

Guidelines

5/18/07

10. Horizontal Issues

Guideline 10/1
<p>[Original version as adopted on: 28 Jan 1999]</p> <p>Pressure equipment directive 97/23/EC Commission's Working Group "Pressure"</p> <p>Guideline related to:</p> <p>Question: Must the pressure equipment directive be applied to used pressure equipment imported from outside the European Economic Area?</p> <p>Answer: Yes.</p> <p>Reason:</p> <ul style="list-style-type: none"> - Blue guide, point 2.1 "Products submitted to directives"; - Blue guide, point 7.2 "Products to be CE-marked" <p>Accepted by WPG on: 18 Feb 2000</p> <p>Accepted by Working Group "pressure": 28 Jan 1999</p> <p>Remarks:</p>
Guideline 10/2
<p>[Original version as adopted on: 28 Jan 1999 and modified on 28 Jun 2005]</p> <p>Pressure equipment directive 97/23/EC Commission's Working Group "Pressure"</p> <p>Guideline related to:</p> <p>Question: Must the pressure equipment directive be applied to used pressure equipment imported from another country of the European Economic Area (EEA), if it was not manufactured under the regime to PED ?</p> <p>Answer: No, but national legislation of the receiving country will apply.</p> <p>Reason: Guide to the Implementation of Directives Based on New Approach and Global Approach, point 2 "Scope of New Approach directives" (footnote 20 to be noted) and point 9.1 "The agreement on the European Economic Area".</p>

Accepted by WPG on: **28 Jan 1999**

Accepted by Working Group "pressure": **28 Jan 1999**

Remarks:

Guideline 10/3

[Original version as adopted on: *08 Nov 2000*]

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

Guideline related to: [Article 20 Paragraph 3](#)

Question: Article 20, section 3 states that the transition period extends up to and includes 29 May 2002. If a manufacturer intends to place pressure equipment or assemblies on the market according to pre-PED national Regulations during the transition period, what conditions must be met?

Answer:

1. A necessary condition is that all manufacturing and conformity assessment operations required by the pre-PED national Regulations have been completed on or before 29 May 2002.
2. In addition, given that one of the purposes of including a transition period in the Directive is to provide time for manufacturers to reduce stocks, items of pre-PED pressure equipment must be physically transferred to the customer or distribution chain on or before 29 May 2002. unless the transfer of ownership has occurred before this date.

Supplementary points

Provided the conditions in 1 and 2 have been met, there are no restrictions on the subsequent sale of pre-PED pressure equipment (through a distribution chain for example) or when such equipment is eventually put into service within the respective Member state.
 If a manufacturer retains some stocks of pre-PED pressure equipment or assemblies after 29 May 2002, then they can only be subsequently placed on the market if they are shown to be in compliance with the PED (This is not necessary if the items are intended for export to a country outside the Community). For subsequent use of such an item of pressure equipment in an assembly, refer to guideline [3/11](#).

Accepted by WPG on: **02 Oct 2000**

Accepted by Working Group "pressure": **08 Nov 2000**

Remarks:

Guideline 10/4

[Original version as adopted on: *28 Nov 2001*]

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

Guideline related to: [Article 1 Paragraph 2.1.5](#) , [Article 3 Paragraph 2.2](#)

Question: When an assembly is built by a subsidiary or affiliated company of the final user, is such an assembly covered by the PED?

Answer: Yes.

As the subsidiary or affiliate company is a separate legal entity – even if it is part of the same industrial group – the assembly is transferred between the two companies and hence is placed on the market. The subsidiary or affiliate company is to be considered the manufacturer.

Note: If the subsidiary or affiliate company acts under the overall responsibility of the user (as an installer or sub-contractor), the PED does not apply to this "installation" (see guideline [3/2](#)).

Accepted by WPG on: **31 Aug 2001**

Accepted by Working Group "pressure": **28 Nov 2001**

Remarks:

Guideline 10/5

[Original version as adopted on: *29 Nov 2001*]

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

Guideline related to: [Article 5](#)

Question: Harmonized standards frequently use normative references to other EN and non-EN standards. Do these referenced standards also confer presumption of conformity to the ESRs?

Answer: It depends on the type of reference :

1. When a reference (which is contained in a part of a standard which provides pre-sumption of conformity) to a particular, limited section of another standard, is used as a particular description in the harmonized standard, then the presumption of conformity extends to this reference. In exceptional cases, an entire standard can be used as a particular description in the harmonized standard (test standards for instance). In both cases, the referenced standards shall be dated. If it is not dated, the version valid at the time of publication of the standard containing the reference shall be used.

It should be noted, that the presumption of conformity is not valid for the referenced parts or standards independently, but only when applied in the context of the harmonized standard containing the references.

