Draft Project plan for the CEN Workshop on "Guideline for introducing and implementing real-time instrumental-based tools for biomechanical risk assessment"

Requests to participate in the Workshop and/or comments on the project plan are to be submitted by
2022-10-09 to
Friederike.Nabrdalik@din.de[1]

Recipients of this project plan are kindly requested to name all patent rights known to them to be relevant to the Workshop and to make available all supporting documents.

Berlin, 05.09.2022 (Version 1)

[1] Applications for participating in the Workshop and comments on the project plan that are not received by the deadline do not need to be taken into consideration. Once constituted, the Workshop will decide whether or not to consider the comments received in good time.

Contents

Summary

The European research project SOPHIA is working on the development of a new generation of human–robot collaboration (HRC) technologies able to support in manual material handling (MMH) activities.

In this context also human ergonomics in MMH is investigated and comparatively compared with and without HRC. For this a real-time instrumental-based tool for ergonomic measurements during the execution of (MMH) activities was developed. With the acquisition of kinematic, kinetic, and electromyography signals from appropriate wearable sensor networks the physical condition of humans can be monitored. The collected specific data can possibly be used to classify the biomechanical risk of several MMH and thus help reducing work-related musculoskeletal disorders (WMD) incidence and prevalence, associated costs, sick leave and disability in many occupational populations.

The guideline to be developed in this CWA aims to support the application of intelligent wearable wireless sensors networks for measuring human load in MMH activities. This can create in the following new options for the biomechanical risk assessment in the “Industry 4.0” era as supplement to traditional methods. As the developed approaches have a considerable technical and computational complexity in their structure, the workshop aims to describe the requirements regarding materials and procedures to be used to perform a proper and simply applicable instrumental-based data collection as basis for biomechanical risk assessment.

Despite the high readiness of human augmentation technologies and collaborative robots a lack of standards is to be filled to acknowledge the application and enable the potentials for ergonomics.

1 Status of the project plan

Draft project plan for public commenting (Version 1.0)

This draft project plan is intended to inform the public of a new Workshop. Any interested party can take part in this Workshop and/or comment on this draft project plan. Please send any requests to participate or comments by e-mail to **Friederike.Nabrdalik@din.de** .

All those who have applied for participation or have commented on the project plan by the deadline will be invited to the kick-off meeting of the Workshop on 2022-10-13.

2 Workshop proposer and Workshop participants

2.1 Workshop proposer

Person or organisation	Short description and interest in the subject
Name: Alberto Ranavolo Organization: INAIL (National Institute for Insurance against Accidents at Work) Email: a.ranavolo@inail.it Phone: +39 432 240233 Webpage: https://www.inail.it/cs/internet/home.html	Alberto Ranavolo is Senior Researcher at the Department of Occupational and Environmental Medicine, Epidemiology and Hygiene of INAIL. MSc degree in Electronic Engineering at Federico II University of Naples and PhD in Rehabilitation Medicine of the locomotor System at Sapienza University of Rome. His main research interests are human factors and ergonomics, job accommodation, clinical biomechanics, neurophysiology, movement disorders and movement analysis. He dedicated special attention to instrumental-based techniques for the biomechanical risk assessment in lifting activities and repetitive movements. Furthermore, he focused his interest on “return to work” of workers affected by several musculoskeletal disorders. He is author of about 70 scientific papers in international peer-review journals, of the book „Principi di elettromiografia di

	superficie“ and of 3 paragraphs of national and international books and encyclopedias. He is currently professor at the University’s Master in Neurorehabilitation at Sapienza University of Rome, he is serving as INAIL PI in the H2020 “SOPHIA” project and as Guest Editor of the Special Issue “Wearable Monitoring and Assistive Devices for the Risk Prevention and Return to Work” (IJERPH). Alberto Ranavolo is in the Editorial Committee and serves as reviewer for many journals in the area of biomedical engineering. He will be the co-chairman of the 2023 SIAMOC conference in Rome.

2.2 Other potential participants

This CWA will be developed in a Workshop (temporary body) that is open to any interested party. The participation of other experts would be helpful and is desired. It is recommended that:

- Research institutes for prevention of Accidents at Work;
- Societies for Ergonomics;
- Industry, commerce, agriculture and construction sector;
- Industries of the automotive sector;
- Airports;
- Academic and research;
- Standards developers and applicants;

take part in the development of this CWA.

