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Guidelines for the development and use of safety testing procedures in human-robot collaboration

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European foreword

This CEN Workshop Agreement (CWA 17835:2022) has been developed in accordance with the CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization" and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by a Workshop of representatives of interested parties on 2021-11-24, the constitution of which was supported by CEN following the public call for participation made on 2021-03-26. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

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Introduction

The traditional concept of industrial robots refers to bulky machines, where the robot workspace is physically separated from the operator working area. The concept of collaborative applications reached the industrial domain and was elevated to one of the key-enabling technologies of the Industry 4.0 paradigm. Similar approaches can be nowadays applied to a wide variety of other machines, designed to work closely with humans. At the same time, we are witnessing increasing implementation of service robots in several domains, such as personal care, agriculture and logistics. Moreover, medical equipment and systems based on robotic technologies are more and more implemented in current medical practice and rehabilitation and assistance robots in particular have become relevant, as aging populations are increasingly affected by chronic disabilities.

In general, robot systems and applications characterized by close human-robot interaction (such as collaborative applications in industrial robotics or rehabilitation robots in medical applications) are accompanied by new challenges from the safety perspective (i.e. the potential contact or the intension of contact between human and robot introduces a higher exposure to mechanical hazards). In such cases, ensuring safety is potentially highly complex and variable, depending on the specific implementation scenario and the safety-related measures implemented. The new safety-related challenges need to be properly addressed and validated.

According to robot categorization, standards provide different means to ensure safety in *human-robot collaboration*, and several test methods have been recommended in the last few years, characterized by different levels of detail and addressing different robot categories. Considering the common challenges due to *human-robot collaboration* for various application domains, the objective of this CWA is to provide a framework for compiling testing procedures for the validation of the residual risks related to the mechanical hazards arising in *human-robot collaboration*, by using a category-transversal approach based on standards and on well-established best practices. The following stakeholders can benefit from this CWA:

— for industrial robots: integrators or users planning the evaluation of specific mechanical hazards of a certain collaborative application, considered as a whole;

— for the medical robotics field: manufacturers planning the residual risk evaluation (where not diversely indicated by EN ISO 14971:2020 and CEN ISO/TR 24971:2020), as part of the risk management process, or other users planning the evaluation of the mechanical hazards in some use scenarios;

— for service robots: manufacturers or other professional users planning the evaluation of the mechanical hazards in some use scenarios.

The systematic pooling of practices and information belonging to different robot categories can significantly expand the base of knowledge available for the stakeholders. As an example, ISO/TR 23482-1:2020 refers to ISO/TS 15066:2016 for the data of pain onset for physical contacts and EN IEC 80601-2-78:2020 refers to EN ISO 13482:2014 for the consideration of risk reduction measures for robot collision with safety-related obstacles. This document intends to provide methodology and criteria to support stakeholders in the consistent development and use of uniform, transversal testing procedures for mechanical safety. Applicability of these transversal testing procedures may facilitate demonstration of compliance for applications where multiple legislation, or parts of legislation, may apply, e.g. when a medical robot should comply also with machinery-specific requirements.

The evaluation of risks in human-robot collaboration may be variable and requires specific assessment. The *system-level validation* addressed in this document targets the risks characterizing a robot implementation or robotic application; although it may be considered that mechanical safety is not the only relevant dimension of safety when dealing with *human-robot collaboration* [1], the document is limited to the scope of mechanical hazards.

1 Scope

This document gives guidelines for a uniform framework, transversal with respect to the different robot categories and limited to those robots and robotic applications characterized by *human-robot collaboration*, for the development and/or use of testing procedures, applicable to different robot categories and use scenarios.

This document is informative and is not aimed at substituting or simplifying verification and/or validation procedures required by standards. The objectives of this document are the following:

— define an approach for the development and use of procedures for testing safety in *human-robot collaboration* at a system level, based on *safety-relevant human-robot collaboration skills* and limited to the mechanical hazards;

— define a comprehensive list of application-driven, technology-invariant *safety-relevant human-robot collaboration skills* valid across different domains;

— provide a template for *system-level validation protocols*;

— by way of example, present two *system-level validation protocols*, applicable to multiple domains.

This document does not apply to the following devices, systems and applications: autonomous vehicles for the transportation of persons, drones, rescue robots (including ground, marine and aerial vehicles), surgical robots in relation to the body of the patient, passive wearable devices, external limb prostheses.

NOTE 1 This document aims at providing harmonization in the compilation of structured testing procedures, to supplement safety validation of specific robot applications, building, where possible, on test methods provided in the relevant standards. It does not propose any safety requirement, nor is it intended to provide alternatives for or simplification of the relevant standards for each robot category. Users of this document are expected to be proficient in directives, regulations and standards applicable for the specific robot system and application. An overview of robot categorization is provided in A.1.

NOTE 2 This document does not address “functional safety” (e.g. the performance level of safety-related parts of control systems), nor criteria for its validation and verification.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at https://www.electropedia.org/

EN 16271, *Value management - Functional expression of the need and functional performance specification - Requirements for expressing and validating the need to be satisfied within the process of purchasing or obtaining a product*

EN 62304, *Medical device software – Software lifecycle processes*

EN 62366-1, *Medical devices – Part 1: Application of usability engineering to medical devices*

EN ISO 3691-4:2020, *Industrial trucks — Safety requirements and verification — Part 4: Driverless industrial trucks and their systems*

EN ISO 10218-1, Robots and robotic devices — Safety requirements for industrial robots — Part 1: Robots[1]

EN ISO 10218-2, Robots and robotic devices — Safety requirements for industrial robots — Part 2: Robot systems and integration[2]

EN ISO 12100:2010, *Safety of machinery – General principles for design – Risk assessment and risk reduction*

EN ISO 13482:2014, *Robots and robotic devices – Safety requirements for personal care robots*

EN ISO 13855, *Safety of machinery — Positioning of safeguards with respect to the approach speeds of parts of the human body*

EN ISO 13857, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs*

EN ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

EN ISO 14971:2020, *Medical devices – Application of risk management to medical devices*

EN ISO 18497:2018, *Agricultural machinery and tractors – Safety of highly automated agricultural machines - Principles for design*

CEN ISO/TR 24971:2020, *Medical devices — Guidance on the application of ISO 14971*

EN IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

EN IEC 80601-2-78:2020, *Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation*

EN IEC 80601-2-77:2021, *Medical electrical equipment — Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment*

ISO 8373:2021, *Robots and robotic devices – Vocabulary*

ISO/DIS 10218-1.2:2021, *Robotics – Safety requirements – Part 1: Industrial robots*

ISO/FDIS 10218-2:2021, *Robotics – Safety requirements – Part 2: Industrial robot systems, robot applications and robot cells*

ISO 18646-1:2016, *Robotics — Performance criteria and related test methods for service robots — Part 1: Locomotion for wheeled robots*

ISO 18646-2:2019, *Robotics — Performance criteria and related test methods for service robots — Part 2: Navigation*

[1] Under preparation. Stage at the time of publication: ISO/DIS 10218-1.2:2021.
[2] Under preparation. Stage at the time of publication: ISO/FDIS 10218-2:2021.

ISO 18646-3:2021, *Robotics — Performance criteria and related test methods for service robots — Part 3: Manipulation*

ISO 18646-4:2021, *Robotics — Performance criteria and related test methods for service robots — Part 4: Lower-back support robots*

ISO 19649:2017, *Mobile robots – Vocabulary*

ISO/TS 15066:2016, *Robots and robotic devices – Collaborative robots*

ISO/TR 23482-1:2020, *Robotics — Application of ISO 13482 — Part 1: Safety-related test methods*

ISO/TR 23482-2:2019, *Robotics — Application of ISO 13482 — Part 2: Application guidelines*

IEC/TR 60601-4-1:2017, *Medical electrical equipment — Part 4-1: Guidance and interpretation — Medical electrical equipment and medical electrical systems employing a degree of autonomy*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8373:2021, EN ISO 12100:2010 and the following apply.

3.1
human-robot collaboration (HRC)
human-robot interaction in a shared space in which contact with robots, workpieces, loads, or instruments is either prevented or envisaged but harmless

3.2
safety-relevant human-robot collaboration skill (HRC skill)
abstract representation (model) of the ability of an HRC application to reduce a risk defined irrespective of the way it is implemented, be it due to an inherent design feature or a dedicated risk reduction/risk control measure/strategy/policy

Note 1 to entry: an HRC skill can be achieved by the implementation of risk reduction measures or risk control measures, depending on the application domain and the applicable requirements.

3.3
system-level validation of a safety-relevant human-robot collaboration skill
system-level validation (SLV)
test-based assessment of the behaviour of a complete system with regards to pass/fail criteria for a given HRC skill, considering the real use conditions

Note 1 to entry: pass/fail criteria are defined prior to SLV, considering the robot category and the specific risk assessment.

Note 2 to entry: The SLV may be performed on a subsystem for practical reasons, if this is representative of the behaviour of the complete system from the perspective of the HRC skill under consideration.

3.4
system-level validation protocol
SLV protocol

step-by-step instruction for executing validation measurements; it specifies testing procedures for SLV