2. Other references, such as :

- references contained in an informative part,
- references with no direct relevance to harmonized normative parts,
- references to informative parts/documents,
- reference to pre-standards (ENV), technical specifications (TS); or other deliverables such as Technical reports (TR) or CEN workshop

- agreements (CWA),
- references to non EN standards, non ISO/IEC standards which do not comply with the applicable CEN/CENELEC rules (see note 1),

do not confer this presumption of conformity.

It should also be noted that the entire reference list, which typically is given as clause 2 of EN standards, does not in itself confer presumption of conformity.

Note 1:

Applicable CEN/CENELEC rules require the following:

- ensure that no suitable CEN, CENELEC, ETSI, ISO or IEC documents are available and confirm that there is a necessity to refer to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC;
- confirm that it is impractical to include the relevant text in full;
- justify the need for making reference to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC;
- ensure and confirm that the referenced document shall:
 - have wide acceptance;
 - not be in contradiction with the European legislation, nor create regulatory problems when the EN is implemented by CEN/CENELEC members;
 - have been prepared in accordance with the principles set in the ISO/IEC Guide 59 - Code of Practice for Standardization - (with the definitions of EN 45020) and in the ISO/IEC Directives;
 - have clearance in respect of possible IPR (Intellectual Property Rights) issues as prescribed in CEN/CENELEC Memorandum 8;
 - not be a draft, but shall be an adopted document with an identified and dated issue;
 - be publicly available in official CEN/CENELEC languages, at least in English.

Note 2:

For a harmonized standard whose reference is published in the OJEC, the annex ZA gives the relation between the ESR's covered by the standard and the corresponding clauses of this standard.

Accepted by WPG on: **30 Aug 2001**

Accepted by Working Group "pressure": **29 Nov 2001**

Remarks:

Guideline 10/6

[Original version as adopted on: *31 Mar 2006*]

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

Guideline related to: [Annex VII](#)

Question: What is the information to be given in the Declaration of Conformity in order to comply with indents 8 and 9 of Annex VII?

Answer: The harmonised standard or specification referred to is the governing document(s) embracing all aspects of materials, design, manufacture and testing of the item of pressure equipment or assembly.

If the governing document is an internal specification or a published technical code, this information shall also be given.

However, as regards conditions related to the use of such documents, see also guidelines [9/5](#) and [9/6](#) particularly.

Reason: According to paragraph 5.4 of the "Guide to implementation of directives based on New Approach and Global Approach", the standards or other documents (such as published technical codes and internal specifications) used should be described in a precise, complete and clearly defined way; It is not requested to give the complete list of the standards used in combination with the governing document.

Accepted by WPG on: **05 Jul 2005**

Accepted by Working Group "pressure": **31 Mar 2006**

Remarks:

Guideline 10/7

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

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

Guideline related to: [Annex III Module D](#) , [Annex III Section D.1](#) , [Annex III Module E](#) , [Annex III Section E.1](#) , [Annex III Module H](#) , [Annex III Section H.1](#)

Question: In Annex III, for modules D, D1, E, E1, H and H1, specific documentation is required to be retained for a period of 10 years after the last date of manufacture.

The text specifically requires that 'documentation concerning the quality system' be retained. Does this also include quality records such as material certificates, test reports etc?

Answer:

Yes.

The provisions concerning the retention of records shall be described in the manufacturer's quality system documentation. The description of technical documentation, in section 3 of module A, should act as the guiding principle for the other modules. This includes results of examinations, test reports, material certificates, etc. and has to be kept by the manufacturer, or his authorised representative, for 10 years after the last of the pressure equipment has been manufactured.

See also the Guide to the Implementation of Directives based on New Approach and Global Approach, sub-clause 5.3.

Accepted by WPG on: **06 Mar 2003**

Accepted by Working Group "pressure": **28 Apr 2003**

Remarks:

Guideline 10/8

[Original version as adopted on: *28 Jun 2005*]

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

Guideline related to: [Annex VII](#)

Question: What is the information to be given in the Declaration of Conformity of assemblies in order to comply with the 4th indent of Annex VII?

Answer: The declaration of conformity of assemblies must contain a description of all items of pressure equipment constituting the assembly together with, for each PED item, the conformity assessment procedure followed.

Note: This description includes the identification of the items of pressure equipment falling under category I to IV.

The other items taken into account in the assessment of the integration of the PED assembly (including Art 3 paragraph 3 equipment or pressure equipment excluded from the PED) shall also be described as part of this assembly. This latter description may be by reference to appropriate information in the instructions for use (e.g. component lists, drawings). See also guideline [3/13](#).

See also paragraph 5.4 of the "Guide to implementation of directives based on New Approach and Global Approach".

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Remarks: