



**SAFETY OF
MACHINERY**

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The starting gun for the new EU Machinery Regulation

After long and tortuous deliberation, the EU's Member States have reached an agreement with the European Parliament and the Commission on a new Machinery Regulation. The current revision process, which first took form in April 2021 with presentation of a draft by the European Commission, aims to ensure that the regulation applies directly in the EU Member States. The regulation's content is also to be updated.

As in the past, the essential health and safety requirements continue to be the crucial aspect for the occupational safety and health lobby. However, the questions raised by the revision regarding the addition of requirements concerning artificial intelligence in machine control systems and tighter criteria for their conformity assessment and placing on the market have been answered only in part. The original idea of coupling the Machinery Regulation with the forthcoming AI Regulation in the interests of coherence has been dropped. The familiar concept of "high-risk machines", which initially was still included in the draft (in a new Annex I), was ultimately also abandoned, as was a definition of AI that would have covered a large proportion of machines already in existence. However, machines which have the purpose of ensuring safety and at the same time exhibit self-evolving behaviour are to be subject to stricter criteria and independent conformity assessment by notified bodies, owing to their poor transparency and their potential autonomy.

Of particular interest to the standards community is whether the European Commission will make use of the newly introduced instrument of implementing acts to adopt common specifications – or indeed whether it will have no other option, if standardization mandates are not adequately satisfied. Irrespective of whether a specification is formulated by standards organizations or appointed expert groups, the occupational safety and health lobby should be involved as a matter of priority, to enable innovative fields of technology to be applied with a human-centric focus in company operations.. «

New European Machinery Regulation replaces Machinery Directive

The new European Machinery Regulation has been finalized. What are the principal changes and transition periods?

The regulation was approved by the European Parliament on 18 April 2023 and the European Council on 22 May¹. The Machinery Regulation is now expected to be published in the Official Journal of the European Union in June of this year and to enter into force 20 days later. However, its application will not become mandatory for economic operators until 42 months after its entry into force. Until then, the current Machinery Directive 2006/42/EC must continue to be applied.

In Germany, a national implementing act for the Machinery Regulation is pending and in progress. This act will include provisions governing the official language and penalties for violation of the Regulation.

Structural and technical changes

The European Machinery Regulation consists of 52 articles of the regulation itself and ten applicable annexes. On the one hand, the procedures affecting the Member States and the Commission have been brought into line with the "New Legislative Framework". Furthermore, the procedures by which the economic operators attain conformity are set out in great detail and conclusively.

At the same time, technical content has been tightened up and adapted. In addition to articles being structured more comprehensibly, the subdivision of the new Annex I governing machines presenting a serious inherent potential risk is worthy of mention, as is the implementation of the topics of artificial intelligence and cybersecurity. The latter are covered by the Machinery Regulation itself, which can be applied directly to them without reference to further legal acts.

The annexes have been re-ordered. The present Annex I, containing essential health and safety requirements, becomes Annex III. The present Annex IV, containing a list of machinery and products for which third-party certification is mandatory, becomes Annex I.

What are the highlights of the new regulation?

- Delegated acts: the European Commission may, in accordance with a defined procedure and after consulting the standards organizations CEN or CENELEC, draw up acts in order to regulate matters which it considers neglected where they have not been addressed in standards by the standards organizations within a time frame previously specified.



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- The Machinery Regulation has been decoupled from the planned AI Regulation; major fundamental points concerning artificial intelligence are addressed with respect to machinery in the Machinery Regulation.
- The term “economic operator” is new: this is defined as manufacturer, authorized representative of the manufacturer in the EU, importer or seller.
- The procedure for the “substantial modification” of machinery which has been followed for some time in Germany has been implemented in the regulation. Briefly: a “significant modification” exists when the safety technology implemented in a machine is no longer sufficient to counter new hazards arising following the machine’s modification.
- The new Annex I covering machinery and products presenting a serious inherent potential risk consists of two parts. Part A covers machinery and products that always require type examination by a notified body. Vehicle servicing lift machinery, removable mechanical transmission devices including their guards, safety components with fully or partially self-evolving behaviour and portable cartridge-operated fixing and other impact machinery must pass a third-party inspection. Part B describes machinery and products for which manufacturers may continue to declare conformity without involving a notified body, provided they apply harmonized European standards that cover all risks.
- Requirements for machinery with fully or partially self-evolving behaviour or logic are included within the section covering control systems.
- Autonomous mobile machinery is covered in an almost completely new section in Annex III.
- E-bikes, e-scooters and other personal transportation devices are classified as machinery; filter systems for air purification in drivers’ cabs are now deemed to be safety components.

In summary, the essence of the new European Machinery Regulation may be considered a positive achievement and as well integrated into current EU legislation. Further discussions will be needed to determine whether the aspects incorporated into the regulation prove effective in practice and implementation is unequivocally successful.

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¹ <https://data.consilium.europa.eu/doc/document/PE-6-2023-INIT/en/pdf> (draft adopted by the Parliament and Council; not legally binding until published in the Official Journal of the EU)

Deadlines for particular aspects of the new European Machinery Regulation

20 days after publication in the EU Official Journal	Entry into force
	Article 7 (safety components) and Article 48 (committee procedure) apply
12 months after entry into force	Procedure for delegated acts: evaluation and scrutiny in particular of the essential health and safety requirements in Annex III
24 months after entry into force	Arrangements for notified bodies apply
39 months after entry into force	Arrangements for penalties must be transposed at national level
42 months after entry into force	Transition period for manufacturers; until then, application of the Machinery Directive remains mandatory
60 months after entry into force, thereafter at intervals of five years	The European Commission must submit a public report to the European Council on an evaluation of the European Machinery Regulation

Revision of EN ISO 10218, Safety requirements for industrial robots

Advances in recent years in materials science and developments in automation and drive technology have made industrial robots more powerful, versatile and cost-effective. To bring the safety requirements into line with these developments, the EN ISO 10218 series of standards has been thoroughly revised. A new approach to risk assessment was taken here.

The EN ISO 10218 series of standards describes and explains safety requirements for robots that are suitable for application in practice. Part 1 of the standard series contains requirements for industrial robots, Part 2 requirements for applications such as robot systems, robot cells, etc. Having the status of harmonized standards, both parts give rise to a presumption of conformity with the essential health and safety requirements of the Machinery Directive 2006/42/EC.

Revision of EN ISO 10218, which has now been in progress for almost five years, had the following objectives:

- Maintaining the standards' status as harmonized standards. Two-thirds of the world may not necessarily require this, but it is very important for the EU, and all robot manufacturers and many integrators¹ wish this status to be retained.

- Correcting errors and taking account of technological developments and the results of scientific research.
- Specification of more detailed requirements for collaborative applications.
- Formulation of flexible requirements by which the safety can be adapted to different application risk levels.

Both parts will become longer and more detailed as a result of the revision. Firstly, many requirements have been added that reflect certain essential health and safety requirements of the Machinery Directive. Secondly, the supporting documents ISO/TS 15066 (containing additional requirements concerning the safety-related design of collaborative robot applications) and ISO/TR 20218-1 and -2 (containing

additional information and guidance on the safe design of gripper end-effectors and manual load/unload stations of robot systems) have been incorporated into Part 2 of the series of standards.

New approach to functional safety

Owing to the wide range of applications for industrial robot systems, it is not always possible to list all significant hazards, hazardous situations or incidents that may arise. Furthermore, applications of the same type may differ in their risk levels, depending on their design and the application scenario. This may lead to a flexibility in the requirements for the performance of safety functions which appears at first glance to be at variance with the rigid requirements of the current standard.

It follows that revision of the standard should not result in a rigid requirement being stated for the safety function's performance. Nor should the standard specify which of the possible methods is to be used to determine the required Performance Level, since this would constrain users of the standard unnecessarily. Instead, the Performance Level should be derived from a risk assessment that takes account of the risk elements described in ISO 12100. The normative Annex C sets out the ranges, thresholds and other parameters to be applied during this process. It describes all safety functions required for mitigation of significant risks. For this purpose, the respective triggering event and intended result are stated, i.e. the response of the safety-related parts of the control system to detection of a fault.

Application of these risk parameters is mandatory. Users of the standard are however free to choose which risk assessment method they use for this



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purpose. This new standardization approach results in the required performance of the safety-related parts of the control system being specified uniformly and verifiably, and yields similar results for comparable applications.

Robot design

Following the revision, the standards now include new requirements for the following:

- Mechanical strength and materials used: the design must reduce corners, edges and protrusions to a minimum, and give consideration to wear and fatigue of the material.
- Safe handling, storage, transport and packaging of robots and components.
- Limiting the temperature of touchable surfaces; protection against fire.
- Use of electrical, pneumatic and hydraulic energy: These requirements govern the scenario of power loss or change. They also govern behaviour in the event of component malfunction or failure, particularly where a combination of power failure and gravity may cause unexpected hazardous movement of the manipulator (the moving part of the robot to which the tool is attached).
- Adjustment of the tool centre point (TCP), safety settings determined by the load, and special equipment to be supplied with the robot where required for safe adjustment and maintenance and for safe use.

Part 1 of the standard defines two robot classes. Class I covers robots with a maximum total manipulator mass of 10 kg, a force of 50 N and a velocity of 250 mm/s. All robots with higher values are covered by Class II. Class I robots, the testing methodology for which is described in Annex E, are subject to much lower requirements.

Cybersecurity

Should the cybersecurity assessment reveal that unauthorized access to the control system presents security risks, appropriate protective measures must be taken. Part 1 lists appro-

priate measures to be taken by the robot manufacturer. For further information and requirements, Part 1 makes reference to the IEC 62443 series of standards, Security for industrial automation and control systems. Security Level 2 (in accordance with IEC 62443) is generally assumed adequate for parts of the control system that may impact negatively upon safety (start, stop, change of safety settings, etc.), Security Level 1 for other parts.

Control and operating modes

Certain requirements have been added for control of the robot functions:

- Only one control station may be active at any one time (including the control stations for remote access).
- Operating modes and their safety requirements are now described more clearly in both standards.
- Mere selection of the operating mode is not considered a safety function, only its activation. This prevents hazards from being caused by incorrect selection of operating modes.

Robots must have at least two operating modes: manual mode (programming) and automatic mode (execution of the program). The option of manual high-speed operation with protective devices partially deactivated (process observation), as provided for in previous editions of the standard, is no longer permitted.

Any portable control station (teach pendant, control panel, smartphone, tablet, etc.) capable of initiating motion or other potentially hazardous situations must possess an emergency stop function to ISO 13850 and a 3-stage enabling button.

Safety functions for collaborative applications

“Collaborative operation” and similar terms have been deleted from both documents, as they describe only the type of application and not the mode or a property of the robot. Experts agree that there is no such thing as a “collaborative robot” or a “collabora-

tive mode,” and certainly no such thing as a speed that can be termed “collaborative”.

For safe collaborative applications, the series of standards now describes only three different safety functions: hand guiding, speed and separation monitoring, and power and force limiting. The fourth function originally described, monitored safe stop, is no longer listed, as it is also required for non-collaborative applications.

Outlook

Final drafts of the two parts were submitted in March 2022 to the HAS Consultant for evaluation. Should the result of the evaluation be favourable, they will be submitted to ISO and CEN for final voting. Publication and harmonization are anticipated for the second or third quarter of 2023 in the best-case scenario. A time frame for listing of the standards in the Official Journal of the EU cannot be stated at present.

The final drafts also contain content consistent with certain additional requirements of the new EU Machinery Directive. However, some requirements are not supported, for example concerning the application of self-developing AI in safety functions, or certain requirements concerning mobile autonomous machinery and the cybersecurity of hardware.

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¹ Integrators equip a robot with tools and integrate it physically, electrically and/or by the use of control systems into the defined working environment. Only then does it become a complete machine and may bear CE marking.

For further details on the revised edition of the EN ISO 10218 series of standards, refer to the extended version of the article at www.kan.de/en/publications/kanbrief/2/23/revision-of-en-iso-10218-safety-requirements-for-industrial-robots

The implementing act: an instrument for harmonized implementation of EU legislation

Primary responsibility for implementing EU legislation lies with the Member States. In specified areas, the European Commission or the Council may pass implementing acts to ensure harmonized implementation.

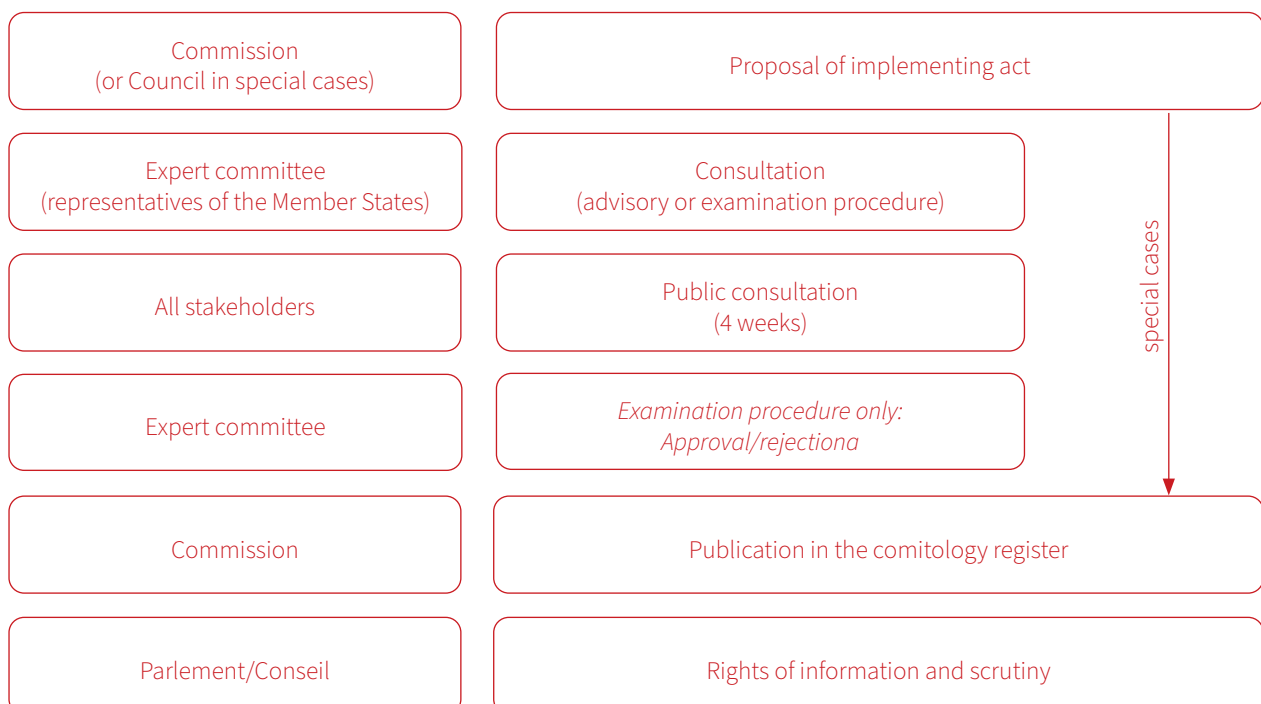
To ensure that EU legislation is transposed and applied uniformly, the Commission – and in special cases also the Council – has the power to pass implementing acts. This mechanism is also intended to address ongoing developments that would otherwise necessitate revision of legislation that has already been adopted.

Implementing acts may be adopted only in areas where harmonized conditions for implementation are necessary. These areas include the safeguarding of human safety and health. A further requirement is that the initial legislation concerned must make provision for an implementing act to be adopted, defining the specific objectives and requirements of this instrument. Although in the majority of cases the power to adopt implementing acts is conferred upon the Commission, it may be conferred upon the Council in duly justified special cases and in the cases provided for in Articles 24 and 25 of the Treaty of the European Union (common foreign and security policy).

Implementing acts may be employed in a variety of ways, for example:

- To establish framework conditions for harmonized implementation of legislation (e.g. limit values for chemical substances in toys involving a high degree of exposure, Directive 2009/48/EC)
- During safeguard clause procedures, in the form of a decision as to whether or not a measure taken at national level for implementing a legal provision is justified (e.g. Article 71, Commission proposal of a Construction Products Regulation COM(2022) 144; Article 64, Commission proposal of an Ecodesign Regulation COM(2022) 142)

Committee procedure for the adoption of delegated acts



For more information on the committee procedure refer to www.consilium.europa.eu/en/council-eu/decision-making/implementing-and-delegated-acts

- As a basis for the adoption of common specifications (e.g. Article 20 of the current draft text of the Machinery Regulation¹).

Procedure for the adoption of implementing acts

Pursuant to Article 291 of the Treaty on the Functioning of the European Union, general rules and principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers are set out in the initial legislative act by the European Parliament and the Council. This is supplemented by Regulation (EU) No. 182/2011 on committee proceedings².

Under these comitology rules, as they are known, a committee of experts is consulted when implementing acts are drafted. This committee is composed of representatives of the Member States. The latter are thereby involved in the adoption of an implementing act. However, this procedure is not mandatory for all implementing acts: in certain cases, such as the allocation of grants below a certain threshold, the Commission may adopt implementing acts without consulting a committee.

The Better Regulation agenda³ also granted citizens and stakeholders four weeks in which they can submit comments before the committee rules on the implementing act. The committee's discussions are summarized and published in the comitology register⁴. Whereas the European Parliament and the Council must expressly consent to delegated acts (see infobox), they possess only rights of information and scrutiny when implementing acts are adopted. The right of scrutiny makes provision for the Parliament and/or the Council to reject an implementing act should it exceed the powers conferred by the initial act. Explicit consent is not required.

Implementing acts in the Machinery Regulation

The implementing acts serve an important purpose in the new Machinery Regulation. Article 20 of the draft text, which was recently adopted by the European Parliament and the European Council¹, empowers the Commission to establish common specifications for the essential health and safety requirements by means of implementing acts as an exceptional fall back solution, i.e. where the European standards organizations fail to propose suitable standards for harmonization. The exact procedure is as yet unclear, however. The question arising is not least how the technical expertise and appropriate participation of all stakeholders can be ensured during adoption of any implementing acts.

Delegated acts

Besides implementing acts, the European Commission may also adopt delegated acts to support other legislation. The differences between the two instruments are described in KANBrief 4/22.

<https://www.kan.de/en/publications/kanbrief/4/22/use-of-delegated-acts-in-european-legislation>

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¹ <https://data.consilium.europa.eu/doc/document/PE-6-2023-INIT/en/pdf> (draft adopted by the Parliament and Council; not legally binding until published in the Official Journal of the EU)

² <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32011R0182>

³ Better regulation: guidelines and toolbox, <https://t1p.de/jdq9k>

⁴ <https://ec.europa.eu/transparency/comitology-register/screen/home?lang=de>

KAN expert report provides an overview of the body of regulations governing lighting

The body of official German state rules and regulations governing workplace lighting and those of the German Social Accident Insurance Institutions stand beside requirements set out in standards. A KAN expert report¹ reveals where overlaps, discrepancies and correlations between the different documents exist.

KAN has been addressing EN 12464-1, Light and lighting – Lighting of work places – Part 1: Indoor work places, for several years. The standard includes comprehensive requirements concerning the safety and health of workers at work, such as minimum values for the lighting of different workplaces. In accordance with the policy paper on the role of standardization in the safety and health of workers at work², this area should not be a subject for standardization.

Owing to the many overlaps between the content of EN 12464-1 with state rules and regulations and those of the accident insurance institutions, KAN has already discussed earlier editions of this standard with the responsible DIN standards committee. KAN's comments resulted in paragraphs concerning safety and health being added to the national foreword and to the scope.

The areas of overlap, deviations and links between the standard on the one hand and the body of German regulations and those of the accident insurance institutions on the other present challenges in practice, for example for persons responsible for the planning of lighting. EN 12464-1 is frequently referenced in contracts governing the planning of lighting systems. At the same time, a state document governing lighting exists in the form of ASR A3.4. This document gives rise to a presumption of conformity with the requirements concerning lighting set out in the German Regulation on Workplaces (ArbStättV) and thus takes precedence over standards.

KAN's objective is to promote a practical, cohesive body of OSH regulations. Therefore, clarification was first necessary of where OSH documents and the standard coincide in their requirements, and where they differ. The resulting implications for practical application were also to be considered. For this purpose, KAN invited tenders in 2022 for production of an expert report comparing the requirements for workplace lighting in the body of German state rules and regulations and those of the German Social Accident Insurance Institutions on the one hand and those in standards on the other, and tasked the German Federal Institute for Occupational Safety and Health (BAuA) with producing the report.



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Expert report serving as a source of information for committees

The report compares the requirements concerning workplace lighting set out in the body of OSH regulations with those formulated in standards. Owing to the presumption of conformity to which it gives rise with the safety and health requirements of the German Regulation on Workplaces (ArbStättV), the focus lies on the content of the ASR A3.4 workplace regulation governing lighting. On the standards side, EN 12464-1:2021 is the key document for the planning of lighting for indoor workplaces. The comparison includes other documents issued by the state or the accident insurance institutions and standards that are closely related to the two documents already referred to.

The requirements and recommendations of the documents under consideration are compared systematically and deviations concerning occupational safety and health evaluated against a scale developed by the author. In the comparison of the ASR with the standardization documents, the author emphasizes the different groups for which they are intended and the divergence in the documents' binding status. The rules governing workplaces, for example, are directed at employers: they give rise to a presumption of conformity with the occupational safety and health regulations that are to be supported. Conversely, the standards are intended for lighting planners; they are often referenced in contracts between such parties and their customers (typically employers or building owners).

Fundamental differences also exist in the fields of regulation. Outdoor workplaces and safety lighting, for example, are addressed only in ASR A3.4. One clear difference concerns the treatment of daylight, since EN 12464-1 makes no distinction between daylight and artificial lighting. Definitions of terminology differ and affect the entire document concerned. Shadows, flicker and glare are treated differently. More minor deviations can be found in the tables of requirements for specific workplaces/visual tasks in ASR A3.4 and EN 12464-1.

Non-visual effects of light are addressed by a recommendation made by the ASTA committee for working premises which focuses on lighting at night. As yet, this topic is not addressed in the ASR itself. DGUV informative document 215-220 governing the non-visual effects of light on human beings also provides information and broad recommendations in this respect. EN 12464-1 addresses the non-visual effects of light in its informative annex.

KAN recommendations

In two meetings, experts from among KAN's stakeholders discussed the report and formulated recommendations based upon it. KAN recommends that the results of the study be made known and made available to the BMAS, the relevant OSH bodies and standardization bodies for further use.

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¹ www.kan.de/fileadmin/Redaktion/Dokumente/KAN-Studie/de/2023-06-Vergleich_Beleuchtung_Arbeitsstaetten.pdf (in German, summary in English)

² www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/2021-02_Grundsatzpapier-Update-en.pdf

Exoskeletons: the current state of standardization activity

Exoskeletons can assist workers with certain movements and postures. A number of DIN working groups have now been standardizing the properties, ergonomic requirements and test methods for exoskeletons for around two years.

Exoskeletons are technical systems worn on the human body. Coupled mechanically with human beings and interacting with them, they are able to support the latter in adopting defined body postures and performing defined movements. For example, some are designed to make it easier for workers to lift loads, by directing a part of the forces acting upon the body away from the lower back. Other exoskeletons support employees' arms, particularly during prolonged work above shoulder level, thereby relieving the stress upon the shoulder and neck area. The intention is that the use of exoskeletons will reduce stress upon workers and avoid adverse consequences for their health in scenarios in which other measures are not effective.

Further development requires standards

Exoskeletons have not yet been adopted widely at workplaces. Development is nevertheless progressing, leading to a steady rise in the number of exoskeletons available on the market that can be used for a variety of purposes. Besides further research, particularly into the longer-term impact of exoskeletons, a need also exists for standards. These standards could formulate general, safety and ergonomic requirements for exoskeletons, and recommendations for their development and testing. The requirements set out in the standards provide clarity concerning the properties and possible applications of exoskeletons.



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Standardization work on exoskeletons began in Germany in January 2021 with the establishment of joint working committee NA 023-00-08 GA: Exoskeletons at DIN. The Standards Committee Ergonomics, which holds overall responsibility, cooperates in the joint committee with the Standards Committee Mechanical Engineering (Robotics) and the Standards Committee Optics and Precision Mechanics (Orthopaedic technology). A broad range of stakeholders are participating in the work. These include representatives from the scientific and research community, the German Social Accident Insurance Institutions, the German Federal Institute for Occupational Safety and Health (BAuA), company employee representatives and a number of users. A representative of the KAN Secretariat also serves on the committee and provides support to the OSH stakeholders.

Joint working committee NA 023-00-08 GA: Exoskeletons has set up three working groups. The Structure and Terminology working group has developed a proposal for the classification of exoskeletons. The classification divides exoskeletons into the following areas of use: medical, commercial, military and private. It distinguishes between the form in which support is provided (e.g. facilitating or stabilizing movements), the type of drive (e.g. powered or non-powered), the body region supported (e.g. the lower back or shoulder and neck region) and the exoskeleton's external geometry and structure (e.g. rigid or soft elements). In addition, this working group has formulated proposals for the definition of essential terms related to exoskeletons.

The Effectiveness and Comparability working group is defining parameters for exoskeletons, and test scenarios to ensure comparability between different exoskeletons. Parameters for comparability may include the exoskeleton's inherent weight, the time required for donning and removal, and the battery power. Specified test scenarios may cover specific functions or activities performed with an exoskeleton, such as walking, sitting or climbing stairs. At the same time, the working group is developing standardized measurement procedures focused on the efficacy of the exoskeletons. The group draws attention to a number of measurement methods, such as electromyography (EMG), motion capture and force measurements, by which this can be tested.

The third working group, Physical Interface, is developing provisions and drafting the text of standards governing the human-exoskeleton interface. Since forces act through this interface on soft tissue of the human body, the ergonomic design of the interface is particularly important. It must be designed to prevent excessive pressure from being exerted. Mechanical hazards, such as crush and shear points, must also be considered and avoided. Finally, hygiene is a significant factor for the human-exoskeleton interface. Provisions are therefore also formulated for cleaning and care of elements of the exoskeleton that may come into direct contact with the human skin.

The aim of joint working committee NA 023-00-08 GA: Exoskeletons is to submit the provisions, work item proposals and draft texts to the European standardization process. Committees for this purpose have not yet been created. German representatives are therefore in contact with their counterparts in other European countries and are calling for European standards committees dealing with the subject of exoskeletons to be set up. Should enough countries express interest in participating, such committees could be constituted in 2024.

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Standardization in additive manufacturing

The growing use of additive manufacturing processes, colloquially known as 3D printing, has increased the need for standards to be developed. At ISO level in particular, standards are currently being developed that impinge upon occupational health and safety.

Additive manufacturing processes are increasingly being used for the production of precision-fit components. Additive manufacturing is a generic term that includes all processes in which a machine builds up material layer by layer. A range of technologies and base materials are used, according to the application. Each of these base materials and technologies gives rise to particular hazards for workers.

Detailed specifications in standards needed

As a Type A standard under the Machinery Directive, EN ISO 12100¹ contains essential and general requirements for risk assessment and reduction that are applicable to all types of machinery. At present, no Type C standard currently exists in the field of additive manufacturing containing detailed requirements for individual machine types, despite the fact that machines of this type have been in use in production for some time now. The current development of a possible candidate standard in the form of EN ISO/ASTM 52938-1 should therefore be welcomed. This document defines safety requirements for machines employing a laser beam and bed of metallic powder. The aim of the European stakeholders on the ISO committee is to ensure that the final standard is consistent with the EU Machinery Directive and listed under the latter. To support this objective, the KAN Secretariat was involved in preparation of the draft standard. The document is in the public enquiry phase and can be viewed through DIN's draft standard portal, through which any stakeholder is free to submit comments on the draft text (preferably by 1 July 2023)².



Standardization documents concerning the health and safety of workers at work

A number of organizations wish to use standards and similar documents to address aspects concerning the safety and health of workers at work, as well as product and machine safety. In Germany, the former are governed by a detailed body of regulations issued by the state and the accident insurance institutions. For this reason, the stakeholders represented in KAN are opposed to standards in this area other than in exceptional cases. Blocking each and every such initiative is however not realistic; where this is not possible, it is important that KAN monitor the processes with the aim of ensuring that the documents produced are defensible at least from a technical perspective.

For example, VDI standards in the 3405-6 series highlight the hazards associated with certain additive manufacturing processes. They contain no workplace requirements of their own; rather, as a result of an initiative by KAN, they serve as guides to application of the relevant body of state rules and regulations and those of the accident insurance institutions³. This approach assures a high level of consistency in the body of regulations, and also lends itself readily to application.

At international level, too, there is considerable interest in standards governing the safety and health of workers working with additive manufacturing processes. For this reason, the KAN Secretariat also became involved in the development of ISO/ASTM 52931, which contains general workplace principles for the use of metallic materials in additive manufacturing⁴. ISO published the standard in early 2023. It was adopted as a European standard in the parallel voting procedure and will thus be transposed in the German body of standards as a matter of course in the near future. The KAN Secretariat has lobbied for reference to be made in the document's introduction and at other suitable points to the body of regulations applicable at national level. It is anticipated that work will begin shortly on a further document of the same kind, probably for polymer-based additive manufacturing processes.

Involvement of OSH experts desired

Active participation by OSH experts in development of the relevant standards is essential if a high level of safety is to be achieved. Only then can documents be drafted in the interests of occupational safety and health, and potential problems avoided from the outset. This particularly applies to areas in which established standards are very few in number, as is the case for additive manufacturing. The KAN Secretariat will continue to monitor standardization activity in the field of additive manufacturing. However, greater involvement by further OSH experts in this new area of standardization activity is desirable – particularly experts with practical experience of the machinery concerned. Their knowledge has immense value and may be decisive in the development of further Type C standards. In Germany, responsibility lies with the Additive Manufacturing group of the DIN Standards Committee Technology of Materials.

Hierarchy of machine safety standards

Type A standard: basic safety standard dealing with basic concepts, general principles for design and general requirements applicable to machinery of all types. Only one harmonized Type A standard exists, namely EN ISO 12100.

Type B standard: group safety standard, addressing specific safety aspects (type B1 standards), e.g. safety distances and surface temperature, or protective devices (type B2 standards), e.g. two-hand control devices or interlocks.

Type C standard: product standard setting out detailed safety requirements for a specific machine or group of machines.

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¹ EN ISO 12100:2011, Safety of machinery – General principles for design – Risk assessment and risk reduction

² E DIN EN ISO/ASTM 52938-1 Additive manufacturing of metals – Environment, health and safety – Part 1: Safety requirements for PBF-LB machines; www.din.de/de/mitwirken/normenausschuesse/nwt/entwuerfe/wdc-beuth:din21:368799271

³ VDI 3405, Additive manufacturing processes – User safety on operating the manufacturing facilities – Part 6.1:2019-11, Laser beam melting of metallic parts; Part 6.2:2021-04, Laser sintering of polymers; Part 6.3 draft:2022-02: Resin-based manufacturing processes.

⁴ ISO/ASTM 52931:2023-01, Additive manufacturing of metals – Environment, health and safety – General principles for use of metallic material; www.din.de/de/mitwirken/normenausschuesse/nwt/veroeffentlichungen/wdc-beuth:din21:364023432

OSH interests represented at the German Strategy Forum for Standardization

With the aim of strengthening and expanding the role and participation of German experts in European and international standardization activity, the German Strategy Forum for Standardization has been established at the German Federal Ministry for Economic Affairs and Climate Action (BMWK). The forum's members are 42 prominent persons in business, government, research and wider society, who are appointed for terms of two years. They include representatives of the German Federal Ministry of Labour and Social Affairs (BMAS) and KAN.

Under the leadership of Parliamentary State Secretary Dr Franziska Brantner, the forum is to identify standardization topics and projects of strategic importance for the German economy and its competitiveness in areas relevant to the future, and to contribute to strong participation by German experts in European and international standards bodies. In addition, the Strategy Forum reflects the activities of the European "High Level Forum on Standardization" and advises the BMWK on standardization issues.

For further information, visit www.bmwk.de Search: *Strategieforum*

EU regulation for mobile machinery

On 30 March 2023, the European Commission presented a proposal for a Regulation (EU) on the approval and market surveillance of non-road mobile machinery circulating on public roads and amending Regulation (EU) 2019/1020. The regulation covers requirements for road traffic but not other aspects already governed at European level, such as machine safety or noise emissions.

Up until now, these aspects have been governed at national level, with in some cases considerable variation between countries. The regulation covers a wide range of machinery used, for example in construction, agriculture or landscaping.

The proposed regulation is based on the multi-stage approach that is already part of the EU type-approval framework for motor vehicles. In accordance with this concept, the legislative process involves three steps:

- **Fundamental provisions of the proposed regulation** and its **scope** are defined by the European Parliament and the Council by way of the ordinary legislative procedure. The regulation is based on Article 114 TFEU and thus makes provision for full harmonization of product requirements.
- **Detailed technical specifications** are set out in **delegated acts** adopted by the Commission, rather than in harmonized standards.
- In addition, the Commission adopts **implementing acts**, which set out administrative rules such as the template for the type-approval certificate.

