	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.017 Version 1

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Question related to	☒ PPE Regulation		☐ EN/prEN:	☒ Other:	
Article:	Annex: VIII Module D		Clause:	ISO 9001:2008	

Key words:

Module D minimum requirements

Question:

What are the minimum requirements that systems based upon ISO9001 2008 complying with module D have to cover?

Solution:

The minimum requirements are as attached pages, 2 to 5.

The system shall be documented in the form of a manual, procedures and supporting work instructions or similar. The scope of the system shall be specified.

Generally the manual submitted in support of an application will be a policy document, which will outline the systems operated, and reference the on-site detailed procedures.

The system requirements are limited to category III PPE, CE marked under the PPE Regulation 2016/425/EU

Heading, with reference to ISO9001:2008	Comments
4 Quality management system **4.1 General requirements** Comply with Clause 4.1 of ISO 9001:2008 The quality system ensures compliance of the product with the product described in the EC-Type Examination Certificate(s). System shall be documented in the form of manuals, procedures and work instructions.	Shall include or reference quality objectives. Clear identification and control mechanisms for any outsourced processes to be documented, especially applicable where the company does not manufacture the PPE. Cross reference clause 7.4.1
4.2 Documentation requirements Comply with Clause 4.2 of ISO 9001:2008 **4.2.1 General** Complies with Clause 4.2.1 of ISO 9001:2008 **4.2.2 Quality manual** Complies with Clause 4.2.2 of ISO 9001 :2008 **4.2.3 Control of documents** Complies with Clause 4.2.3 of ISO 9001:2008	To include technical file documents, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards.
4.2.4 Control of quality records Complies with Clause 4.2.4 of ISO 9001:2008 At least the following documents are retained for at least 10 years after supply of the last item: Those arising from regulatory requirements, to include module D.6 (a) the documentation referred to in point 3.1 of module D (b) the information related to the change referred to in point 3.5 of module D (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4 of module D Declaration of conformity, 5.2 module D Training records Inspection and test data Calibration data	Retention period to clearly specify period after supply of the last production item.
5 Management responsibility **5.1 Management commitment** Complies with Clause 5.1 of ISO 9001 :2008	
5.3 Quality policy Complies with Clause 5.3 of ISO 9001:2008	
5.4 Planning **5.4.1 Quality objectives** Complies with Clause 5.4.1 of ISO 9001:2008	

5.4.2 Quality planning Complies with Clause 5.4.2 of ISO 9001:2008 The quality system ensures compliance of the product with the EC-type examination certificate(s) All adopted elements, requirements and provisions are documented in a systematic and orderly manner in the form of written policies, procedures and instruction.	
5.5 Responsibility, authority and communication **5.5.1 Responsibility and authority** Complies with Clause 5.5.1 of ISO 9001:2008 The following shall be defined: A. Need to liaise with notified body responsible for the EC type-examination in case of changes to the design defined in the EC-type examination certificate and the technical documentation B. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes of quality system. C. Need to liaise with notified body responsible for the assessment of the quality system with respect to updating of the quality system in case of changes made to the product or technical file **5.5.2 Management representative** Complies with Clause 5.5.2 of ISO 9001 :2008 **5.5.3 Internal communication** Complies with Clause 5.5.3 of ISO 9001:2008	Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.
5.6 Management review **5.6.1 General** Complies with Clause 5.6.1 of ISO 9001:2008 A. Intervals should be at least every 12 months, but with a maximum of 14 months B. Top management chairs the review C. The authorized person(s) participate(s) in the review **5.6.2 Review input** Complies with Clause 5.6.2 of ISO 9001:2008 **5.6.3 Review output** Complies with Clause 5.6.3 of ISO 9001 :2008	The review and audit systems must include those departments / positions responsible for compliance with the PPE Regulation.
6 Resource management **6.1 Provision of resources** Complies with Clause 6.1 of ISO 9001 :2008 **6.2 Human resources** **6.2.1 General** Complies with Clause 6.2.1 of ISO 9001:2008 **6.2.2.Competence, awareness and training** Complies with Clause 6,2.2 of ISO 9001 :2008 **6.3 Infrastructure** Complies with Clause 6.3 of ISO 9001 :2008 **6.4 Work environment** Complies with Clause 6.4 of ISO 9001 :2008	To include all personnel involved in those system elements covered by these requirements.

7 Product realization **7.1 Planning of product realization** Complies with Clause 7.1 of ISO 9001:2008	
7.4 Purchasing. **7.4.1 Purchasing process** Complies with Clause 7.4.1 of ISO 9001:2008 Where the processes of manufacture, tests and final inspection are sub-contracted the following shall apply: (the responsibility to ensure compliance to specific requirements cannot be sub-contracted) A. Subcontractor has been selected after an evaluation has demonstrated the capability of ensuring compliance with all specific requirements B. The evaluation has been performed by one of the following methods; - third party quality system certification - documented evaluation which provides objective evidence of the capabilities - documented site assessment to ensure all relevant capabilities C. Where the features affecting the type of protection cannot be verified at a later stage, the evaluation shall include initial and periodic site assessments at the suppliers premises to ensure that relevant controls are available, documented, understood and effective D. Suppliers not used for a period of one year are re-evaluated prior to placing of the contract E. Ability of supplier is reviewed at least once a year	The Notified Body is responsible for ensuring that the manufacturer's quality system complies with module D requirements, and this may include on-site audits of any sub-contracted activities which potentially impact upon conformity with the EU Type Examination and / or module D.
7.4.2 Purchasing information Complies with Clause 7.4.2 of ISO 9001:2008 **7.4.3 Verification of purchased products** Complies with Clause 7.4.3 of ISO 9001:2008 A. Verification arrangements are implemented if purchased product can compromise the type of protection B. Routine tests or inspections confirmed with declaration of conformity.	
7.5 Production and service operations **7.5.1 Control of production and service provision** Complies with Clause 7.5.1 of ISO 9001:2008 Requirements contained in the EU-Type Examination Certificates are considered. **7.5.2 Validation of processes for production and service provision** Complies with Clause 7.5.2 of ISO 9001:2008 **7.5.3 Identification and traceability** Complies with Clause 7.5.3 of ISO 9001:2008 Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained **7.5.4 Customer property** Complies with Clause 7.5.4 of ISO 9001:2008 **7.5.5 Preservation of product** Complies with Clause 7.5.5 of ISO 9001 :2008	Traceability is not required. Identification of product is required to cover type, batch or serial number, reference Article 8.5

7.6 Control of measuring and monitoring devices Complies with Clause 7,6 of ISO 9001 :2008 If the certificate of the calibrated instrument does not bear the accreditation logo of a national authority then the certificate shall contain the following: -an unambiguous identification of the item calibrated -traceability to (inter)national standards -the method of calibration -a statement of compliance with any relevant specification -the calibration results -the uncertainty of measurement, where relevant -the environmental conditions, where relevant -the date of calibration -the signature of the person under whose authority the certificate was issued -the name and address of issuing organization and the date of the certificate -a unique identification of the calibration certificate	
8 Measurement, analyses and improvement **8.1 General** Complies with Clause 8.1 of ISO 9001:2008	
8.2 Measuring and monitoring **8.2.2 Internal audit** Complies with Clause 8.2.2 of ISO 9001:2008 The audit program addresses the effectiveness of the elements of the quality system described in this standard. The audits should be carried out at least every 12 months, but within a maximum of 14 months **8.2.3 Monitoring and measurement of processes** Complies with Clause 8.2.3 of ISO 9001:2008 **8.2.4 Measurement and monitoring of product** Complies with Clause 8.2.4 of ISO 9001 :2008 The system shall include inspection and testing from purchased material to finished product, to the extent necessary to demonstrate continued compliance with the type-examined and the reference product specification, normally a standard. These activities shall be carried out by the manufacturer on a regular basis and shall be linked to production volumes, time or both. To include correct marking of the product, including the CE mark format and user information to include NB details.	
8.3 Control of nonconformity Complies with Clause 8.3 of ISO 9001 :2008 a) There shall be a system for the customer to be identified b) The manufacturer takes action if nonconforming product has been supplied to a customer c) In case of b) the manufacturer informs the customer and the Notified Body responsible for module D supervision. d) In case of b) and the nature of the nonconformity could affect user protection, and if not possible to trace the product, then additional actions shall be taken to inform the users, for example, notices placed in appropriate publications e) Product concessions that could affect user safety are not permitted. All concessions to be documented and authorised.	
8.4 Analyses of data Complies with Clause 8.4 of ISO 9001:2008	
8.5 Improvement **8.5.2 / 8.5.3 Corrective action / Preventive action** Complies with Clause 8.5.2 of ISO 9001:2008	To include customer complaints, warranty returns and returned products