

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE		PPE-R/00.068 Version 0 4 ³
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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:			
Article: Annex: V Clause: 4(f), 7.1, 7.2, 7.4(b)			
Key words: State of the art / EU type examination			
Question: When conducting <u>EU</u> type-examination for a manufacturer, which standards and technical document <u>ations</u> available to the notified body (NB) should be considered when assessing the conformity of a product, and considering “state of the art”?			
Solution: The manufacturer is solely responsible for identifying the standards and or technical document<u>ations</u> they use to evidence compliance with the Essential Health and Safety Requirements (EHSR) – i.e. as part of their Risk Assessment. As such, they instruct the notified body on which standards and or technical document<u>ations</u> to consider in initial type-examination. The notified body cannot instruct a customer to apply a particular standard or technical document<u>ation</u>, however it can confirm through <u>EU</u> type- examination if any standard and or technical document<u>ation</u> chosen does or does not comply with the EHSR. In conducting the <u>EU</u> type-examination the notified body may consider any additional source / reference to that chosen by the manufacturer, when determining if the manufacturer has met the EHSR. [See PPER, Annex V, 4(f)] In conducting the <u>EU</u> type-examination, the notified body may consider additional sources / references to that chosen by the manufacturer, when determining if the manufacturer has met the EHSRs, and identify any non-compliance or risks not covered. Following issue of an EU type-examination certificate, a change to standards and or technical specifications may indicate that the approved type may no longer comply with its applicable EHSR – the manufacturer should be invited to consider this change in information, with respect to their compliance with the EHSR [See PPER, Annex V, 7.1 & 7.2 & 7.4(b)]. Where there is a safety concern (i.e. no longer complies with EHSR), the notified body has to confirm the manufacturer is aware of the change, and accepts to take action to address the change(s). A verbal commitment by the manufacturer is not sufficient for the NB. The ‘change’ must be ‘<u>generally acknowledged</u>’ to require notified body action on certificates issued. “<i>Generally acknowledged</i>” means widely available to economic operators and notified bodies, freely or through common purchase. The table 1 below is for information purposes, and shows what common standards and or technical specification sources are available, and whether they could be considered ‘generally acknowledged’.			
Table 1			
Item No	Type / nature of document	Remarks – Generally Acknowledged?	
1	Harmonised standard	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.	
2	RFU endorsed by European Commission (horizontal and vertical RFUs)	Publicly available, via EC’s PPE homepage, for free: https://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment-ppe_en To be considered by NBs as per PPER Annex V, 7.1.	

3	Published European standard (CEN/CENELEC)	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1
4	Horizontal C-validated RFU approved by HC (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
5	VG validated RFU approved by HC (not yet endorsed by European Commission, nor subject to comment(s) from PPE EG)	Publicly available, via ppe-rfu.eu website, for free. To be considered by NBs as per PPER Annex V, 7.1.
6	Other National / International Standards	Widely publicly available, typically via purchase. To be considered by NBs as per PPER Annex V, 7.1.
7	Industry Standards / Technical Specifications	Publicly available, typically for free. To be considered by NBs as per PPER Annex V, 7.1.
8	Private developed protocol by NB for specific product	Private / Confidential to single Manufacturer. To be considered by NBs in PPER Annex V, 7.1.
9	Standard Project (TS, pr or other drafts)	Not to be considered by NBs in PPER Annex V, 7.1.