2.3 Participants at the kick-off meeting

The following persons or organisations already signed up to the kick-off meeting prior to the publication of the draft project plan.

Person	**Organisation**
Ph.D. Alberto Ranavolo	National Institute for Insurance against Accidents at Work (INAIL)
Ph.D. Giorgia Chini	National Institute for Insurance against Accidents at Work (INAIL)
Ph.D. Tiwana Varrecchia	National Institute for Insurance against Accidents at Work (INAIL)
Ph.D. Francesco Draicchio	National Institute for Insurance against Accidents at Work (INAIL)
Ph.D. Arash Ajoudani	Italian Institute of Technology (IIT)
Ph.D. Marta Lorenzini	Italian Institute of Technology (IIT)
Emir Mobedi	Italian Institute of Technology (IIT)
Ph.D. Irfan Refai	University Twente (UT)

Tom Turcksin	Vrije Universiteit Brussel (VUB)
Friederike Nabrdalik	DIN German Institute for Standardisation
Nico Kimpel	DIN German Institute for Standardisation

3 Workshop objectives and scope

3.1 Background

3.1.1 Introduction to the SOPHIA project

The European research project SOPHIA[2] [1] aims at developing a new generation of human–robot collaboration (HRC) technologies (wearbots and cobots) able to improve human ergonomics during the execution of manual material handling (MMH) activities. HRC technologies will embed new real-time instrumental-based tools for monitoring human physical states that can be used for classifying the biomechanical risk in the future. Supervised machine-learning and statistical algorithms have been developed to optimize the interaction between HRC technologies and workers in terms of human loads. Technological advances deriving from the project activities will allow a better management of the challenging occupational health problems represented in Europe by work-related musculoskeletal disorders (WMDs).

More information can be found here https://project-sophia.eu/.

3.1.2 Motivation for the creation of this Workshop

The workshop aims to create a basis for the introduction and establishment of a new technological supported supplement to the traditional methods for assessing human ergonomics listed within the ISO 11228 parts 1, 2 and 3, 11226, the technical reports 12295 and 12296 [2–7]. The objective and data-based approach aims to improve the detection of risk condition levels and thus assessing the efficacy of appropriate ergonomic interventions on the reduction of biomechanical risk attempting to prevent and reduce the risk of WMDs associated to all the MMH activities at work. As the traditional methods require the manual measure of specific parameters (i.e., forces, frequencies, joint angles, etc.), the new approaches may improve the risk classification accuracy and reliability.

Additionally the market for intelligent wearable wireless sensors networks is growing so that they are becoming easily available at workplace. The new opportunities for workers monitoring and alerting are introducing new options for the biomechanical risk assessment at work. In fact, the most recent innovative miniaturized wireless wearable sensors attached to the workers body (e.g., inertial measurement units (IMUs), insoles for measuring reaction forces and surface electromyography (sEMG) sensors, etc.), as well as 3D depth cameras measuring human motion can strongly enhance the accuracy and precision of the biomechanical risk evaluation [8–18]. These devices could be used for both quantitative “direct instrumental evaluations” and “rating of Standard methods”, allowing certain improvements over traditional approaches [8]. Direct instrumental evaluations could be used for sensor-based biomechanical risk assessments when existing methods are not usable or, when usable, to obtain confirmation of their goodness. The rating of standard methods could be used to improve the measurement of some parameters.

More motivation emerges by a good possible application and integration of the new approach within “Industry 4.0” scenarios. Indeed, the presence of new human augmentation technologies (wearbots and cobots) in many MMH activities is currently only partially included in the standards with the consequent difficulty of associating a biomechanical risk with changing tasks.

By defining a guide for the use of real-time instrumental-based tools in the context of human ergonomics in form of the CWA some of the SOPHIA and literature results can be systematized.

SOPHIA developments want to allow to the Smart and Medium-Enterprises and the Big industry and their organizations (employers, occupational health and safety technicians, ergonomists, occupational physicians, etc.) to improve the biomechanical risk classification and, overall, the daily life activities at work by reducing the WMDs

[2] The research project “SOPHIA—Socio-Physical Interaction Skills for Cooperative Human–Robot Systems in Agile Production” has received funding from the European Union’s Horizon 2020 research and innovation program under grant agreement No. 871237.

incidence and prevalence, associated costs, sick leave and disability in many occupational populations and determining a positive impact on the health and productivity of employees.

The Workshop should fill a gap in standardization to support the application of technologies with high readiness for an instrumental, quantitative and real-time assessment of biomechanical risk of all the MMH activities such as manual heavy lifting, handling low loads at high frequency, computer work and awkward body postures. As these approaches have a considerable technical and computational complexity in their structure, the workshop aims to describe the materials and procedures to be used to perform a proper and simply instrumental-based biomechanical risk assessment.

The aim of the CWA is to show the progress that is being made in this field by offering the possibility of identifying possible advantages that could be taken into account for future developments and could be imported into ergonomic standards in the coming years. Throughout the development of the CWA, special care is taken to ensure that it complies with the standard series EN 1005 - Parts 1-4 which have a harmonized status under the Machinery Directive.

3.1.3 Market environment

A tool for instrumental assessment of biomechanical risk in all MMH activities is not yet on the market.
There are isolated experiences of wearable sensor manufacturers that offer the possibility to do an indirect risk assessment within their software (e.g. XSens) but only with kinematic data and not for all tasks.
Furthermore, to the best of our knowledge, a traditional biomechanical risk assessment approach (EAWS) is starting to be used even in the presence of wearable assistive technologies.
The guide presented by this workshop differs from what is now on the market in that it performs accurate and precise real-time estimation of biomechanical risk by acquiring kinematic, kinetic, and electromyography signals from employees using appropriate wearable sensor networks. Furthermore, because it is based on methodologies and results published in the international scientific literature, the categorization can be applied to all MMH activities. Finally, the guide describes a tool that includes artificial intelligence, such as artificial neural networks. [16].

3.1.4 Legal environment (Directives and relevant national legislation)

In Italy directives are all included within the D. Lgs. 2008, n. 81 in the field of health and safety protection in the workplace.

3.2 Scope

Title: Guideline for introducing and implementing real-time instrumental-based tools for biomechanical risk assessment

Scope: The planned CEN Workshop Agreement will define guideline for establishing and executing an instrumental-based approach for data collection regarding human load during the execution of MMH activities, both with and without HRC technologies support. The guideline will describe all necessary requirements and procedures to be used for recording and monitoring data leading to a quantitative risk assessment. The performed assessment represents only an estimation to show the potential of monitoring human loads by the developed approach and tools. The CWA will not define specific limit values for assessing biomechanical risk which could be included in following standardisation activities. The instrumental based tools use a new generation of wearable sensors and machine learning algorithms to detect the biomechanical risk levels on the base of the previous detected limit values of the methods listed within the ISO 11228 series.

The planned CEN Workshop Agreement is intended to be used by all individuals who work in the field of occupational health and safety, particularly those involved in the prevention of WMDs through proper biomechanical risk assessment, ergonomic intervention planning, and effectiveness evaluation. The guideline could be useful and applied by professionals such as occupational health and safety technicians, ergonomists and occupational physicians. In addition, it could be used by members of technical committees involved in writing and/or modifying ergonomic standards.

3.3 Potential content

- **Chapter 1: What is meant by “online instrumental-based tools for biomechanical risk assessment”?**
  Introduction, definitions and fields of application. An in-depth description of all the MMH activities that can be assessed by the online instrumental-based tools for biomechanical risk assessment will also be provided.

- **Chapter 2: Hardware description**
  Wireless wearable inertial Measurement Units, sensorised shoes, bipolar and High-Density sEMG will be described in order to provide information on the sensors network which has to be used for a full risk assessment.

Figure 1. Example of wireless wearable sensors: high density (HD) and bipolar sEMG sensors and IMUS.

- **Chapter 3: Sensors setup and sensors placement**
  Body joints and muscles involved during work activities are MMH-dependent and for this reason a specific sensors setup has to be selected. Furthermore, the body sensors have to be placed in accordance with validated protocols from the International Society of Biomechanics. This chapter will describe both the topics.

