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DRAFT

Project Plan for the CEN Workshop COVR on:

Safety skills in collaborative robotics applications: procedures for validation tests

Workshop (to be approved during the Kick-off meeting on 2021-04-28)

1. Status of the Project Plan

Initial draft Project Plan, to be further developed, prior to submission for approval

2. Background to the Workshop

The well-established concept of robots refers to bulky machines confined to the industrial environment, carrying out repetitive tasks. In traditional industrial robotics, the operations of robot and operator are complementary and belong to separated workspaces. In the last years, we are witnessing the increasing implementation of robots and robotic devices in a number of other domains, such as minimally invasive surgery, healthcare, rehabilitation, agriculture and logistics. The concept of collaborative robots reached the industrial domain and was elevated to one of the key-enabling technologies of the Industry 4.0 paradigm. It can be nowadays applied to a wide variety of other machines, designed to work closely with humans.

Focusing on the industrial environment, a number of “collaborative robot” models is nowadays available on the market and human robot interaction (HRI) is further promoted by the possible implementation of multi-modal interfaces, enabling extreme synergy. Besides task optimization due to the combination of robot precision and human awareness, the overall flexibility extremely increases, also considering the user-friendly programming possibilities [1]. Processes based on these technologies can be more reactive and reconfigurable, complying with new market requirements, characterized by small production lots and mass customization. The European Union, as global leader in many high value-added industries, can benefit considerably from the implementation of collaborative robots, due to the highly skilled and talented workforce [2]. It is worth to observe that some collaborative operations rely on the use of traditional robot, complemented by adequate (generally external) safety measures, and that conversely a robot commercialized as a “collaborative robot” does not ensure safety by itself, the safety needing to be considered at the application level, with a defined intended use.

While the maturity of the technology is increasing quickly, legislation and standardization timing is reasonably different. The EN ISO 10218-1:2006 (updated 2011) and EN ISO 10218-2:2011, whose scope is the safety of industrial robots, were the first standards dealing with collaborative operations, subsequently complemented by the ISO/TS 15066:2016. However, only a few safety-related validation procedures are provided by standards, even considering the current revision drafts, and similar conditions can be met in other domains. The main aim of the EU funded project "Being safe around collaborative and versatile robots in shared spaces (COVR)" is to provide a contribution to fill this gap; as a result of a research project, the COVR approach goes beyond the classical domain-based categorization, exploiting the experience on best practice and cross-fertilization among different domains [3], [4]. This is implemented by proposing a unified validation process at a system level, to optionally complement requirements and processes provided by standards, basing the assessment on transversal safety skills, applicable to different scenarios, including those characterized by close HRI. The developed testing protocols are verified by in-house trials before the publication in the COVR toolkit [5].

NOTE: The proposed CWA is not intended to be an alternative to the relevant standards of each specific domain, which are the main references for the development of robotic applications. It is aimed instead at providing, with a domain-transversal approach, additional testing procedures to support developers or users in when they wonder how to test the safety of their applications. Not questioning the traditional domain-based categorization, the term "cobot" is here used referring to a variety of robotic devices characterized by close HRI, such as industrial robots used in a collaborative application, robots for personal care, exoskeletons, rehabilitation robots, etc.

<u>Relevant EU policies</u>

"Healthy, safe and well-adapted work environment and data protection" is one of the twenty principles of the European Pillar of Social Rights. Health and safety at work is one of the areas where the EU has had the most relevant impact, based on a solid legal framework covering an extremely high number of risks with a relatively low number of regulations. On the other hand, the topic of collaborative robots is extensively addressed on the European research landscape and a wide range of projects were funded within the Horizon 2020 program, belonging to the FP7 and H2020 calls on ICT (Information and Communication Technology) and Factories of the Future.

In [6], a classification and general description of 66 of the related projects funded by the European Commission (including COVR) is provided, covering a total budget of €413 million. The report provides a specific section in the conclusions dedicated to the standardization actions, defining a "continuous challenge" for Europe to play a role in standardization, recognizing research projects as a fundamental drive, due to their collaborative nature, and encouraging the participants to promote and take part in standardisation, certification, interoperability, benchmarking and reproducible research.

The interest within the EU community towards robotics and cobots is not expected to drop in the next years. In the co-design process for the preparation of the next European research and innovation programme, Horizon Europe (2021-2027), in particular in the second pillar "Global challenges and European industrial competitiveness" [7], robotics is recognized as an enabling technology for biomedical research, prevention and therapy. Furthermore, it is observed that the percentage of SMEs using industrial robots is about half of the percentage characterizing larger companies; this suggests that collaborative robots, easier to implement, cheaper and more suitable for small-scale production, could play a role in bridging this gap. Finally, "improving smart, collaborative, safe and efficient robots" is an explicit target, individuating human-robot collaboration (HRC) as a driver for improving the quality of jobs.

Market Environment

Most recent trends in manufacturing move from mass production to mass customization. Mass-customized products are both affordable and close to market-specific needs. The production paradigm needs to comply with these requirements and collaborative robot operations exhibit key features from this viewpoint, based on the combination of human intelligence and problem-solving with reliability, precision and endurance of machines.

Europe represented the largest collaborative robot market share in 2017 and the expectation is that the Asia-Pacific region will get ahead of Europe in 2025, due to the spread of collaborative robots in electronic, automotive and metal machining SMEs. On a global basis, the market is expected to grow from USD 710 million in 2018 to USD 12.3 billion by 2025, with a yearly growing rate of 50.31% [8].

The European manufacturing landscape is characterized by high density of SMEs, referring to enterprises with up to 250 employees. In 2018, European SMEs accounted for about the 66.8% of employment within the EU-28 non-financial business sector [9]. SMEs usually have limited financial, logistic and organizational resources to transform production lines or single manufacturing tasks; the reduced setup time, together with the low prices and the basic installation requirements, makes cobots an affordable and suitable solution towards digitalization.

From the employment viewpoint, it is worth to consider that collaborative robots do not necessarily substitute human workforce. They instead become useful tools to increase the quality and the level of the job performed by the human operator. At the same time, a series of new jobs and qualifications is expected to arise, connected to the collaborative trend in automation.

The role of Europe in the cobot market is fundamental even considering that European robot manufacturers already provide several collaborative robots in their portfolios: ABB has YuMi and Roberta, the Aura robot belongs to Comau and Kuka propose the LBR iiwa. New cobot-specific companies were founded, such as Universal Robots and Franka Emika. Other non-roboticist companies launched their own cobots, such as the Festo Bionic Cobot and APAS by Bosch.

Legal Framework

The proposed CWA is not intended to take away the need for the developers to get to know the applicable standards and comply with the relevant laws.

The Machinery Directive applies to robotics, with a few exceptions (listed in the directive):

- Directive 2006/42/EC: Machinery Directive;

The following EU Directives and Regulations can be relevant for collaborative robots, depending on the domain and the specific application. In particular, in case of robots dedicated to consumer market, the following Directives applies:

- Directive 2001/95/EC: General product safety;
- Directive 85/374/EEC: Liability for defective products.

In medical robotics and rehabilitation, the medical device regulation replaced the directive for new products

- Regulation 2017/745: Medical Device Regulation;
- Directive 93/42/EEC: Medical Device Directive.
- Some others directive may apply based on the specific equipment or technology, not specifically addressing safety, such as:Directive 2014/35/EU: Low Voltage Directive;
- Directive 2014/30/EU: Electromagnetic Compatibility Directive;
- Directive 2014/53/EU: Radio Equipment Directive.

Some other applies for specific dangerous environment or products, as ATEX and REACH directives.

