

Cross reference - European Directives quality modules – ISO 9001:2015*

Relevant standard / Para. /Item		Directive requirements			Especially for PPER module D**
		D, D1	E, E1	H, H1	
ISO 9001	4.1 Understanding the organization and its context	X	X	X	-
	4.2 Understanding the needs and expectations of interested parties	X	X	X	-
	4.3 Determining the scope of the quality management system	X	X	X	-
	4.4 Quality management system and its processes	X	X	X	X
	5.1 Leadership and commitment	X	X	X	X
	5.1.2 Customer focus	-	-	-	X
	5.2 Policy	X	X	X	X
	5.3 Organizational roles, responsibilities and authorities	X	X	X	X
	6.1 Actions to address risks and opportunities	X	X	X	-
	6.2 Quality objectives and planning to achieve them	X	X	X	X
	6.3 Planning of changes	X	X	X	X
	7 Support	X	X	X	X excl. 7.1.6
	8.1 Operational planning and control	X	-	X	X
	8.2.1 Customer communication	X	-	X	-
	8.2.2 Determining the requirements for products and services	X	X	X	-
	8.2.3 Review of the requirements for products and services	X	X	X	-
	8.2.4 Changes to requirements for products and services	X	X	X	-
	8.3 Design and development of products and services	-	-	X	-
	8.4 Control of externally provided processes, products and services	X	-	X	X
	8.5.1 Control of production and service provision	X	-	X	X
	8.5.2 Identification and traceability	X	-	X	X
	8.5.3 Property belonging to customers or external providers	X	X	X	X
	8.5.4 Preservation	X	X	X	X
	8.5.5 Post-delivery activities	X	-	X	X
	8.5.6 Control of changes	X	X	X	X
	8.6 Release of products and services	X	X	X	X
	8.7 Control of nonconforming outputs	X	X	X	X
	9.1.1 Monitoring, measurement, analysis and evaluation	X	X	X	X
	9.1.2 Customer satisfaction	-	-	-	-
	9.1.3 Analysis and evaluation	X	X	X	X
	9.2 Internal audit	X	X	X	X
	9.3 Management review	X	X	X	X
	10.1 Improvement	-	-	-	X
10.2 Nonconformity and corrective action	X	X	X	X	
10.3 Continual improvement	-	-	-	-	

*) Reference to ISO 9001 is in accordance with the EU Parliament and Council statutory order No. 768/2008/EC dated 9th July 2008, Annex II, Table: Conformity Assessment Procedures in Community Legislation. As the decision has been prepared on the basis of ISO 9001:2008, the above clauses in ISO 9001:2015 is determined by the International Organization for Standardizations document "Correlation matrices between ISO 9001:2008 and ISO 9001:2005" (ISO/TC176/SC2/N1270) which can be found here: www.iso.org/tc176/sc02/public.

***) Reference to Horizontal Committee & EU PPE Working Group "Recommendation for use" (Best practice), document PPE-R/00.018, version 2 Approved 30 MAY 2018 and 22 APR 2019