Text of the proposed regulation: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2023:178:FIN>

European product liability legislation updated

The European Commission has presented two proposals for directives updating product liability legislation. The purpose of these directives is to create greater legal certainty, as a growing number of products exists which, should they cause harm, currently leave consumers with no legal recourse for compensation.

The revised Product Liability Directive is intended to be applicable to products of all types. In the future, this will also include software updates, artificial intelligence systems, smartphone apps and refurbished or modified products not covered by the previous directive. Liability will rest with the manufacturer or responsible parties irrespective of fault. In the case of products not manufactured in the EU, provision is to be made in future for liability claims to be asserted not solely against the importer, but also against manufacturers' representatives in the EU and dealers (including online shops).

The scope of the AI Liability Directive further extends to fault-based liability for AI providers in the event of discrimination, data loss or violations of other legally protected rights. Those suffering harm should not have to demonstrate in detail how the harm was caused by an AI malfunction, but only show that a causal relationship with the AI behaviour is probable. In contrast to the Product Liability Directive, claims under the AI Liability Directive can also be brought by legal persons.

Proposal for the Product Liability Directive: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52022PC0495>

Proposal for the AI Liability Directive: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022PC0496>

Conference on introducing standardization to the young generation

Students, trainees and skilled workers in companies often have to deal with particular standards. However, they may not realize that they can actively shape the content of the standards themselves. To raise awareness systematically of this opportunity in the course of education and training, DIN and DKE are holding an interactive conference in Berlin on 28 and 29 September 2023 on the subject of training in standardization. Lecturers and other teaching staff in higher education will gain insights into the significance, procedures and benefits of standardization, and information on materials they can use in their teaching activity.

Information and registration: <https://t1p.de/durchstarten-mit-normung>

Events



27.06.23 » Berlin

Workshop

**Auf welches Klima-Szenario müssen wir aus
Vorsorgegründen vorbereitet sein?**

DIN/DKE/VDI

[www.din.de/de/din-und-seine-partner/termine/termine/
auf-welches-klima-szenario-muessen-wir-aus-
vorsorgegruenden-vorbereitet-sein--906784](http://www.din.de/de/din-und-seine-partner/termine/termine/auf-welches-klima-szenario-muessen-wir-aus-vorsorgegruenden-vorbereitet-sein--906784)

05.-07.07.23 » Dresden

Seminar

Maschinensicherheit und Produkthaftung

Institut für Arbeitsschutz der DGUV (IAG)

https://asp.veda.net/webgate_dguv_prod 570012

11.-12.07.23 » Nürnberg

Seminar

CE-Kennzeichnung im Maschinen- und Anlagenbau

VDI

www.vdi-wissensforum.de CE-Kennzeichnung

20.-24.07.23 » San Francisco/ Hybrid

Konferenz

Applied Human factors and Ergonomics (AHFE 2023)

AHFE International

<https://ahfe.org/>

23.-28.07.23 » Copenhagen

Conference

HCI International – Human-computer interaction - 2023

HCI

<https://2023.hci.international>

12.-13.09.23 » Berlin

Seminar

Produktsicherheitsgesetz (ProdSG) und Produkthaftung

VDI

www.vdi-wissensforum.de Produkthaftung

18.-19.09.23 » Bonn

Seminar

Maschinenrichtlinie 2006/42/EG

MBT Ostermann GmbH

[www.maschinenbautage.eu/seminare/
seminarmaschinenrichtlinie1/](http://www.maschinenbautage.eu/seminare/seminarmaschinenrichtlinie1/)

19.09.23 » Dortmund

Fachtagung

Smarte IKT und AR im Arbeitskontext

BauA

[www.baua.de/DE/Angebote/Veranstaltungen/Termine/
2023/09.19-Smarte-IKT-und-AR.html](http://www.baua.de/DE/Angebote/Veranstaltungen/Termine/2023/09.19-Smarte-IKT-und-AR.html)

28.-29.09.23 » Berlin

Konferenz

Durchstarten mit Normung

DIN/DKE

www.din.de/de/mitwirken/young-professionals

17.-19.10.23 » Köln

Konferenz

Maschinenbautage 2023 mit Maschinenrechtstag

MBT Ostermann GmbH

[www.maschinenbautage.eu/konferenzen/
konferenz-maschinenrichtlinie-2023/](http://www.maschinenbautage.eu/konferenzen/konferenz-maschinenrichtlinie-2023/)

18.-20.10.23 » Dresden

Seminar

**Manipulation an Maschinen und Anlagen:
Risiken erkennen, Maßnahmen ergreifen**

Institut für Arbeitsschutz der DGUV (IAG)

https://asp.veda.net/webgate_dguv_prod 570089

25.-27.10.23 » Dresden

Seminar

Grundlagen der Normungsarbeit im Arbeitsschutz

Institut für Arbeitsschutz der DGUV (IAG)/KAN

https://asp.veda.net/webgate_dguv_prod 570044

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