, when the user is exposed to a certain hazard or hazardous situation (like maintenance, normal work, trial work) can give assessment on duration of exposure (F):

01. F1- rarely,

02. F2- frequently or always.

Parameter P (possibility to limit or avoid harmful event) includes data on work experiences and trainings, speed of hazardous event, availability of any kind of warnings, possibility to withdraw in time from the hazardous area and could be:

01. P1- possible,

02. P2- possible under certain conditions,

03. P3- impossible.

Parameter W (possibility to limit or avoid harmful event) gives a value that describes known accidents or harmful events already recorded in the past (accident statistics) or can be compared to similar machinery:

01. W1- low,

02. W2- middle,

03. W3- high.

2.7.2
Hazard identification

For the widely used types of machinery, the product standards have been developed and a list of hazards associated with a specific type of machinery is a mandatory part of such a standard.

The situation is different with one-off machinery, as no product standards exist for it. Identifying hazards is an initial step in the risk assessment and should thoroughly encompass all life cycles of the machinery and all origins and nature of the hazards.

It should first take place in the early design stage of machine and should preferably be reassessed when the machine is physically built up due to the fact that it is sometimes hard to foresee all the interactions between operators/maintenance personnel and machine. Performing a thorough physical inspection of the machine and its working environment is also a task when the machine is delivered to the user. Look for any visible signs of danger, such as exposed wiring, slippery floors, unguarded machinery, or sharp objects. Pay attention to environmental factors, such as poor lighting, inadequate ventilation, or excessive noise, which can also pose hazards.

Again, standard EN ISO 12100 can make the identification much easier as it contains in Annex B a checklist of all possible hazards that may occur with machinery. A good practice is, that the hazard identification should be a team task, so as to prevent overlooking certain hazards or have different opinions about handling them. Besides the designer of the machine, user's side should also take part in the task to consider human factors such as fatigue, ergonomics, stress, distractions, and human error that can contribute to hazards.

In the industrial machinery sector, advanced standardized methods have been developed such as Hazard and Operability Study (HAZOP), Failure Modes and Effects Analysis (FMEA), or Fault Tree Analysis (FTA) to address safety/quality issues in a very detailed and comprehensive manner. Special attention is given to functional safety of machinery.

2.7.3
Functional safety of the machinery (design and validation)

Functional safety of machinery refers to the ability of a machine to operate in a safe manner, even when things go wrong, mitigating the risks associated with its intended use. It involves the implementation of safety measures through safety-related parts of the control system to ensure that the machine functions as intended and does not pose unreasonable risks to operators, maintenance personnel, or other individuals in its vicinity. The following steps need to be taken to address functional safety:

Step 1 - Identify and define the safety functions that the machinery must perform to reduce or eliminate risks. Safety functions are actions or features designed to detect, prevent, or mitigate hazardous situations. They include input element – logic unit – output element. Examples include:

01. input elements: sensors, emergency button, interlocks, optoelectronic detection, etc.

02. logic units: safety relays, programmable logic controller, etc.

03. output elements: circuit breakers, shut-off valves, brakes, etc.

Define specific safety objectives for each hazard to be addressed. These objectives should describe the desired safety outcome, such as "Prevent unintended machine start-up" or "Detect and stop excessive pressure build-up." Each safety objective should be measurable and achievable.

Step 2 – Determine necessary Performance Level (PL) to be achieved in relation to estimated risk level. Determined PL will influence the control system architecture (one-channel or redundancy) and reliability requirements for safety component selection.

Performance Levels range from PL a (lowest) to PL e (highest), with each level representing a different level of risk reduction and reliability of the safety function.

Note 1: Redundancy - a control system, where one circuit is being monitored by another and vice versa. When different values appear in the system, then a signal for malfunction shall be given. Control system shall take the necessary measures like failure of the component in the control system triggers the sequential safety measures (for example: stop – supply disconnection – unexpected start-up prevention).

Note 2: Control system diagnostic coverage – during cyclic or continuous performance of safety functions, the proper functioning of safety related control system part is being monitored. If during monitoring failure occurs, the failure is detected and machine needs to be safely stopped automatically. The highest category of control system (i.e. Performance Level e) can be obtained with the combination of redundancy, reliable components and diagnostic coverage. In this case, a failure in the control circuit will be detected during self monitoring and loss of one control channel will be substituted by the redundant channel.

Step 3 - Select and incorporate safety-related parts and components that meet the required safety integrity levels (SIL) or performance levels (PL). These parts and components should have sufficient reliability and functional characteristics to perform their intended safety functions.

As a general rule, use certified components - consider using components that are certified or designed specifically for safety applications. Look for components that have undergone safety assessments, such as those with SIL or PL ratings. These components are specifically engineered and tested to meet the required safety standards and provide reliable performance.

Pay attention to reliability and diagnostic capabilities - ensure that the selected components have the required reliability and diagnostic capabilities to perform the intended safety functions. Components should be able to detect faults, failures, and malfunctions, and provide appropriate diagnostic feedback, if necessary. Review the technical documentation provided by the component manufacturers. Ensure that the documentation includes relevant safety-related information, such as failure rates, diagnostic coverage, and any specific requirements for installation, operation, and maintenance.

Step 4 - Ensure compliance with relevant safety standards and regulations applicable to the machinery. Standards such as ISO 13849 (Safety of Machinery - Safety-Related Parts of Control Systems) and IEC 61508 (Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems) provide guidelines for the design (calculation), implementation, and verification (validation) of safety functions.

Ensure that the safety functions are integrated and compatible with the overall machine design. Consider factors such as main control systems and communication networks required to implement the safety functions effectively.

It's important to note that the process of determining the required Performance Level can be complex and may require expertise in risk assessment, safety standards, and functional safety. Involving knowledgeable professionals or consultants in this process can help ensure that the Performance Level determination is accurate, reliable, and compliant with the applicable requirements.

Step 5 - Conduct thorough verification and validation of the safety functions and systems. This includes testing, inspections, and analysis to ensure that the safety measures are functioning correctly and effectively reducing the identified risks. Perform periodic inspections and maintenance to ensure ongoing functional safety.

Step 6 - Prepare clear and comprehensive documentation related to the functional safety of the machinery. This includes safety manuals, operating procedures, maintenance instructions, and training materials for operators and maintenance personnel. Provide clear instructions on the safe operation, maintenance, and troubleshooting of the machine.

2.7.4 Difference between hazard and risk

Hazard and risk are two related but distinct concepts in the context of safety and risk assessment. Here's the difference between hazard and risk:

Hazard: A hazard refers to a potential source of harm, danger, or adverse effect. It is a condition, substance, activity, or situation that has the potential to cause harm to people, property, or the environment. Hazards can be physical (e.g., moving machinery parts, energy releases, etc.), electrical, thermal, biological (e.g., infectious agents), chemical (e.g., toxic substances), behavioural (e.g., unsafe work practices), etc. Hazards exist regardless of whether they pose an immediate risk or not.

Risk: Risk, on the other hand, is the likelihood or probability that a hazard will cause harm or adverse consequences. It involves the potential for an unwanted event to occur and the severity of its impact. Risk is a combination of the likelihood of exposure to a hazard and the potential consequences if that hazard is realized. Risk assessment involves evaluating the likelihood and potential severity of harm resulting from exposure to a hazard.

In summary, a hazard refers to the potential for harm or danger, whereas risk involves the likelihood and severity of harm resulting from exposure to a hazard. Hazard assessment identifies potential sources of harm, while risk assessment evaluates the probability and consequences of that harm occurring. Both hazard and risk assessments are crucial for managing safety effectively and implementing appropriate risk mitigation measures (risk controls).

3. Role of Standards in Machine Design

3.1 General

Harmonised standards play an important role in conformity assurance of the machinery. When used and applied thoroughly in the process of design, construction and conformity assessment of the machine, they give presumption of conformity with the provisions of the directive(s).

Use of harmonized standards is not mandatory. However it is warmly recommended as it is the easiest way to achieve compliance with the EHSRs. Namely, the EHSRs of the MD (Annex I) give no technical solutions to meet them. In support of their equal understanding and to set a minimum level of the state of the art in the machinery sector, the EU commission has ordered a development of numerous standards at CEN (European Standardisation Committee) that will give minimum technical requirements for all the lifecycle stages of the machinery:

01. assembly and disassembly,

02. setting,

03. normal use,

04. maintenance,

05. transport.

Harmonised standards are constantly being developed. Existing standards change, new standards appear, some of the existing standards undergo safeguard clauses, etc. So manufacturers are expected to follow changes in the standardization for their products.

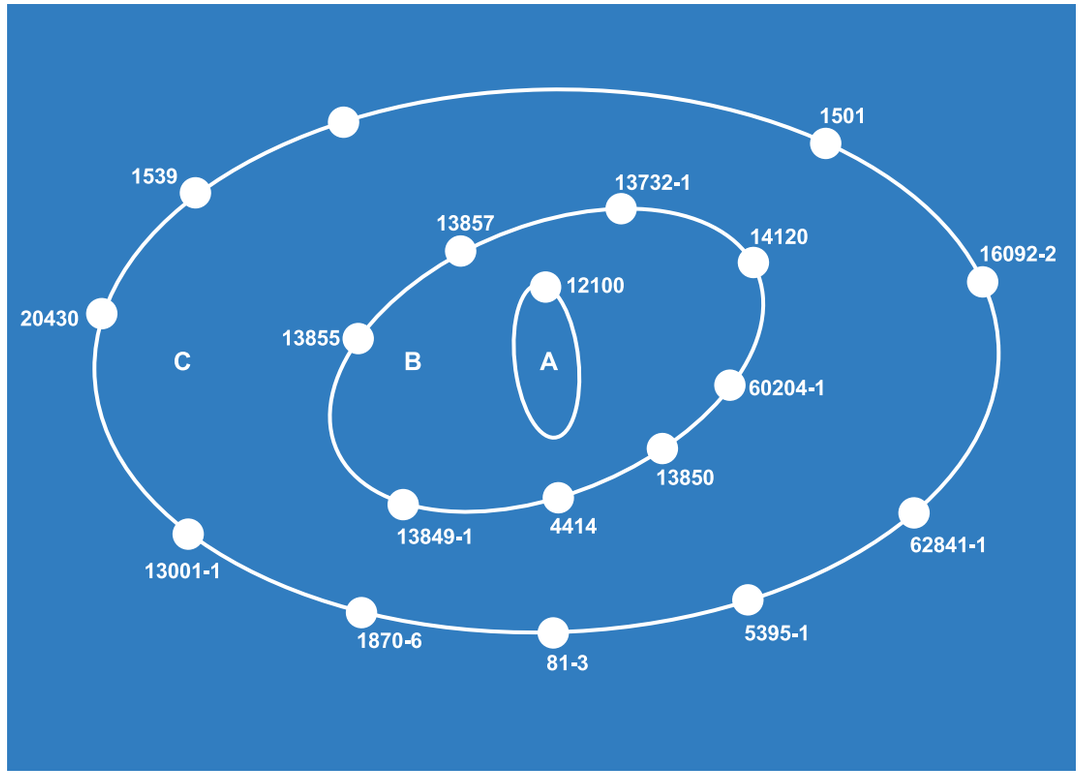
3.2 Types of standards

Due to the enormous variety of machinery (lots of them are unique) it is not possible to make (product) standards for each type of machine. Therefore, standards for machinery safety make a unique system consisting of three different types:

01. Type A (basic standards): give only guidelines to the designers on how to approach to the safety strategy in the design phase of the machine.

02. Type B (group standards):
- Type B1 determine requirements for different safety aspects (for example: safety distances, allowed surface temperatures, noise limits, ergonomics, etc.),
- Type B2 determine requirements for safety appliances (for example: two-hand control units, interlocking guards, automatic optical presence detection of persons, safety mats, etc.),

03. Type C (product standards): give detailed requirements for each type of machine (driven hand-held tools, garden equipment, some classic industrial machinery like presses, saws, moulders, etc.).



Planetarium system of safety standards in the machinery sector

It is very common that the designer of a machine has to use more than one standard in order to achieve the compliance with the directive(s). Generic group standards usually cover only one or a couple of EHSRs of MD. But how to find and choose the appropriate standard(s) for my machine?

The general approach shall be:

01. if one plans to design a ''standard'' machine, especially if it is to be made in series, than a high probability exists that the product standard (type C) already exists. ''Standard'' machine means a type of machine that has been widely known on the market in a consumer or industrial use (driven hand-held tools, garden tools, industrial machinery, construction machinery, forming machinery, etc.). Use of a product standard means also that the risk assessment need not be done by the manufacturer again (as it was already done by the standardization body). Still, some of these machines do not have their own product standard due to various possible reasons or the product standard does not cover all safety aspects. Before the actual application of the standard, the manufacturer should verify that the standard is really applicable for his product (not to be misled by the title, for example).
An internet search machine for standards may be very useful to help for determination of standards.

02. For other types of machinery and inevitably for unique machines the way to compliance is by using the group standards (types A, B1 and B2). Which standards (and their parts) the manufacturer shall use to eliminate or lower the risk to an acceptable level is a part of the risk assessment procedure.
Standards of B1 type are related to specific hazard group: dangerous substances, fire and explosion, extreme temperatures, radiation, vibrations, noise emission, ergonomi-cs, hygiene, safety distances, electric safety, machine integration, etc.
Standards of B2 type are related to specific technical safety controls: guards, safety appliances, emergency stop, lighting, machine controls, control system, electrical equipment, pneumatic/hydraulic equipment, etc.

Standards establish best professional practices, guidelines, and design principles that help ensure safe machine design. They also provide recommendations on factors such as selection of materials, dimensions, tolerances, ergonomics, environmental considerations, and sustainability. Adhering to design standards helps promote safety, efficiency, reliability and user-friendliness in machine design.

Standards also drive innovation and technological advancement in machine design. They serve as a reference point for emerging technologies, new methodologies, and best practices. Standards bodies continuously update and revise standards to incorporate new knowledge, advancements, and industry trends, fostering innovation and pushing the boundaries of machine design.

3.3 Structure of the standard

Standards may consist of few or even over 100 pages. Not all parts or requirements may be applicable for use and that can be seen from the scope of the standard and Annex ZA.

For their easier applications, a structure of the (product) harmonised standard is summarized in:

01. scope of applications (and exclusions),

02. references (EN or ISO or IEC standards, guidelines),

03. terminology,

04. hazard analysis,

05. technical specifications,

06. conformity assessment (description of tests),

07. product marking and contents of instructions for use.

Annexes (normative and/or informative)

Annex ZA (relation between the standard and applicable directive(s)).

Annex ZA should not be neglected as it gives information to the user on the following:

01. which EHSRs are covered by the specification of this standard,

02. that use of the standard is one of the possible ways to fulfil the requirements of the directive(s),

03. that user should carefully check whether additional regulation for the product exist at the moment being.

Even though standards are of voluntary nature in the machinery sector, when applied the modal verb ''shall'' means mandatory application and ''should'' means optional application of a requirement.

It's important to note that product standards and generic standards are not mutually exclusive. In many cases, product standards incorporate and reference relevant generic standards to ensure comprehensive compliance.

Standardization body that is a full CEN/CENELEC member is obliged to transpose without any modification the harmonized standards into the list of local standards.

3.4 Technical documentation

The purpose of the Technical Construction File (TCF) is to demonstrate the compliance of the product or the prototype of the serial product against the requirements of the applicable directive(s). It shall contain the necessary information on design, construction and conformity assessment of the product. From this point, it is clear that only the manufacturer can be responsible for its preparation. The complexity of the TCF and its contents depend on the nature of the product. The more directives that apply the bigger it gets. The fewer standards are used, the more precise and exhaustive documentation on risk assessment shall be. However, common principles for preparation of the TCF for machinery exist:

01. an overall drawing of the machine together with drawings of the control circuits (electrical, hydraulic, pneumatic schemes) in order to identify and depict the intended use of the machine in the design stage,

02. full detailed drawings, accompanied by any calculation notes, test results, etc. of those parts of the machine that are required to be checked for conformity with the ESHRs,

03. a list of:

- the applicable EHSRs of MD to be taken into account or list of hazards detected (Annex B of EN ISO 12100 can be used for the check list),
- standards and directives that were used when the machinery was designed and manufactured,
- a description of methods adopted to eliminate hazards presented by the machinery (risk assessment) and a list of the standards used (if any),

04. any technical report or certificate the manufacturer has obtained from a conformity assessment body for the machine in question,

05. when declaring conformity of the machine with a harmonised standard(s), any technical report giving the results of tests carried out at the manufacturer's choice either in house or by a competent conformity assessment body,

06. a copy of the instructions for use for the machine,

07. the internal measures that will be implemented to ensure that the serial production of the machine (if any) remains in conformity with the provisions of the MD.

It is very important for the manufacturer to document all the tests or verifications of the machine in order to demonstrate its compliance against the standards and EHSRs of the MD. The documented compliance shall prove that the machine is safe for transportation, assembly, start-up, use, maintenance and disassembly. When harmonized standards are use, referring to the clauses of the standards is a simple and fast way. When standards are not used, then a detailed description of all the steps (risk assessment) that led the manufacturer to the compliance need to be documented. This includes the verification of the safety solutions in comparison with the standardized solutions. The documents in the form of test reports, measurement records, videos or photographs shall be therefore included in the TCF.

When several directives apply, the documentation of compliance with them can be kept in one single TCF. Also, it is not necessary for the manufacturer to have the TCF ready as one entity. It is normal that different documents can be found at different locations or even different premises of the company, for example, test reports can be stored in the laboratory, while drawings in the construction department, declarations of conformity in the purchasing department, etc. However, manufacturer shall, if asked so by the authorities, be able to prepare the TCF in a certain time, for example a few days, so in any case, the manufacturer must be sure that the contents of TCF exist before placing the product on the market.

The TCF shall be kept at least 10 years after the production of the last machine in series. It is the responsibility of the manufacturer or his authorized representative or importer. Importers shall obtain a copy of the TCF from the manufacturer before placing the product on the market or, even better, before making a deal with the manufacturer for the import or at least sign an agreement with the manufacturer that the manufacturer will participate in the communication with market surveillance authorities. The TCF shall be available in one of the official languages of the EU. The declaration of conformity as well as instructions for use shall be available in the language of the target market. The manufacturer is not obliged to demonstrate the TCF to anyone else but the authorities. Failing to present the TCF to the authorities means that it is enough for authorities to take necessary actions as they would in case of a noncompliant machine.

