

Webinar of 2022-06-02

Online Workshop 'Workshop "Smart PPE – standardization for design and use'

Questions & Answers / remarks received in the chat

1	<p>Most Notified Bodies in the PPE Sector do not have knowledge on AI. This has been so far the bottleneck for the certification of innovative products. Plus, there is no common European understanding on this topic.</p>	<p>(remark)</p>
2	<p>AI is mostly based on algorithm. Date background is mostly 84% male and only 16% female. How will be taken care about sex neutral AI?"</p>	<p>This might not answer your question perfectly and we will come back to it: For the question on sex neutral AI - please note we have an online workshop next week: https://www.cencenelec.eu/news-and-events/events/2022/2022-06-08-phis/ TOPIC: Putting Science into Standards workshop on Data quality requirements for inclusive, non-biased and trustworthy AI.</p>
3	<p>If CEN-CENELEC will publish some standards (which would possibly Harmonized by the Commission) on AI, this means that a product will need to comply with two standards. While this is not uncommon, do you see possibilities that the same requirements could be developed under the PPE product standard?</p>	<p>It is common practice to avoid repeating content of other standards. Referencing other standards is the common way. However, if new or specific requirements for smart PPE are developed and not yet included in general AI standards, it has to be decided, in what form these requirements can be included in PPE product standards.</p>
4	<p>What is the definition of Smart PPE? Does the definition also apply to e.g. hearing protectors with communication- and ambient listening features?</p>	<p>Definition is available in CEN/TR 17512:2020, term 3.6.1 on smart personal protective system "combination of single items of PPE that protect against applicable/relevant risks encountered by the wearer and which exhibits an intended and exploitable response either to changes in its surroundings/environment or to an external signal/input" NOTES:</p>

		<ul style="list-style-type: none"> • Smart PPE is used as mentonomy for smart personal protective system • The presence of electronics does not automatically mean smart and there might be other ways to make a personal protective system smart than by electronics. <p>Definition also included in EN 17673.</p>
5	Great insight by Wolfgang i would like to discuss how we can get the expertise the group requires.	Always open to suggestions on how to involve (new) experts in the standardization work.
6	<p>Question for Mr Scalzo:</p> <p>The fact definition of High Risk AI safety components is linked to the assessment by NB in the product legislation where the AI system is embedded won't it lead to distortion between legislation (while a similar IA system could be considered high risk or not due to its integration in a product legislation)? Won't it be clearer and easier for the IA system provider, and market, to consider that IA ensuring safety functions have to be considered High Risk AI?</p>	A high-risk AI system which is a safety component of a product exerts a safety function in relation to that product. Thus the magnitude of the risks to safety linked to a safety component are to a large extent linked to the risk level of the product in question. For this reason, it appears logical and proportionate that the risk classification under the AI Act of AI systems which are safety components should be dependent on the risk classification of the related product under sectorial legislation.
7	What is the idea of supporting technical committees for current product groups in such interdisciplinary issues as "smart PPE" taking into account the aspects of ethics, data privacy, ICT / IT. Permanent consultants and experts in particular fields participating in the development of guidelines and requirements seem to be a reasonable direction? Smart garments seem to be leading the way in this discussion, any experiences from this group?	None reported so far. Certainly a valid point.
8	How is IOT reflected in the build of smart PPE standards as well as AI or is in defined in the same context?	Not really reflected at the moment specifically for PPE. Other sectors (e.g. machinery) are more advanced on this.

9	AI in clothing needs electronics to work, how can you ensure the functionality in mechanically rough, extreme cold and in hi EMC areas (with high-voltage work)?	Specific testing might have to be developed for these extreme conditions. A first step was made in EN 17673:2022 (heat and flame)
10	Is CEN/CENELEC somehow working with other parties that work on standards e.g. for e-textiles like IPC in the US? if so, how does that work?	Specific working groups have contacts and/or liaisons with other groups working on relevant standards
11	<p>For Boudewijn :</p> <p>An exoskeleton could be a potential PPE ONLY if we can prove that the exoskeleton protect worker. Currently it is not still the reality... perhaps in the future with next exoskeleton generation (human centred exoskeleton vs user centred exoskeleton !!!!!)</p>	I fully agree that exoskeletons need to prove to protect the worker. From our opinion, there is a large body of evidence that this is the case. For example, biomechanical studies show reduced back compression during use. Also, 9 out of 10 workers that use our product and have (a history of) back pain report a reduction of back injuries or problems. I don't see the difference between human-user design.
12	Don't we need new categories in NANDO database to fit smart PPE?	Good point. Will need discussion between the coordination of PPE notified bodies and EU Commission DG GROW
13	<p>For Marco :</p> <p>Which are the applicable EHSR from PPE Regulation for exoskeleton? Which one have been identified by RICOTEST?</p>	<p>1.1. Design principles 1.2. Innocuousness of PPE 1.3. Comfort and effectiveness 1.4. Manufacturer's instructions and information Lightness and strength 2.1. PPE incorporating adjustment systems 2.5. PPE which may be caught up during use 2.7. PPE intended for rapid intervention or to be put on or removed rapidly 2.9. PPE incorporating components which can be adjusted or removed by the user 3.2 Protection against static compression of a part of the body"</p>
14	Are there notified bodies available who have competence to certify smart PPE? Not only speaking of complex AI as before but of (simple) electronics...This I see as a real existing bottleneck for placing new smart products on the market! A manufacturer must be able to find a NB who is able to do the certification – at the moment this is not	This is indeed a bottleneck

