Reference No: **CABF-R-042**	Conformity Assessment Bodies Forum PED/SPV (CABF) CABF
Relation to PED: **Annex III Modules D, D1, E, E1, H, H1**	CABF Recommendation
Question:	What are the essential differences between a quality system certified to ISO9001:2015 and the requirements of the Directive's quality modules?
Answer:	1. Some elements of ISO 9001:2015 are not required for the Pressure Equipment Directive. These are: a. Section 4 (Context of the Organisation) b. Section 10.3 (Continual Improvement) c. A Process-based approach. 2. Some elements of Annexe III are not specifically included in ISO 9001. These include: a. The requirement in Annex III, Modules D1 and E1 para 5.2, and Modules D, H and H1 para 3.2 for written policies, procedures and instructions for all elements relevant to the production of CE-marked product. b. The requirement in Annex III Modules D1 and E1 para 5.5, and Modules D, H and H1 para 3.5 to obtain Notified Body approval of any proposed changes to the quality system. 3. According to Annex III Modules D1 and E1 para 5.3, and Modules D, H and H1 para 3.3, where a manufacturer is certified to ISO 9001 the Notified Body shall presume conformity. 4. The auditing team shall have at least one member experienced as assessor in the pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive.
Reason:	ISO 9001:2015 is harmonised with the New Legal Framework, 768/2008/EU, which identifies the requirements for the Modules listed above but it is not a mandatory requirement for approval to the quality modules. The Blue Guide 2016 Annex 5 gives advice on the relationship between ISO 9001:2008 and the quality system modules, but not ISO9 001:2015.
Original Reference:	TRG 135 Rev 3
Approved by CABF on: 2019-06-04/05	
Note:	