3.5 Integrated Manufacturing Systems

Special emphasis shall be given to the manufacturers of integrated manufacturing systems (IMS). The integrator is responsible for the compliance of the whole production line and should cover overall compliance. It is very wrong if the integrator only collects technical documentation from the suppliers of the subassemblies. The IMS manufacturer should carry out safety engineering of the whole line acting as a single machine. By using the documentation of the suppliers, the manufacturer can cover compliance only partially. At least, safety strategy with appropriate solutions and integral control systems as well as careful preparations of instructions for use with residual risk warnings are typically the responsibility of IMS manufacturers.

Safety integration related tasks	Information flow	Item	Sub-item
IMS functionality	U>I>S	IMS performances	Availability
			Maintainability
IMS limits and constraints	U>I>S	IMS constraints	Batch modifications Number of shift
			Product characteristics
			Personnel knowledge and qualifications
			Environment
			Available surfaces and areas
			Production organization
	S>I	Technical subsystem(s) data	Performances
			Interfaces
			Noise level/vibrations
			Wastes
			Emissions
Hazard identification	S>I I>S U>I	Hazards linked to IMS configuration	-
Risk assessment	S>I>U	Risks related to IMS configuration	Residual risks
Legend: U = user, S = supplier(s), I = integrator			

Flow of information between the suppliers, integrator and users of IMS (excerpt from EN ISO 11161)

It is not necessary to obtain the whole TCFs for each machine integrated into a line. The supplier is not obliged to do that (except for the conformity declaration and instructions), however the supplier must forward all the relevant necessary information regarding the compliance to the integrator. Therefore, it is wise and recommended to obtain this information through the agreement or contract. If the supplier agrees to participate in the possible surveillance visits by the authorities, it is even better.

3.6 Declaring conformity

The Declaration of Conformity for any kind of machinery must contain the following:

01. Name and address of the manufacturer and/or his authorized representative in the EU,

02. Product name of the machine and type identification (type, model),

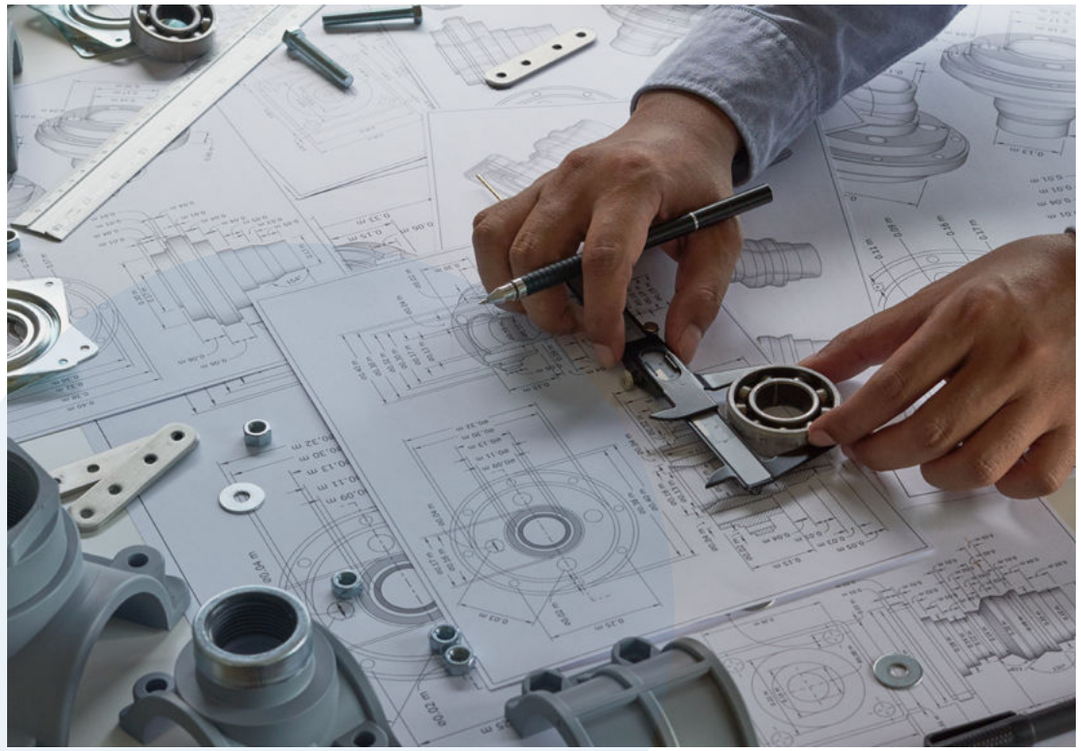
03. Reference to the applicable directives,

04. Reference to applied harmonized standards or other international or local standards (if any),

05. Where appropriate, the name and address of the notified body which has carried out the conformity assessment of any kind (applicable for Annex IV machinery),

06. Identification of the person empowered to sign on behalf of the manufacturer or the manufacturer's authorized representatives.

In addition, for the unfinished machinery, a manufacturer shall also put the statement on the declaration of conformity that the machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the MD (Declaration of incorporation, II.B).



3.7 Instructions for use

Any machinery delivered within EEA shall be accompanied by the instructions for use in the language of local use and original ones. Instructions for use shall encompass all necessary information for the safe and healthy use of the machine in all the phases of its life cycle. Instructions for use (in the form of handbook or manual) typically consist of:

01. Technical data and information about the supplier/manufacturer,

02. Type or model designation,

03. Description of the intended use and foreseeable misuses,

04. Description of the residual risks and protective measures,

05. List of personal protective equipment to be used (if any),

06. Safety precautions and warning, prohibitions,

07. Explanations of pictograms on the machinery,

08. Graphical presentation of the product with important parts,

09. Description of transport,

10. Description of (dis)assembly,

11. Description of connection of supplies (electricity, water, air, oil, gas...)

12. Description of setting,

13. Use of the product,

14. Best working practices,

15. Description on maintenance activities (lubrication, cleaning, replacements),

16. Specifications of tools and auxiliaries (if any),

17. Troubleshooting,

18. Environmental aspects (wastes, emissions, noise)

19. List of spare parts (and authorized service locations),

20. Declaration of Conformity (original one and its translation into the local official EU language).

Use of graphics is stipulated. An excerpt of main (safety) information from the Instructions (handbook or e-book) about the machine should be available at workplaces (industrial machinery). Normally, an importer or supplier of the machinery is responsible for the translation of the instructions. Where C-type standards exist, normative information shall be included in the instructions.

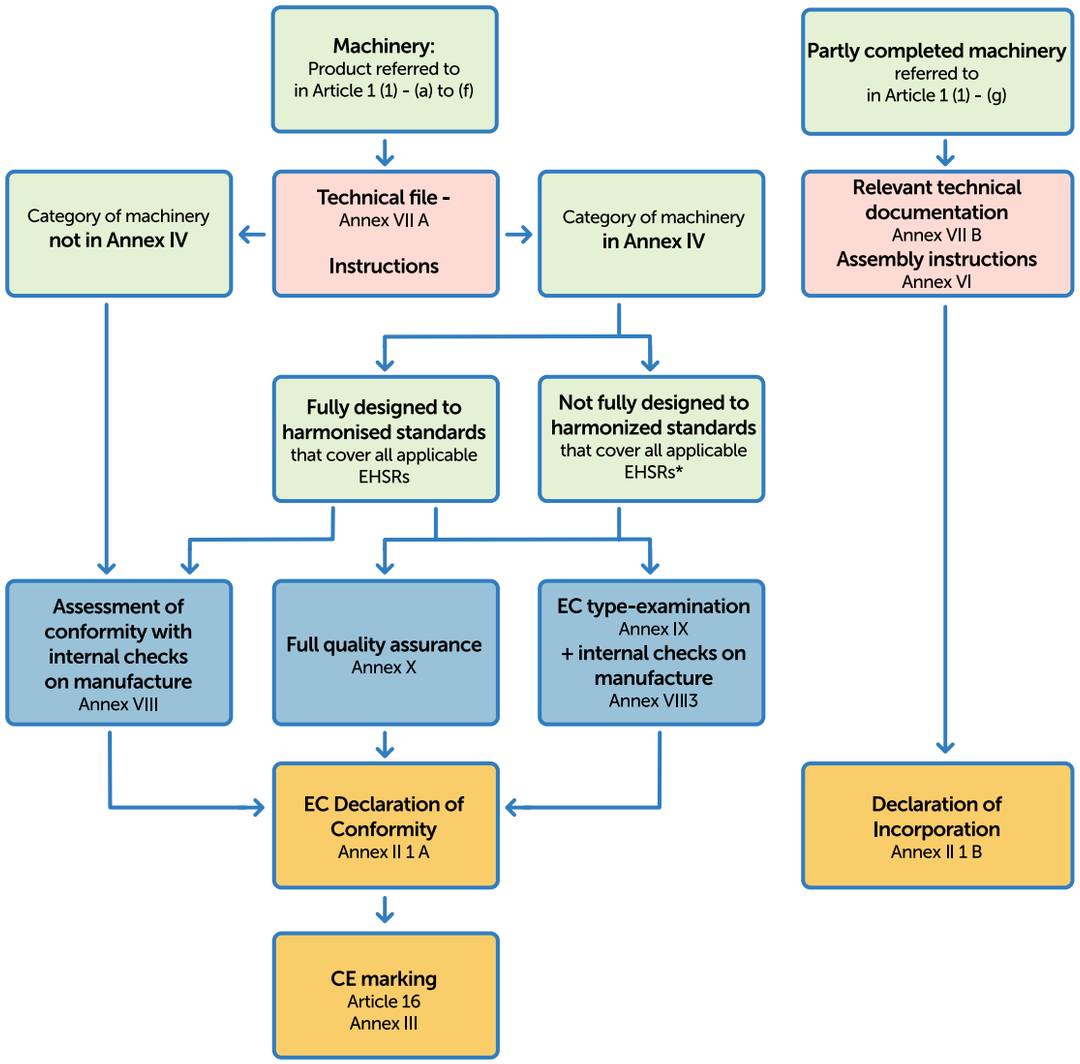
4. Conformity Assessment of Machinery

4.1 General

Appropriate conformity assessment procedures shall be carried out by the manufacturer to determine compliance with the EHSRs of the Machinery Directive. For the types of machinery that are specifically listed in Annex IV and where all EHSRs are not covered by or conforming to harmonised standards, the manufacturer shall include in the activity an independent institution called Notified Body. This applies specifically to EU member states and to machinery to be exported to the EU. This third party will assess compliance of the machinery through one of two possible conformity assessment routes:

01. Module B + Module C (EC-type examination by Notified Body + internal checks by manufacturer)

02. Module H (Full quality assurance system by Notified Body)



Conformity assessment modules for machinery sector

4.2 Type examination of machinery with high risks (module B)

With this option, the manufacturer submits a sample of the machine together with the full TCF for conformity assessment to a third party (Notified Body).

Once the manufacturer has chosen a Notified Body to carry out the EC type-examination for a given type of machinery, the manufacturer must declare that an application has not been made to any other Notified Body for the same type of machinery, that is to say for machinery with the same design, technical characteristics and application.

The Notified Body must determine the appropriate inspections, evaluations, measurements and tests to verify the conformity of the assessed machinery with the applicable EHSRs. Notified Body therefore has to:

01. examine the TCF,

02. check that the type was manufactured in accordance with the TCF,

03. establish which parts or aspects of the machinery have been designed in accordance with the relevant provisions of the harmonised standards or other technical specifications.

In its work, the Notified Body shall also use Recommendations for Use issued by the coordination of Notified Bodies for Machinery (CNB-M).

Practical criteria for deciding on the appropriate place include the size of the machinery and the nature of the inspections, measurements and tests to be carried out. In some cases, in particular for large machinery, it may be appropriate for the machinery as a whole to be examined at the manufacturer's premises, while some components or sub-assemblies may be brought to the Notified Body's premises for examination. In the case of EC type-examination of machinery assembled at the user's premises or of purpose-built machinery, it is often necessary to perform the inspection, measurement and testing at the site of installation.

If the conformity criteria are passed, the Notified Body issues an EC-type examination Certificate. The manufacturer and the Notified Body must keep a copy of the EC type-examination certificate, the technical file for the machinery and related documents for 15 years after the issue of the certificate.

EC type-examination certificates do not have to accompany the machinery when it is placed on the market, but the EC Declaration of Conformity must indicate the particulars of the Notified Body which carried out the EC type-examination and the number of the EC type-examination certificate.

If the applicant intends to modify the certified machine type, it first has to inform the Notified Body of any modifications he intends to make to the approved type. The Notified Body then has to decide whether or not the modification affects the validity of the EC type-examination certificate.

The holder of an EC type-examination certificate has an obligation to request a periodic review of the validity of the certificate every five years. Consequently, if the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the type of machinery concerned, since it can no longer be considered to comply with the requirements of the Machinery Directive.

4.3 Full quality assurance system

The basic objective of the full quality assurance system is to ensure that the machinery is designed and constructed in conformity with the relevant EHSRs of the Machinery Directive and that the manufacturer has the full ability to check the conformity of the machinery produced on an ongoing basis. This means that the Notified Body has to assess whether the manufacturer has all the necessary knowledge, equipment and procedures in place to design, produce and asses the machinery before it is placed on the market or is put into use.

The manufacturer can apply for the assessment of Annex IV machinery by a Notified Body only after it has submitted the TCF. All the elements of the TCF, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

In particular, it must contain an adequate description of:

01. the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,

02. the technical design specifications, including standards that will be applied and, where the standards are not applied in full, the means that will be used to ensure that the essential health and safety requirements of Machinery Directive are fulfilled,

03. the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by the Machinery Directive,

04. the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

05. the inspections and tests that will be carried out before, during and after production, and the frequency with which they will be carried out,

06. the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel in question,

07. the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

The design, inspection and review shall be carried out under controlled conditions with clear instructions, checklists etc. It is good practice to have the design inspection and verification performed by persons who are not directly involved in the design process itself.

The Notified Body team will eye-witness the application of procedures in practice including those that require evaluation knowledge (such as design calculations, design of control system, selection of components, etc.) and testing capabilities. If the Notified Body confirms its ability to do design approval and conformity assessment, the manufacturer will be issued a Full Quality Assurance certificate.

According to the Recommendation for Use CNB/M/13.021– the period between audits should not be longer than 12 months. The Notified Body shall also take into account the experience from previous audits when determining the frequency of periodic audits.

If certain periodic audits are limited to parts of the full quality assurance system, the Notified Body shall ensure that all elements of the system are reassessed at least every three years.

4.4 Internal production control

For most machinery, the manufacturer itself can conduct conformity assessment. However, the results of the conformity assessment activities need to be fully traceable and repeatable. That said, a manufacturer needs to establish its own internal management system that will assure that results of conformity assessment can be reproducible when it comes to market surveillance checks.

Such (quality) management system does not need to be certified but it is advised to follow requirements of the ISO 9001 standard to ensure the above objectives are met. In particular, special care shall be taken to fulfil requirements on design validation (clause 8.3.3., ISO 9001) and production validation (clause 8.5.3, ISO 9001). This involves implementing controls and checks at various stages of production to verify compliance with the applicable standards and specifications. Records showing compliance with the EHSRs shall be kept for 10 years.

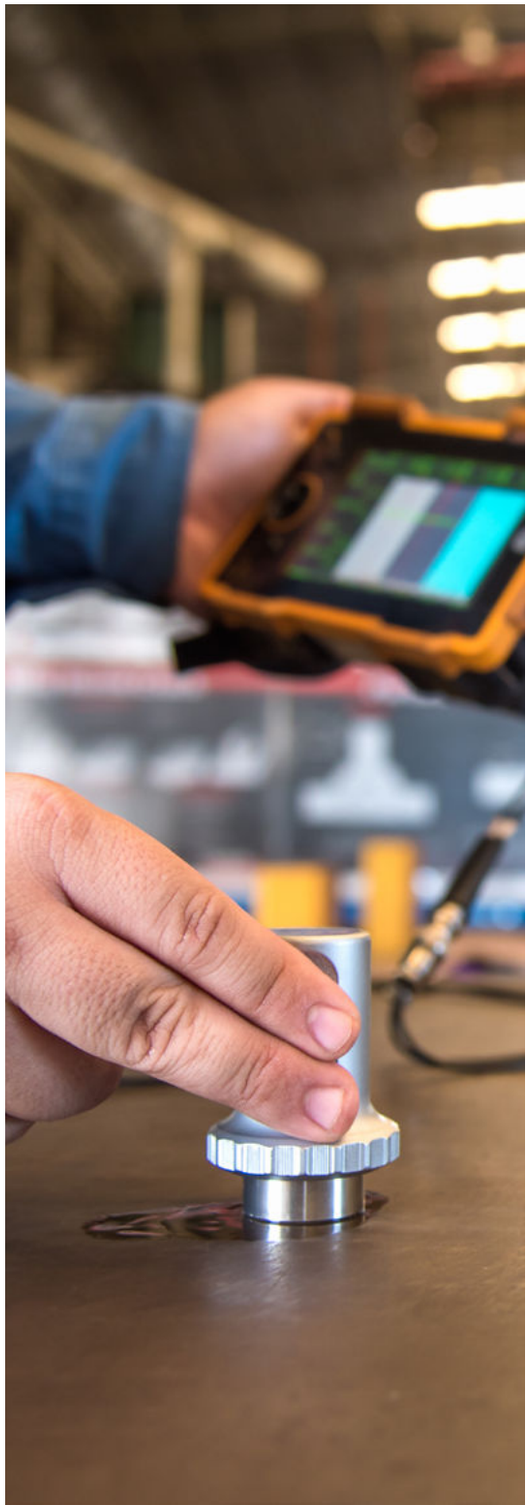
Key enablers for the manufacturer to conduct in house conformity assessment are:

01. competencies of responsible personnel (knowledge and technical experiences),

02. sound testing equipment (may include testing rigs or set-ups, measuring devices),

03. procedures in place (the procedures should address aspects such as risk assessment, design verification, component selection and final product conformity verification).

It is also very important for the manufacturer to keep up with the latest developments in legislation and standardisation. The management shall be aware that the final responsibility for the safety of the machinery is assigned to them and shall take it with all seriousness.



4.5 Testing equipment for compliance assessment

When it comes to testing equipment for machinery safety, the need for testing equipment depends on the nature of the machinery and its risk assessment. However, several key areas are considered most often.

Electrical safety testing – wattmeters, multimeters or clamp meters, insulation testers, ground bond testers, and leakage current testers are commonly used for these tests.

Functional testing – specific type may be needed such as measuring unit for response time or stopping time, units to measure speed of movements, forces or energy impacts and similar.

Load and stress testing - load cells, strain gauges, and dynamometers are commonly used for these tests.

Noise and vibration testing - sound level meters, vibration analysers and accelerometers are commonly used to measure and assess noise and vibration levels.

Environmental testing – testing racks or units for measuring temperature, humidity, dust, and other environmental factors. Environmental chambers, temperature sensors, and humidity meters are used to conduct these tests.

It's important to note that specific testing equipment is needed for specific types of machinery (for example: kick-back test for hand-held or stationary sawing machinery, braking unit for electric hand-held tools, etc.)

5. Further Guidance on the Notification Procedure of Designated Bodies for Machinery (based on EA 2-17:2020) in the EU

EU Decision 768/2008/EC provides general guidelines on notified bodies. In view of notifying bodies for the purposes of technical legislation, it is essential that at least the relevant provisions concerning notified bodies (which include in particular the requirements and obligations of those bodies) are transposed into national law. In addition, notification procedures need to be communicated to the Commission and other Member States, and Member States need to appoint the notifying authority for that particular Union harmonisation legislation (like Machinery Directive).

Notification is essentially an act of the notifying authority informing the Commission and the other Member States that a conformity assessment body has been designated to carry out conformity assessment according

to a Union harmonisation act and that it fulfils the requirements relating to notified bodies set out in that Union harmonisation act.

Member States take the final responsibility for the competence of their notified bodies with respect to the other Member States and the EU institutions. The assessment of a conformity assessment body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity. Accreditation is the preferred way to assess the technical competence of notified bodies. For the notification purposes, EA has developed specific guidelines, EA 2-17 M:2020, that link preferred accreditation standards to conformity assessment routes in technical regulations.

Accreditation is defined in Regulation 765/2008/EC as "an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity". Therefore, NABs shall use Harmonised Standards (HS) in assessments for accreditation. However, the conformity assessment activities described in the modules defined in Decision 768/2008/EC are not described in a way which fits exactly with the description in the HS (i.e. testing, inspection and certification), and each module does not identify the HS to be used for its conformity assessment activities. This means that, for each module, different HS may be considered for accreditation of the NB, but they may have to be supplemented by the above mentioned "additional requirements".

EA has developed a preferred HS approach in order to provide a consistent and comparable implementation of accreditation for notification purposes. The table in Annex A identifies the HS which is the preferred standard for each module and legislation, and, in addition, the table in Annex B includes the additional requirements taken from other HS which are needed to underpin the standard for an appropriate assessment of the competence and performance under each module.

In the area of Machinery Directive, a notified body performs conformity assessment upon request of the manufacturer of high-risk machinery listed in Annex IV of the directive. Two conformity assessment routes (modules) are available:

01. Annex IX – EC-type examination

02. Annex X – Full quality assurance system audit

Preferred accreditation standards for these modules are:

01. ISO 17065 for the CABs performing EC-type examination (i.e. certification body for products),

02. ISO 17021-1 for the CABs performing Full quality assurance system audit (i.e. certification body for management systems).

Table A from EA 2-17:2020: Preferred standards for Aligned Directives/Regulations and related Conformity Assessments Activities:

Module		Other references equivalent to this module	Preferred Standard	Exceptions
A1	Internal production control plus supervised product testing		ISO/IEC 17020	
A2	Internal production control plus supervised product checks at random intervals		ISO/IEC 17020	Measuring Instruments Directive No 2014/32/EU: ISO/IEC 17065
B	EU Type Examination	Machinery Directive No 2006/42 EC- Annex IX; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex V; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex III;	ISO/IEC 17065	
C	Conformity to EU-type based on internal production control		ISO/IEC 17020 (SPV) ISO/IEC 17065 (HWB)	Module C does not require a NB with the exception of: Simple Pressure Vessels Directive No. 2014/29/EU (SPV) Hot-Water Boilers Directive No. 92/42/EEC (HWB)
H	Conformity based on full quality assurance	Machinery Directive No 2006/42/EC Annex X; Noise emission in the environment by equipment for use outdoors Directive No 2000/14/EC Annex VIII In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex IV; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex II;	ISO/IEC 17021-1	
H1	Conformity based on full quality assurance plus design examination		ISO/IEC 17065	

ANNEX B: APPLICABILITY OF STANDARDS (HS) (mandatory)

Table B from EA 2-17:2020: Conformity Assessment Standards for Accreditation for Notification Purposes including Applicable Additional requirements:

Module	Description	EN ISO/IEC 17065	EN ISO/IEC 17020	EN ISO/IEC 17021-1	EN ISO/IEC 17025
A	Internal production control	N/A	N/A	N/A	N/A
A1	Internal production control plus supervised product testing	1 + t	***1+ t + cd**		1 + cd
A2	Internal production control plus supervised product checks at random intervals	1 + t	***1+ t + cd**		1 + cd
B	EC type examination	***1 + t + pk**	1 + t + cd		
C	Conformity to type based on internal production control	N/A	N/A	N/A	N/A
C1	Conformity to type based on internal production control plus supervised product testing	***1 + t + pk**	1 + t + cd		1 + cd + pk
C2	Conformity to type based on internal production control plus supervised product checks at random intervals	***1 + t + pk**	1 + t + cd		1 + cd + pk
D	Conformity to type based on quality assurance of the production process	***1 + qa**	1 + qa	1 + pk	
D1	Quality assurance of the production process	***1 + qa**	1 + qa	1 + pk	
E	Conformity to type based on product quality assurance	***1 + qa**	1 + qa	1 + pk	
E1	Quality assurance of final product inspection and testing	***1 + qa**	1 + qa	1 + pk	
F	Conformity with type based on product verification	***1 + t + pk**	1 + t + cd		
F1	Conformity based on product verification	***1 + t + pk**	1 + t + cd		
G	Conformity based on unit verification	***1 + t + pk**	1 + t + cd		
H	Conformity based on full quality assurance	1 + qa	1 + qa	***1 + pk**	
H1	Conformity based on full quality assurance plus design examination	***1 + qa**	1 + qa	1 + pk	

Key

***** Indicates for the corresponding module the preferred standard that shall be used whenever possible (refer to annex A for details of specific legislation).