	<p>the case, or am I wrong?</p> <p>In particular I point to the competence to assess the electric/electronic parts in the smart PPE. Please note that the smart PPE must be tested as a whole – not only classical PPE parts alone on one side and (even already certified) electric parts on the other side. Effects of combination must be assessed – must be checked whether no additional risk is created by that combination.</p> <p>AND in parallel we need standards, as Marco mentioned. NBs want to have standards, but they indeed need standards to perform the required tests. Without standards it will be very hard...</p>	
15	<p>It shows that a smart PPE is not only covered by PPE regulation but other regulations. NB on the field of PPE are not attempted to make evaluation on other legislation (EMC for example)</p>	(remark)
16	<p>Yes indeed. DEKRA Testing and Certification. It depends on the product but in the most cases we will find a solution with our competence in electrical safety, functional safety, RED..... The main problem from our side is the quality of the technical documentation of the manufacturer.</p>	comment to 14 above
17	<p>Can we see a exoskeleton? (a person using it as PPE)</p>	<p>Boudewijn :</p> <p>The website has several pictures: https://www.laevo-exoskeletons.com/</p> <p>Please contact me at boudewijn@laevo.nl for any demo/video/referral, etc.</p>
18	<p>I think that exoskeletons as product is not PPE, it enhances a body function in work. But the use of exoskeletons may require use of PPE, or include some smart PPE to set the exoskeleton to a safe mode in danger.</p>	<p>Boudewijn:</p> <p>Exoskeletons are an innovative type of device. They can be viewed as medical device for patients, e.g. when intended to be used by back pain patients. They can be viewed as a machine, e.g. when intended to enhance a body function</p>

		<p>work. Or as a PPE, when intended to be used by workers to maintain their health and safety.</p> <p>As for all products, exoskeletons can have additional advantages outside their (primary) intended use [off label use]. For our exo, we intend to use it as PPE, because: [a] people [companies and end-users] view/treat the EXO as a PPE. [b] we also do not encourage people to use the EXO to start lifting more/heavier weights. That could have an increased risk on injury, e.g. for the hands. [c] the product needs to be applied only where there is a high risk on back injuries. But for sure it can be used [‘off label’] e.g. by patients or people that do want to lift more.</p> <p>Kalev:</p> <p>Regarding exoskeletons as PPE then in my opinion (from the health and safety viewpoint) exoskeleton are PPE until they are used either to reduce the load of a working human and/or shield him from harmful environment. If the aim is to increase the performance, e.g. enhance load bearing capacity, then it becomes into a tool or a machine. If a protective component is kept, e.g. encapsulating exoskeleton to protect the worker from harmful environment, but also for improving the performance, then it is both and has to be evaluated as such. And yes, in this case it has to be covered by 2 or more regulations. This may depend on intended use (defined by manufacturer) and/or possible predictable use (user intention but not misuse).</p> <p>General :</p> <p>PPE or not is an ongoing discussion in the PPE Expert Group. Manufacturers claim different functionalities for their exoskeletons and that has to be taken into account.</p>
19	<p>Why is it not coordinated worldwide? Just to think very quick first association - we do have lots of organizations: CEN, ISO, ASTM,</p>	<p>These are strategic decisions for the different organisations.</p>

	IEEE, IPC, EN, AATCC... I find it confusing... why not to consolidate!?	
20	You have to take into account that we are under several legal framework, we received several questions in UNE (Spain) regarding the differences between medical devices (power driven) and non-power driven devices (PPE)	Remark to point 18 above
21	In the UK we are looking at what agile standards may bring to bridge any initial gaps our view in BSI is that smart PPE can be defined potentially as PPE with data. The real issue for innovators is also funding, without assurance it is very hard to find. So without assurance there is no potential innovation	(remark)
	The UNI/TR 11858:2022 on IoT technologies applied to PPE. The document describes the characteristics of IoT technologies applied to PPE, their management and the interaction they have with the wearer and the work environment. Innovation, particularly when it impacts health and safety UNI/TR 11858 is a first normative, in order to spread and be used needs requirements and rules that indicate the correct ways and limits of its use.	(remark)
22	Really great workshop! we have a way to go. We do need standards that are available to everyone and are understandable and repeatable / consistent. We need to be mindful not to restrict on certification capacity as this will restrict the delivery to market.	(remark)