Guidelines **5/18/07**

4. Evaluation Assessment

Guideline 4/1

[Original version as adopted on: *28 Jan 1999*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex III Module G**

Question: Is design approval by a notified body required under module G ?

Answer: Module G does not explicitly require formal design approval by a notified body but it does require the manufacturer to submit to a notified body, technical documentation to enable the design, manufacture and operation of the pressure equipment to be understood. It also requires the notified body to examine the design and construction of the pressure equipment to ensure its conformity with the requirements of the Directive which apply to it. It is expected that the notified body will report the outcome of the examination of the design to the manufacturer and this will effectively constitute design approval.

Reason: As stated above, module G does not contain any explicit requirement for approval of the design by the notified body. However, it is understood that design approval is common practice for the types of pressure equipment to which module G would be applied. Module G does require that a notified body must examine the design of the pressure equipment and it is considered reasonable to expect the notified body to inform the manufacturer of the results of the examination.

Accepted by WPG on: **18 Sep 1998**

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Remarks:

Guideline 4/2

[Original version as adopted on: *28 Jan 1999*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to:

Question: Can a manufacturer´s existing QA certification which is in accordance with the standards EN ISO 9000 be taken into account by the notified bodies when approving QA systems for modules D, D1, E, E1, H or H1 of the PED?

Answer: A notified body when approving QA systems according to the modules D, D1, E, E1, H or H1 should take into account that the manufacturer already has ISO 9000 certification particularly if it has been certified by an accredited certifying organisation. However, the notified body has overall responsibility for ensuring that the QA systems satisfy the pressure equipment directive in particular on aspects in pressure equipment technology.

Reason: Q.A. systems under the modules D, D1, E, E1, H or H1 must cover the technical aspects in relation to the pressure equipment.

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Remarks:

Guideline 4/3

[Original version as adopted on: *29 Jun 2000*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: Annex III

Question: How to apply conformity assessment modules when some parts of an item of pressure equipment or some operations are sub-contracted ?

Answer: There is only one manufacturer taking responsibility for each item of pressure equipment, who chooses one module (or combination of modules).

The conformity assessment is related to an item of pressure equipment and not to the parts considered alone.

It is the responsibility of the pressure equipment manufacturer to obtain from his sub-contractor the information and documentation required for the application of the module chosen. Depending on the module, the notified body could be required to visit the sub-contractor site, and it is the responsibility of the pressure equipment manufacturer to ensure access. If relevant work has been performed by different notified bodies at the sub-contractor site, it should be taken into account.

See also the Blue Guide (Guide to the implementation of directives based on New approach and Global approach) 3.1.1

Accepted by WPG on: **04 May 2000**

Accepted by Working Group "pressure": **29 Jun 2000**

Remarks:

Guideline 4/4

[Original version as adopted on: *29 Jun 2000*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex III**

Question: If a manufacturer chooses to apply module B or B1 for the design phase, in combination with another module for the production phase, does the manufacturer have to choose the same notified body for the design and production modules?

Answer: No.

As requested by modules B and B1 (Annex III, points 5 and 6 of the corresponding modules), the examination certificate shall annex a list of the relevant parts of the technical documentation and any other relevant information, which allow the requirements of the production modules to be applied.

The number to be affixed to the pressure equipment is the number of the body involved at the production control phase (Article 15).

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Remarks:

Guideline 4/5

[Original version as adopted on: *26 Jun 2001*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex III Section B.1**

Question: Clauses 3 and 4 of module B1 in Annex III deal with information concerning qualifications or approvals of permanent joining that may not be available at the design stage. What are the minimum requirements in clause 3, last indent, and clause 4.1, 2nd and 3rd indents?

Answer: Approval of operating procedures for permanent joining shall be made at the design stage, if not previously approved

For the personnel performing permanent joining and non-destructive tests, the requirement at the design stage may be limited to the verification of the criteria for qualifications or approvals.

The need to perform the personnel approval verification at a later date before start of production should be pointed out in the design examination certificate.

See also guideline **4/4**.

Accepted by WPG on: **23 Apr 2001**

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Remarks:

Guideline 4/6

[Original version as adopted on: *07 Nov 2000*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Article 10 Paragraph 2** , **Annex III**

Question: Can an assembly be composed of pressure equipment dealt with using different conformity assessment modules ?

Answer: Yes, by application of Article 10.2a).

For example, the valves can have a module different from that applied to the vessel or the piping on which they are placed.

Accepted by WPG on: **25 Aug 2000**

Accepted by Working Group "pressure": **07 Nov 2000**

Remarks:

Guideline 4/7

[Original version as adopted on: *23 May 2002*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex I Section 1.2** , **Annex I Section 3.2.1** , **Annex I Section 3.4** , **Annex III**

Question: Shall the manufacturer of pressure equipment submit operating instructions as part of the conformity assessment by a Notified Body, and shall the Notified Body verify the content?

Answer: Yes.

PED requires the manufacturer to prepare operating instructions (see guideline **8/3**) and supply them together with the equipment.