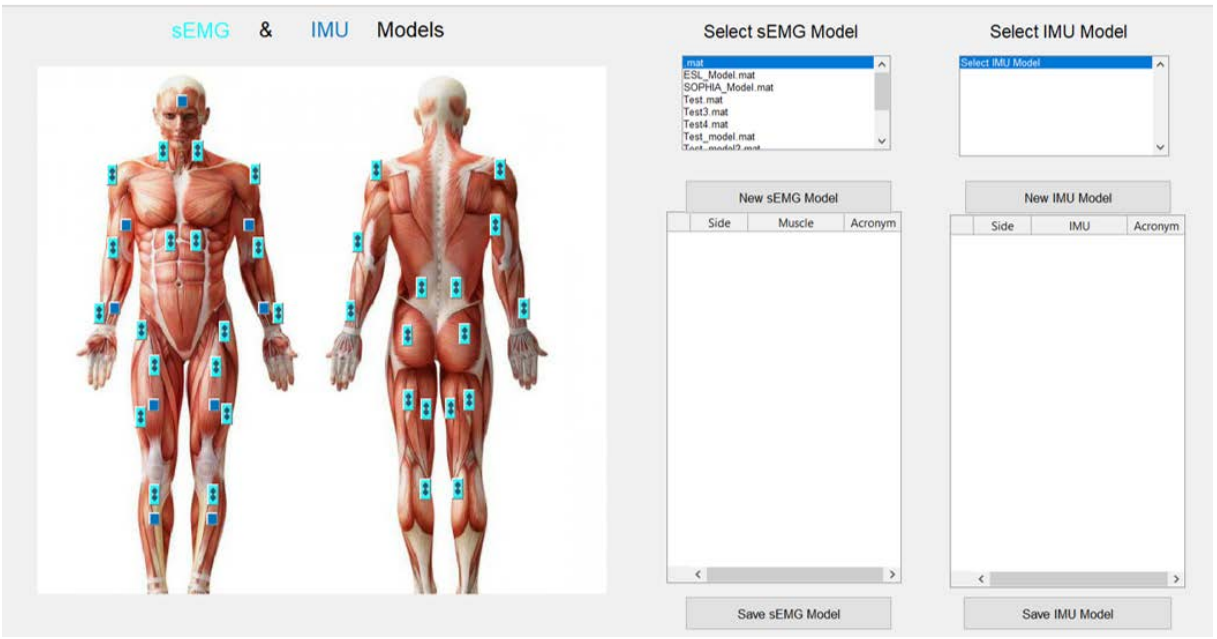


Figure 2. Interface to select IMUs and SEMG sensors.

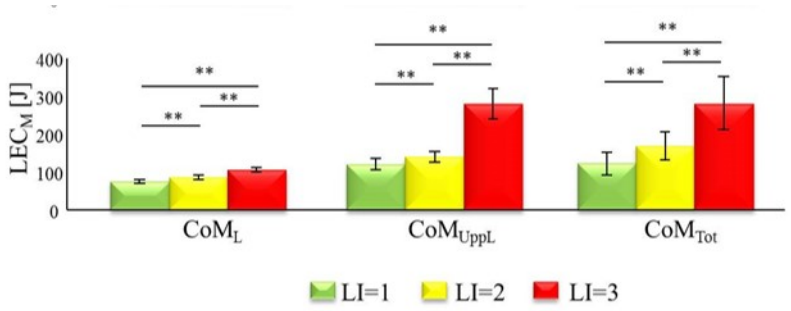
- **Chapter 4: Software description**
  An overview of how a software interface for occupational risk assessment should be implemented will be given.

Figure 3. Example of the users' interface of the instrumental-tool for biomechanical risk assessment.

- **Chapter 5: Data processing and indices**

In this chapter the reader will be given an insight into the most appropriate procedures for processing kinematic, kinetic and sEMG signals taken from the worker's body. Furthermore, a series of indices from the literature for biomechanical risk assessment will be listed and explained.

A)



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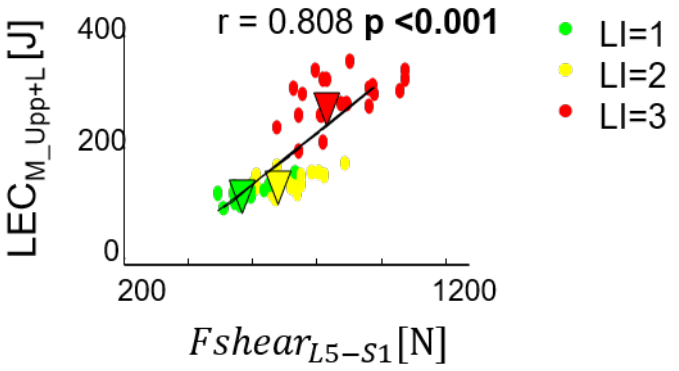

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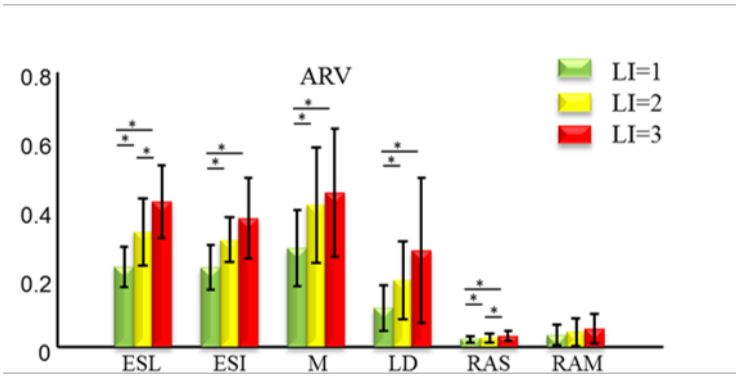

Figure 4. A) Example of a kinematic index (mechanical energy consumption), [17]. B) Correlation between a kinematic index (mechanical energy consumption) and shear force on L%-S1 joint, [17]. C) Bar plot of the average rectified value (ARV) of the sEMG from different muscles (Erector Spinae Longissimus, ESL, Erector Spinae Iliocostalis, ESI, Multifidus, M, Latissimus Dorsi, LD, Rectus Abdominis Superior, RAS and Rectus Abdominis Medium, RAM), [18].

- **Chapter 6: Machine learning algorithms for risk classification**
  The tools for biomechanical risk classification have to be intelligent enough to cover most of the work activities that need to be classified. This chapter will describe the automatic learning models that can be used to optimize the biomechanical risk classification.

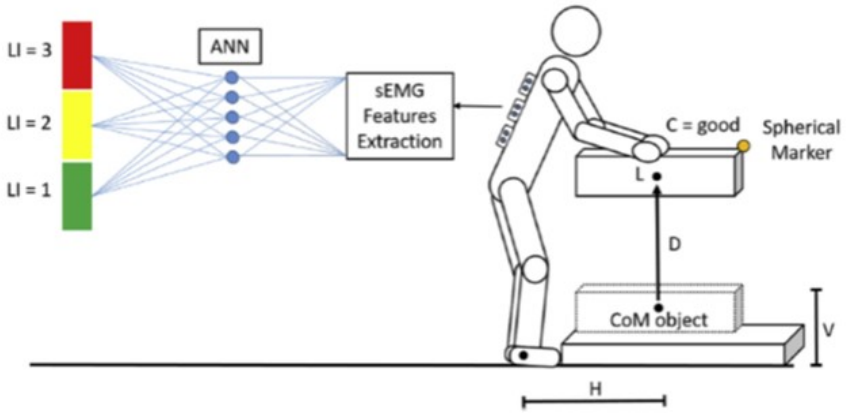

Figure 5. Description of experimental set-up and methodological approach. A schematic description of the lifting task and artificial neural network method used to map surface electromyography features on the Lifting Index (1, 2, and 3) levels. C, hand-to-object coupling; D, vertical travel distance; H, horizontal location; L, load weight; V, vertical location.

3.4 Related activities

The subject of the planned CWA is not at present the subject of a standard. However, there are committees, standards and/or other technical specifications that deal with related subjects and thus need to be taken into account - and involved, where necessary - during this Workshop:

- standards committee, working group etc.:
  - ISO 11228 part 1:2021: Ergonomics – Manual handling – Part 1: Lifting and carrying.
  - ISO 11228 part 2:2007: Ergonomics — Manual handling — Part 2: Pushing and pulling.
  - ISO 11228 part 3:2007: Ergonomics — Manual handling — Part 3: Handling of low loads at high frequency.
  - ISO 11226:2000: Ergonomics — Evaluation of static working postures.
  - ISO TR 12295:2014: Ergonomics — Application document for International Standards on manual handling (ISO 11228-1, ISO 11228-2 and ISO 11228-3) and evaluation of static working postures (ISO 11226).
  - ISO TR 12296:2012: Ergonomics — Manual handling of people in the healthcare sector.
  - EN 1005 part 1:2007 Safety of machinery - Human physical performance - Part 1: Terms and definitions Safety of machinery.