1 The possible Harmonised Standards used for accreditation.

+ Additional applicable requirements of the other pertaining Harmonised Standards used for assesing the NB, as relevant to the situation.

t Additional applicable requirements of EN ISO/IEC 17025:217 if testing is required. To this end fulfilment of the applicable requirements of clauses 6 and 7 (with the exception of 7.9) in EN ISO/IEC 17025:2017 shall be demonstrated.

cd Capability of and procedures for judging and deciding based on results of tests and/ or inspections, if the essential requirements are fulfilled and / or the Harmonized Standards have been applied when required. To this end, fulfillment of clauses 4.1.2, 4.1.3, 7.5 and 7.6 in EN ISO/IEC 17065:2012 shall be demonstrated.

pk Ability - based on product knowledge - to make professional judgments related to product requirements where required. To this end fulfilment of clauses 6.1.2, 6.1.3 and 6.1.6 to 6.1.10 in EN ISO/IEC 17020:2012 shall be demonstrated.

qa Ability to assess and approve manufacturer's quality systems where required. To this end, fulfillment of clauses 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10, and 9.1 to 9.4 and 9.6 in EN ISO/IEC 17021-1 :2015 shall be demonstrated.

In addition to the accreditation status (gained under Regulation 765/2008/EC), the designating/notifying authority will require additional obligations for notification to happen, in particular:

01. subscription to civil liability insurance, unless that liability is covered by the state under national law,

02. participation in meetings and activities of Coordination of Notified Bodies,

03. participation in meetings with the Designating Authority,

04. reporting to the Designating Authority about activities, issued/withdrawn certificates, etc.

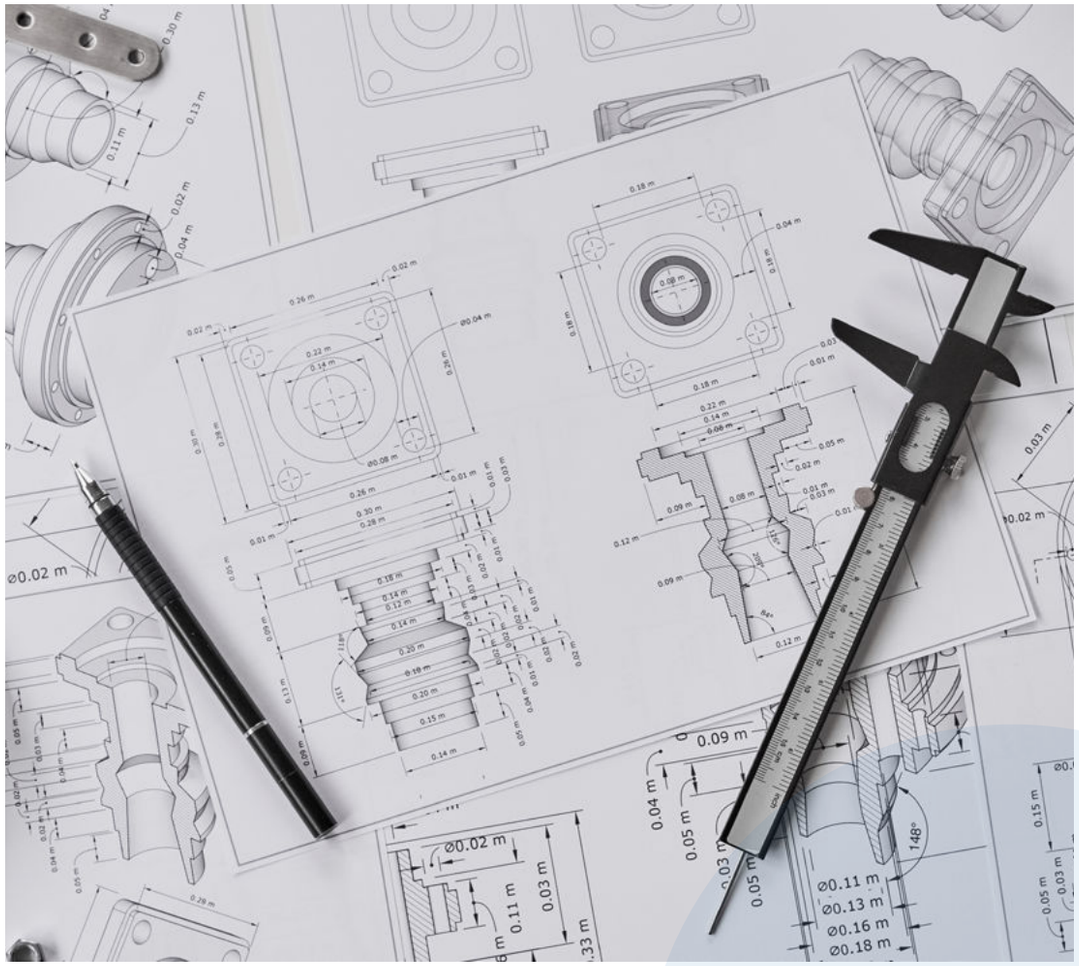
While designation is considered as an act of the designating authority, to delegate legally mandatory conformity assessment to a third party i.e. designated body in a particular Member State – which may be the same body as the notifying authority – it is only the act of notifying to the Commission and the other Member States that allows a 'designated body' to become

a ‘notified body’. Since notification falls within the discretion of Member States, they are not obliged to notify all the bodies demonstrating technical competence. Neither are Member States obliged to notify bodies in respect of each procedure to be applied according to a specific Union harmonisation act.

Notifying authorities and/or accreditation bodies must carry out periodic monitoring to assess the continuity of the competence of notified bodies after they are notified.

The notification of a notified body is sent by the notifying authority to the Commission and the other Member States via NANDO - the electronic notification tool developed and managed by the Commission where a list of all notified bodies can be found.

Note: in the time of writing this guideline, the CEFTA region had not introduced a mechanism of Designated Bodies for technical regulations.



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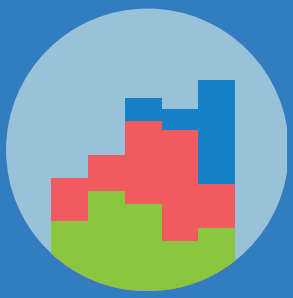
Implementation of Machinery Directive (2006/42/EC)



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