- Related Standards**EN ISO 10218-1:2011** Robots and robotic devices–Safety requirements for industrial robots–Part 1: Robots;
- **EN ISO 10218-2:2011** Robots and robotic devices–Safety requirements for industrial robots–Part 2: Robot systems and integration;
- **ISO/TS 15066:2016** Robots and robotic devices – Collaborative robots;
- **EN ISO 12100:2010** Safety of machinery–General principles for design–Risk assessment and risk reduction;
- **EN ISO 13849-1:2015** Safety of machinery–Safety-related parts of control systems–Part 1: General principles for design;
- **EN ISO 13849-2:2012** Safety of machinery–Safety-related parts of control systems–Part 2: Validation;
- **IEC/EN 60204-1:2018** Safety of machinery–Electrical equipment of machines–Part 1: General requirements.
- **IEC/EN 62061:2005**, Safety of machinery: Functional safety of electrical, electronic and programmable electronic control systems
- **IEC 61508:2010** Functional Safety of Electrical/Electronic/Programmable Electronic Safety-related Systems
- **EN ISO 13482:2014** Robots and robotic devices - Safety requirements for personal care robots (ISO 13482:2014)
- **ISO/TR 23482-1:2020**, “Robotics — Application of ISO 13482 — Part 1: Safety-related test methods”
- **EN ISO 14971:2020** Medical devices – Application of risk management to medical devices
- **EN IEC 60601-1:2020**, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 80601-2-78:2019**, Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation
- **EN ISO 3691-4:2020**, Industrial trucks — Safety requirements and verification — Part 4: Driverless industrial trucks and their systems
- **EN ISO 18497:2019**, Agricultural machinery and tractors - Safety of highly automated agricultural machines - Principles for design

The gap to bridge

Concerning cobot applications, standards are generally not aimed at supporting integrators and users in validation processes at a whole system level. Based on our experience with robot end-users and integrators, the promotion of cobot technologies in different domains is slowed down by the unclear path towards safety validation. This is due to both the limited knowledge about relevant standards, relevant in particular for start-ups or companies extending their portfolios with cobot solutions, and the absence of clear testing procedures to prove the compliance in these standards [10], [11]. The COVR project aims at bridging this gap by providing procedures for cobot safety validation, which can be used as an additional complement to the fulfilment and application of existing standards . Making these safety assessment processes clearer allows cobots to be used with more confidence in more situations; this can be a valuable boost to increase the variety of cobots on the market and the variety of services cobots can offer to the general population.

By way of example, in industry, for a given collaborative robotics application, the safety assessment process starts with the risk analysis, followed by risk elimination or, if not possible, reduction (according to EN ISO 12100). The safety expert identifies the most appropriate measures to make the entire system safe. The open question we intend to address concerns whether the specific installation and setup are appropriate to mitigate each identified risk. Even if the general features of collaborative operations are individuated by the EN ISO 10218-1, and the ISO/TS 15066 provides a more detailed analysis, declaring also the acceptable biomechanical limits, there is still a gap concerning testing procedures, metrics, expected performance. The EN ISO 10218-2 provides a list of “verification and validation methods” (§6.2) individuated depending on the specific safety measures (Annex G); however, instructions on how to conduct “practical tests”, “measurement” or “observation during operation” are out of the scope of the standard. It is worth mentioning that the ISO/DIS 10218-2:2020 (Draft International Standard), currently in the balloting period, include several Annexes dedicated to calculation and tests for collaborative robotic applications. Concerning mobile robots in industrial domain, some testing methods are included in EN ISO 3691-4, addressing obstacle detection and dynamic stability.

Similar considerations hold true for the healthcare domain where various standards of the EN IEC 60601-1 series provide rather general information about requirements for basic safety and essential performance, but concrete advice for testing procedures and applicable limit values is missing. The rehabilitation robot-specific standard IEC 80601-2-78 clarifies a number of items specific to rehabilitation robotics, but still does not address methods for safety testing in satisfactory detail. EN ISO 13482, and the related application Technical Report ISO/TR 23482-1, suggest a number of test methods and corresponding limit values for personal care robots. This is very valuable information, although not applicable for medical applications and not covering all needs regarding guidance about testing procedures and relevant metrics.

Expected impact

The motivation of proposing the CWA “Safety skills in collaborative robotics applications: procedures for validation tests” is to provide a shared framework to propose a unified and specific approach concerning testing procedures for robotics applications in which close human-robot interaction is envisaged. Several standardization working groups are now working on safety issues (i.e. ISO TC299/WG2 – Personal care robot safety, /WG3 - Industrial safety and /WG5 - Medical robot safety) and our expectation is that the approach developed within the COVR project can be the basis for further developments by providing a transversal, multi-domain perspective. Furthermore, the CWA will be an excellent opportunity to disseminate the activities and the results obtained within COVR, gathering useful feedback from a wide network of relevant stakeholders, thus possibly improving the impact of the tools provided through the COVR project.

3. Workshop proposers and Workshop participants

The CEN Workshop is proposed by the COVR consortium. The research project is funded by the European Union under the H2020 R&I programme.

The proposer of the CEN Workshop is the Institute of Intelligent Industrial Technologies and Systems for Advanced Manufacturing of the National Research Council of Italy (CNR-STIIMA). The CEN Workshop Agreement will be developed with the other members of the COVR consortium, in particular with:

- French Alternative Energies and Atomic Energy Commission – Laboratory for Integration of Systems and Technology (CEA/LIST, France);
- Danish Technological Institute (DTI, Denmark);
- Roessingh Research and Development (RRD, The Netherlands).

The participation of manufacturers, end-users and occupational safety & health authorities is strongly encouraged.

Relevant stakeholders will be specifically invited from the Standardization landscape. The following Technical Committees will be indeed informed about the CWA kick-off meeting and informed when the CWA will be submitted to public commenting phase:

- CEN/TC 310 ‘Advanced automation technologies and their applications’
- CEN/TC 114 ‘Safety of machinery’
- CLC/TC 62 ‘Electrical equipment in medical practice’
- CEN-CENELEC Sector Forum on Machinery
- CEN/TC 150 ,‘Industrial Trucks – Safety’ in relation to EN ISO 3691-4
- ISO TC299 – Robotics
- ISO TC199 – Safety of Machinery

Dedicated stakeholders will be invited to join the CWA development from the pool of organizations that actively joined the COVR community by securing COVR awards to develop projects concerning safety in collaborative robotics. Among these, significant contributions to the CWA can be provided by stakeholders holding experience in the legal, standardization and certification fields. The list comprehends, but is not limited to:

- Synch Company from Denmark, dealing with the development of a model for legal risk assessment of cobot operations;
- The eLaw - Center for Law and Digital Technologies, from the University of Leiden (NL), which is working on a project addressing how to generate policy-relevant knowledge from compliance tools, like COVR protocols and Toolkit;

- The Neural Rehabilitation Group of The Spanish National Research Council (CSIC), which is working to develop a standardized test method to quantify safety of locomotion for lower limb exoskeletons;
- Hocoma company (CH), which have relevant expertise and knowledge of the requirements of international norms and legislation in the field of rehabilitation and their application;
- Joanneum Research center from Austria. Its Robotics Evaluation Lab was recently accredited as a testing laboratory according to the EN ISO/IEC 17025.

Participation in the CEN Workshop is open to everyone, and the opportunity to participate is widely advertised prior to the kick-off meeting by the proposers on their large network of national and EU organizations and research institutions.

4. Workshop scope and objectives

The CWA “Safety skills in collaborative robotics applications: procedures for validation tests” is aimed at providing a common framework for proposing a skill-based approach for testing the specific implementations of safety measures applied to mitigate the risks related to HRC.

Such testing procedures are not intended to question the use of existing International and European Standards, whose application provides a presumption of conformity to Directives and Regulations, but to optionally complement them. The identification of potential needs for complements could lead eventually to bringing this as a contribution to international and European standardization, by means of the usual processes of the relevant CEN, CENELEC, ISO and IEC Technical bodies.

The cross-domain feature is a fundamental cornerstone of the proposed approach. Concerning industrial robotics, the available standards do not provide step-by-step system-level testing and validating procedures; in other domains, such as healthcare or agriculture, there is even a lot less information available concerning testing procedures and limit values for mechanical safety in the human-robot interaction. The fast increase of robot spread in different domains requires consistent and well-established procedures, but domain-based strict categorization can be a limit in the potential exploitment of the available base of knowledge and experience. A useful case study in this respect is represented by Rehabilitation Assessment Compensation Alleviation (RACA) robots, which have to comply with both, Machinery Directive 2006/42/EC, due to their inherent system features, and Regulation 2017/745 on Medical Devices, due to their scope of use.

The COVR consortium is developing a number of testing protocols for validating safety of collaborative robot operations. A set of relevant protocols were identified with a “bottom-up” approach, starting from collaborative robotics safety standards in the manufacturing and healthcare domain; a “top-down” method was subsequently applied for the identification of robotic *safety skills* valid for a wide number of domains. The concept of *safety skill* refers to the abstract representation (model) of the ability of the robot system 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 measure/strategy/policy. Different methods for validation testing implementation may derive, depending on the application domain and the existence of (mandatory) requirements. The following skills have been so far identified:

- Limit Physical Interaction Energy;
- Maintain Safe Distance;
- Dynamic Stability;
- Limit Range of Movement;
- Maintain Proper Alignment;
- Limit Restraining Energy.

Therefore, the objectives of the CWA “Safety skills in collaborative robotics applications: procedures for validation tests” are the following:

- Illustrate and refine the general skill-based approach for testing safety at a system level in cobot applications;
- Define a comprehensive list of application-driven, technology-invariant safety skills valid across different domains;
- Provide a template for skill-based testing protocols;
- By way of example, present at least two protocols, related to different application domains.

5. Workshop programme

The CWA will be drafted and published in English.

A tentative time schedule for the CEN Workshop is reported in Figure 1. Timing could vary depending on CWA drafting process.

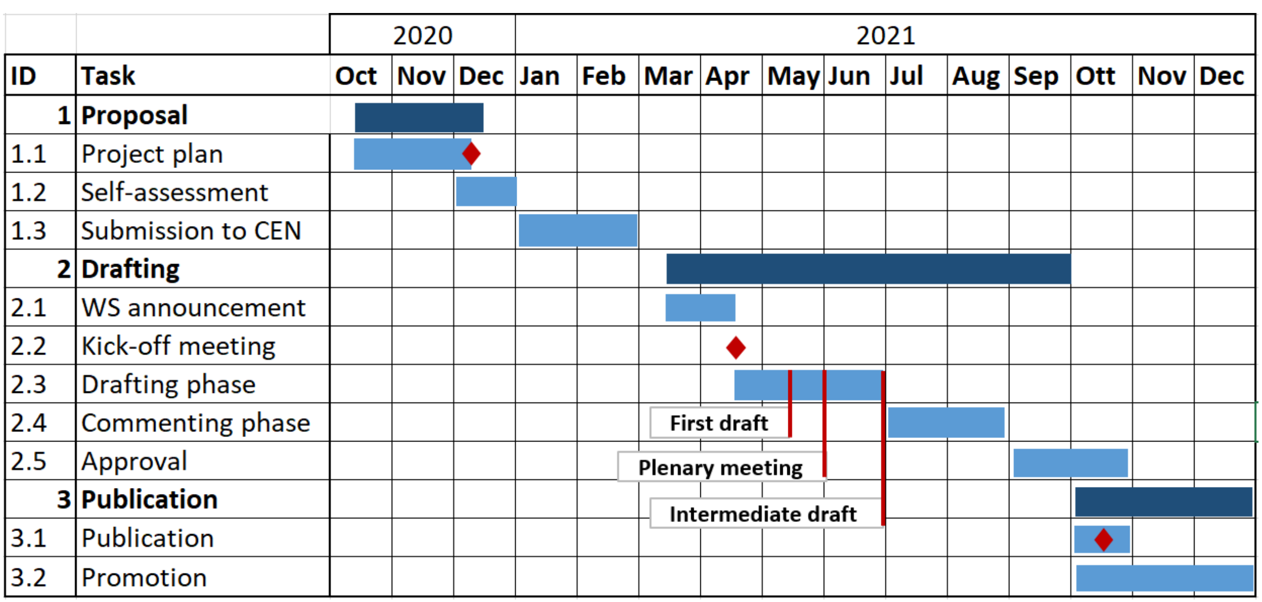

Figure 1: Tentative Timeplan

Anyone can comment on this Project Plan of the envisaged CWA. All comments received will be considered by the chairperson preliminary to the kick-off meeting. At the workshop, each comment received shall be presented, discussed and resolved.

The CEN Workshop participants will actively elaborate content, review incoming drafts and suggest changes as well as additions. Three versions of the CWA will be produced during the CEN Workshop: first draft, one intermediate version, and a final version (dates are tentative and subjected to confirmation). The CWA intermediate version will be submitted for the commenting phase of 60 days. All the submitted comments will be analyzed by the CWA chairperson, and vice-chairpersons. The following steps will be applied to take the comments into account:

- Eligibility evaluation, based on comment pertinence
- Categorization
- Elaboration of amendments
- Produce a tracking report with all comments and reference to the amendments in the text.

6. Workshop structure

The Workshop proposers suggest the following structure. Structure and persons in charge are to be approved during the Workshop Kick-Off meeting.

CEN Workshop chairperson and two vice-chairpersons

Main responsibilities:

- To preside at the Workshop plenary meetings
- To ensure that the Workshop delivers in lines with its Project plan;
- To manage the consensus building process
- To interface with CEN/WS Secretariat and CEN Management Centre regarding strategic indications, problems arising in the development of the CWA
- To consolidate the comments received on the drafts during the enquiries and propose a resolution of comments for discussion with workshop participants
- Supported by the Secretariat, to prepare the drafts CWA to be circulated to CEN/WS participants

CEN Workshop Secretariat

Main responsibilities:

- To offer the infrastructure for electronic operation (i.e. Livelink platform);
- To administer the CEN Workshop's members list(s) and official registration of participants;
- To manage documents and their distribution, and to update the document register;
- To prepare and distribute CEN/WS Documents (i.e. draft agendas and information on meetings arrangements, minutes of the meetings, draft CWAs, etc.);
- To chase actions as decided by the CEN Workshop meeting;

- To advise on the requirements of the CEN/CENELEC Internal Regulations and decisions of the CEN/CA and CEN/BT in the development of a CWA;
- To provide expertise in standardization and provide relevant standards to the Workshop, when or where necessary;
- To check conformity of all of the versions of the draft CEN Workshop Agreement to CEN rules;
- To initiate and manage the CWA approval process, upon decision by the Chairman;
- To record expression of support to the CWA for transmission to the CEN Management Centre;
- To participate to CEN Workshop plenary meetings, audioconferences and meetings with the Chairman.

7. Resource requirements

The registration and participation at this CEN Workshop is free of charge for every member of the Workshop, but each participant will bear his/her own costs for travel and subsistence.

The administrative costs of the Workshop Secretariat and other logistical support will be covered by the CWA proposer.

8. Related activities, liaisons, etc.

The work carried out by the CEN/WS may be of interest for ISO/TC 299, ISO/TC 184 and, while addressing a domain that goes beyond the field of industrial robots and industrial automation, may be of interest also for the CEN/TC 310 Advanced automation technologies and their applications.

In parallel with the CWA initiative, the COVR consortium is developing an ISO PAS (Publicly Available Specification), titled “Collaborative robot devices – Test methods for measuring forces and pressures in quasi-static and transient contacts with humans”. In the ISO PAS, a systematic procedure to validate through measurements the ability of collaborative robotics applications to mitigate risks from accidental contacts is proposed. The aim of these parallel initiatives is to make available and discuss with a wide list of relevant stakeholders the most impactful results and developments obtained within the COVR project.

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