- EN 1005 part 2:2007 Safety of machinery - Human physical performance - Part 2: Manual handling of machinery and component parts of machinery.
- EN 1005 part 3:2007 Safety of machinery - Human physical performance - Part 3: Recommended force limits for machinery operation.
- EN 1005 part 4:2007 Safety of machinery - Human physical performance - Part 4: Evaluation of working postures and movements in relation to machinery.
- EN 1005 part 5:2007 Safety of machinery - Human physical performance - Part 5: Risk assessment for repetitive handling at high frequency.
- ISO/TC 299 Robotics
- ISO/TC 159/SC3/WG4 Human physical strength: manual handling and force limits
- CEN/TC 122/WG 4 Biomechanics
- CEN/TC 251 Health informatics
- CEN/WS 068 Quality criteria for health checks
- CLC/TC 65X Industrial-process measurement, control and automation
- INAIL coordination group

- focus group
  - Focus group of the Italian Society of Ergonomics

- coordination group
  - INAIL coordination group

4 Workshop programme

4.1 General

The kick-off meeting is planned to take place on October 13 via WebEx (Online). A draft for public commenting will not be published.

A total of 5 Workshop meetings (kick-off meeting and Workshop meetings) and web conferences will be held, during which the content of the CWA(s) will be presented, discussed and approved.

The CWA will be drawn up in **English** (language of meetings, minutes, etc.). The CWA will be written in **English**.

4.2 Workshop schedule

Table 1: Workshop schedule (preliminary)

CEN Workshop	7/ 22	08/22	09/22	10/22	11/22	12/22	01/23	02/23	03/23	04/23	05/23	06/23	07/23	08/23	09/23
Initiation															
1. Open commenting period on draft project plan															
2. Consulitation of comments and preparation of Kick-Off meeting															
Operation															
2. Kick-off meeting															
3. CWA development															
4. Finalization and approval through CEN Workshop															
5. CWA publication															
Milestones				**K**		**V**		**V**		**V**		**V**			**P**

K Kick-off
M Workshop meeting
V Virtual Workshop meeting
P Publication of CWA

5 Resource planning

The CEN Workshop is financed by the European research project SOPHIA (Socio-Physical Interaction Skills for Cooperative Human-Robot Systems in Agile Production). This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 871237.

All costs related to the participation of interested parties in the Workshop's activities have to be borne by themselves. The copyright of the final CEN Workshop Agreement will be at CEN. The final document will include the following paragraph: "Results incorporated in this CEN Workshop Agreement received funding from the European Union's HORIZON 2020 research and innovation programme under grant agreement number 871237 (SOPHIA)".

6 Workshop structure and rules of cooperation

6.1 Participation in the Workshop

The Workshop will be constituted during the course of the kick-off meeting. By approving this project plan, the interested parties declare their willingness to participate in the Workshop and will be formally named as Workshop participants, with the associated rights and duties. Participants at the kick-off meeting who do not approve the project plan are not given the status of a Workshop participant and are thus excluded from further decisions made during the kick-off meeting and from any other decisions regarding the Workshop.

As a rule, the request to participate in the Workshop is closed once it is constituted. The current Workshop participants shall decide whether any additional members will be accepted or not.

Any new participant in the Workshop at a later date is decided on by the participants making up the Workshop at that time. It is particularly important to consider these aspects:

a. expansion would be conducive to shortening the duration of the Workshop or to avoiding or averting an impending delay in the planned duration of the Workshop;
b. the expansion would not result in the Workshop taking longer to complete;
c. the new Workshop participant would not address any new or complementary issues beyond the scope defined and approved in the project plan;
d. the new Workshop participant would bring complementary expertise into the Workshop in order to incorporate the latest scientific findings and state-of-the-art knowledge;
e. the new Workshop participant would actively participate in the drafting of the manuscript by submitting concrete, not abstract, proposals and contributions;
f. the new Workshop participant would ensure wider application of the CWA.

All Workshop participants who voted for the publication of the CWA or its draft will be named as authors in the European Foreword, including the organisations which they represent. All Workshop participants who voted against the publication of the CWA, or who have abstained, will not be named in the European Foreword.

