

Reference No: CABF-R-004 rev 1	Conformity Assessment Body Forum PED/SPV (CABF) CABF
Relation to PED: Annex III Module A2	CABF Recommendation
Question:	What activity is required of a Notified Body when performing monitoring of the final assessment as required by Module A2? In particular must the notified body assess the manufacturer's technical documentation?
Answer:	The Manufacturer must comply with the requirements for internal production control, Module A. The notified body shall verify that the manufacturer actually performs and has performed the final assessment accordance with point 3.2 of Annex I . The final assessment consists of: • Final Inspection – assess visually and by examination of documents compliance with requirements of directive • Proof test - test each item of pressure equipment for pressure containment, usually hydrostatic test. • Inspection of safety devices – as applicable for e.g. with respect to assemblies The Notified Body therefore must: 1. Review the number of items produced since the last visit and determine the number of samples required for final assessment under his surveillance. 2. Select samples of pressure equipment and perform or have performed the final assessment*. 3. Review documentation prepared by the manufacturer that demonstrates the final assessment has been performed on all pressure equipment produced. * Scope of final inspection The final inspection involves assessing visually and by examination of accompanying documents, compliance with the requirements of the Directive. This means that the documents, necessary to establish compliance with the Directive (technical documentation, joining procedures and personnel certification, material certification, NDT personnel certification, operating instructions, etc.) shall be available during final assessment. It is not intended that the notified body approve the documentation, only checks that it is available and complete. If the documentation is unavailable or incomplete, the final inspection cannot be concluded and CE marking shall not be affixed, neither can the NB give permission to affix its id number. See also guideline 6/2

Reason:

The description of the final inspection in point 3.2.1 of Annex I includes a visual assessment together with an examination of the accompanying documents to assess conformance with the requirements of the directive. It would not be possible to assess compliance with the directive if the appropriate documentation (Technical Documents) were not available for examination by the Notified Body.

Original Reference: TRG 0012 Rev 1

Approved by CABF on: 2016-03-15/16

Note: