	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.018 Version 1

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Question related to	☒ PPE Regulation		☐ EN/prEN:	☒ Other:	
Article:	Annex: VIII Module D		Clause:	ISO 9001:2015	

Key words:

Module D minimum requirements

Question:

What are the minimum requirements that systems based upon ISO9001 2015 complying with module D have to cover??

Solution:

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

ISO 9001:2015 Applicability to Module D PPE Regulation

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

ISO 9001 2015 clause reference. General compliance plus any specific requirements	Comments / Notes
4.4 Quality management system and its processes	System shall be documented in the form of manuals, procedures and work instructions.
5 Leadership (Section title)	
5.1 Leadership and commitment	
5.2 Policy	
5.3 Organizational roles, responsibilities and authorities The following shall be defined: A. Need to liaise with notified body responsible for the EU type-examination in case of changes to the design defined in the EU-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	Position(s) with responsibility and authority for product quality and contact / advising notified body of any quality system or product problems to be specified.
6 Planning (Section title)	
6.2 Quality objectives and planning to achieve them	
6.3 Planning of changes	
7 Support (Section title)	
7.1 Resources	
7.1.1 General	
7.1.2 People	To include all personnel involved in those system elements covered by these requirements.
7.1.3 Infrastructure	
7.1.4 Environment for the operation of processes	

7.1.5 Monitoring and measuring resources 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	
7.2 Competence	
7.3 Awareness	
7.4 Communication	
7.5 Documented Information	To include technical documentation, certificates and external standards, e.g. ENs. To include any external documents that are relevant to the PPE in question, e.g. standards. Retention period to clearly specify period after supply of the last production item. Items 2, 3, 4 to be held for 10 years relative to each production lot / batch.
7.5.1 General	
7.5.2 Creating and Updating	
7.5.3 Control of Documented Information At least the following documents are retained for at least 10 years after supply of the last item: 1.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 2. Training records 3. Inspection and test data 4. Calibration data	
8 Operation (Section title)	
8.1 Operational planning and control	

8.4 Control of externally provided processes, products and services If manufacture, tests and / or final inspection is sub-contracted the responsibility to ensure compliance to specific requirements cannot be sub-contracted. Controls to be applied where manufacture or testing or inspection is subcontracted: 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 assessment of any subcontracted activities which potentially impact upon conformity with the EU Type Examination and / or Module D.
8.4.1 General	
8.4.2 Type and extent of control	A. Verification arrangements are implemented if purchased product can compromise the type of protection B. Routine tests or inspections confirmed with declaration of conformity.
8.4.3 Information for external providers	
8.5 Production and service provision	
8.5.1 Control of production and service provision	
8.5.2 Identification and traceability Procedures for product identification during all stages of production, final equipment inspection, testing and placing on the market are established and maintained	Traceability is not required. Identification of product is required to cover type, batch or serial number, reference Article 8.5
8.5.3 Property belonging to customers or external providers	
8.5.4 Preservation	
8.5.5 Post-delivery activities	
8.5.6 Control of changes	
8.6 Release of products and services	
8.7 Control of nonconforming outputs	

9 Performance evaluation (Section title)	
9.1 Monitoring, measurement, analysis and evaluation 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.	
9.1.1 General	
9.1.3 Analysis and evaluation	
9.2 Internal audit 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	
9.3 Management review 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	The review and audit systems must include those departments / positions responsible for compliance with the PPE Regulation.
10 Improvement (Section title)	
10.1 General	
10.2 Nonconformity and Corrective Action 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.	To include customer complaints, warranty returns and returned products.