6.2 Workshop responsibilities

The Workshop Chair is responsible for content management and any decision-making and voting procedures. The Workshop Chair is supported by the Workshop Vice-Chair and the responsible Workshop secretariat, whereby the Workshop secretariat will always remain neutral regarding the content of the CWA(s). Furthermore, the Workshop secretariat shall ensure that CEN-CENELEC's rules of procedure, rules of presentation, and the principles governing the publication of CWA(s) have been observed. Should a Workshop Chair no longer be able to carry out her/his duties, the Workshop secretariat shall initiate the election of a new Workshop Chair. The list below covers the main tasks of the Workshop Chair. It is not intended to be exhaustive.

- Content related contact point for the Workshop
- Presides at Workshop meetings
- Ensures that the development of the CWA respects the principles and content of the adopted project plan
- Manages the consensus building process, decides when the Workshop participants have reached agreement on the final CWA, on the basis of the comments received
- Ensures due information exchange with the Workshop secretariat
- Represents the Workshop and its results to exterior

The Workshop secretariat, provided by a CEN/CENELEC national member, is responsible for organising and leading the kick-off meeting, in consultation with the Workshop proposer. Further Workshop meetings and/or web

conferences shall be organised by the Workshop secretariat in consultation with the Workshop Chair. The list below covers the main tasks of the Workshop secretariat. It is not intended to be exhaustive.

- Administrative and organisational contact point for the Workshop
- Ensures that the development of the CWA respects the principles and content of the adopted project plan and of the requirements of the CEN-CENELEC Guide 29
- Formally registers Workshop participants and maintains record of participating organisations and individuals
- Offers infrastructure and manage documents and their distribution through an electronic platform
- Prepares agenda and distribute information on meetings and meeting minutes as well as follow-up actions of the Workshop
- Initiates and manage CWA approval process upon decision by the Workshop Chair
- Interface with CEN-CENELEC Management Centre (CCMC) and Workshop Chair regarding strategic directions, problems arising, and external relationships
- Advises on CEN-CENELEC rules and bring any major problems encountered (if any) in the development of the CWA to the attention of CEN-CENELEC Management Centre (CCMC)
- Administrates the connection with relevant CEN or CENELEC/TCs

6.3 Decision making process

Each Workshop participant is entitled to vote and has one vote. If an organisation sends several experts to the Workshop, that organisation has only one vote, regardless of how many Workshop participants it sends. Transferring voting rights to other Workshop participants is not permitted. During voting procedures, decisions are passed by simple majority; abstentions do not count.

If Workshop participants cannot be present in the meetings when the CWA or its draft is adopted, an alternative means of including them in the voting procedure shall be used.

7 Dissemination and participation strategy

Open commenting period on draft project plan

The project plan will be disseminated to the following relevant stakeholders and bodies for commenting:

- ISO/ TC 159/SC3/WG4, CLC/TC 65X, CEN/TC 122/WG 4;
- SOPHIA Project members;
- ANFIA (Associazione Nazionale della Filiera dell'Industria Automobilistica);
- INAIL;
- Società Italiana di Ergonomia.

In addition to the CCMC website, the project plan and the date of the kick-off meeting will be advertised on https://project-sophia.eu/ to raise awareness. Interested parties are requested to contribute either through commenting of the project plan (short term) or through Workshop participation (long term).

CWA publication

The final CWA will be disseminated to the following relevant stakeholders and bodies:

- ISO/ TC 159/SC3/WG4, CLC/TC 65X, CEN/TC 122/WG 4
- SOPHIA Project members
- Possibly at conferences e.g.:
    - SIE (Socierà Italiana di Ergonomia), Italy, 2023;
    - SIAMOC (Società Italiana di Analisi del Movimento in Clinica), Italy, 2023;
    - 84° Congresso Nazionale di Medicina del Lavoro SIML, Italy, 2023;
    - AHFE (Applied Human Factors and Ergonomics), USA, 2023;
    - IEA, triennial conference of the International Ergonomics Association, Korea, 2024.

In addition to the CCMC website, the final CWA will be advertised on:

- social media, such as Twitter
- https://project-sophia.eu/

8 Contacts

- Workshop Secretariat:

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9 References

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