Appropriate operating instructions are an essential safety requirement (ESR) and shall therefore be part of the conformity assessment procedure.

When the Notified Body´s duty includes performing or monitoring final assessment, it shall verify the existence of operating instructions and check their compliance with the Directive.

When the Notified Body´s duty includes design examination, it shall verify that the intended use and residual hazards are described, and are intended to be included in operating instructions.

For modules based on quality systems, the existence of proper procedures to establish the various elements of the operating instructions shall be verified as part of the assessment of the quality system.

Accepted by WPG on: **10 Apr 2002**

Accepted by Working Group "pressure": **23 May 2002**

Remarks:

Guideline 4/8

[Original version as adopted on: *26 Jun 2001*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex III Section B1.4.2** , **Annex III Section B1.4.3**

Question: Are tests by the notified body required for module B1?

Answer: No.

In contrast to module B, module B1 consists solely of the examination of drawings, calculations and relevant information concerning manufacturing. The experimental design method may not be used in this module. There are no examinations or tests to be performed on a representative example of the production envisaged.

See also guideline **4/5**.

Note : There is inconsistency in some language versions.

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Remarks:

Guideline 4/9

[Original version as adopted on: *28 Apr 2003*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: Annex I , Annex III

Question: Is a manufacturer of component required to include a design examination, proof test and final inspection by a Notified Body if the component is intended for later use in PED equipment ?

Answer: No. Components are not items of pressure equipment, and therefore are not subject to individual conformity assessement procedures.

For requirements on components to be used in pressure equipment, see guidelines **1/22**and **7/19**.

Note 1:
The final inspection including the proof test applies to the complete item of pressure equipment and not to the component itself.

Note 2:
If the component is not designed according to a harmonised standard, design information may also be requested by the equipment manufacturer.

Note 3:
There is no legal basis in PED for a Notified Body to issue a certificate of conformity for components.

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Remarks:

Guideline 4/10

[Original version as adopted on: *28 Apr 2003*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: Article 10 , Annex I , Annex III

Question: There are many organisations that design pressure equipment that is subsequently fabricated by another organisation. Is it permissible for the company responsible for the design to obtain an EC design examination certificate (B1) and the fabricator obtain an appropriate certificate for the manufacturing phase, e.g. Product Verification (F).

Answer: No.

Even if different organisations can be involved, the directive clearly indicates that there can be only one "manufacturer" who is responsible for design, manufacture and conformity assessment of the pressure equipment.

The "manufacturer" may subcontract tasks in relation to design and/or manufacture but must retain overall control and have the necessary competence to take the responsibility for the product.

See also guideline **4/3**.

See also the Guide to the Implementation of Directives based on New Approach and Global Approach

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Remarks:

Guideline 4/11

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Article 1 Paragraph 2.1.3** , **Article 3 Paragraph 1.4** , **Article 15**

Question: Should the holder and the bursting disc which combine to produce a bursting disc safety device for use above 0,5 bar carry separate CE marking?

Answer: No, only the complete safety device can be conformity assessed, and only one CE marking shall be affixed. The CE marking shall be on the holder which is less likely to be replaced.

The declaration of conformity and instructions for use shall describe in an appropriate manner the components of the bursting disc safety device, and instructions for use shall identify which safety discs can be used on a specific holder.

Reason: Bursting disc safety devices are usually supplied as a set containing one holder and several spare discs. While both are components of a safety device and therefore should not be CE marked until assembled, for practical purposes the holder carries CE marking.

See also guideline **1/22**.

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Remarks:

Guideline 4/12

[Original version as adopted on: *31 Mar 2006* and modified on *21 Nov 2006*]

Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex III Section D.3.2** , **Annex III Module D1** , **Annex III Module E** , **Annex III Section E.1** , **Annex III Module H** , **Annex III Section H.1**

Question: What information shall be included in the quality system approval notification document issued by the notified body concerning the scope of products?

Answer: The document for all quality system modules shall contain sufficient information to clearly define the scope of products covered by the approval and where applicable, any limitations or restrictions.

In the case of modules D, E and H1, the initial quality system approval notification document shall include a listing of the relevant EC-type examination or EC- design examination certificates.

In all cases the procedure must require the assessment of whether new or modified products will necessitate changes to the quality system, and that these are submitted to the notified body. The Notified Body shall inform the manufacturer of the suitability or otherwise of the approved quality system. In cases where no changes are required, a new quality system approval notification document does not need to be issued. Any re-issue of the document shall update the list of design and type approval certificates.

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Remarks:

Guideline 4/13

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: **Annex I Section 3.2.1** , **Annex I Section 3.2.2** , **Annex III Section F.4.1** , **Annex III Section G.4**

Question: Is it permissible for the Notified Body to delegate the witnessing of the final inspection and proof test under module F or the proof test under module G to the manufacturer?

Answer: No

In modules F and G, means and resources for carrying out the final inspection and/or proof test can be provided by the manufacturer to the Notified

Body inspector, but the Notified Body shall be present during the final inspection and proof test.
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Remarks: