Guideline G-02

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Section 4.3, third paragraph

Question	**What is a 'competent body' for the certification of the quality (assurance) systems of material manufacturers?**
Answer	A 'competent body' for certification of the quality systems of material manufacturers can be any third party body established as a legal entity within the Community which has recognized competence in the assessment of quality (assurance) systems for the manufacture of materials and in the technology of the materials concerned. Competence can be demonstrated, for example, by accreditation. See also PED Guideline G-07.
Reason	
Note 1	A body not established as a legal entity within the Community, even if it has a recognition agreement through the International Accreditation Forum, does not comply with the requirements of Annex I section 4.3.
Note 2	A notified body may perform this task only if it has a recognized competence in the field of quality assurance, materials and related process technology. For this certification, the possible use of the notification number for PED is irrelevant.
Note 3	The certificate of quality system shall make reference to the legal entity established in the Community and its address.

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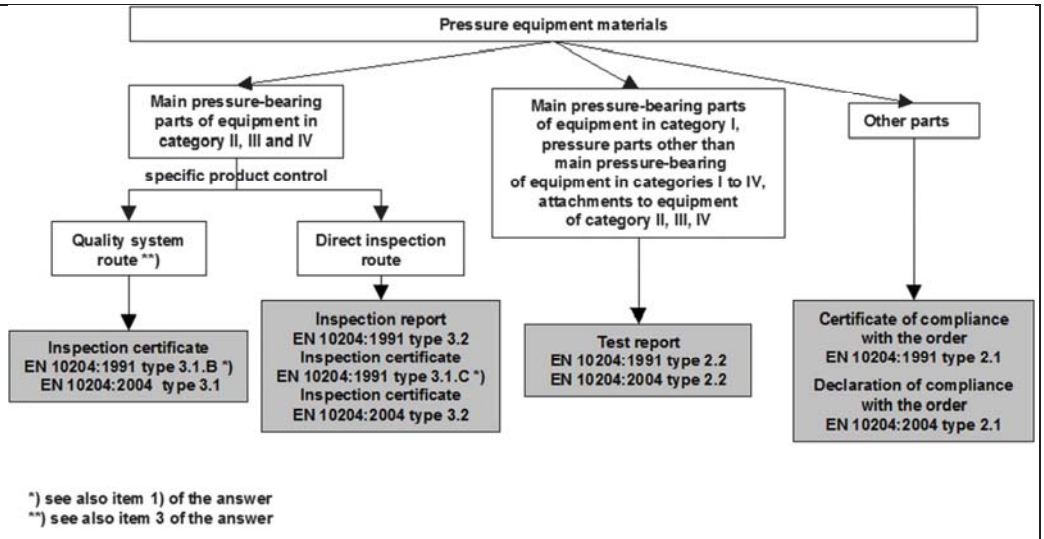
Guideline G-05

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Section 4.3

Question	**Annex I Section 4.3 of the PED requires that the equipment manufacturer must take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification must be obtained for all materials.** **How may these requirements be applied in terms of required inspection documents?**
Answer	1. According to the 1st paragraph of Annex I, section 4.3, the material manufacturer shall certify, that the delivery complies with the requirement of the specification and the order he has received. This affirmation of compliance shall be stated on or appended to the certificate, whichever type is issued. 2. According to the 2nd paragraph of Annex I, section 4.3 a certificate of specific product control is required for the main pressure-bearing parts of pressure equipment in categories II, III and IV. Account shall be taken of the requirements in 4.1 and 4.2 (a) of Annex I. 3. According to the 3rd paragraph of Annex I, section 4.3 a distinction is made for the material manufacturer's fabrication system: where he has an appropriate quality (assurance) system certified by a competent body established within the Community, and having undergone a specific assessment for materials, an inspection document from the manufacturer is appropriate (see also PED Guidelines G-07 and G-16). 4. The general requirements for all other cases are given in the first 2 paragraphs of Annex I, section 4.3. 5. A scheme of the relevant inspection documents when following EN 10204:1991 or EN 10204:2004 is given in the following diagram:



Reason	
Note	1) An inspection document of a higher level is always acceptable. 2) Material from stockists shall be accompanied by inspection documents from the material manufacturer. 3) For traceability and transfer of marking, see also PED Guideline G-04. 4) For main pressure bearing parts, see also PED Guideline G-06, and for attachments see definition in Article 2(1) of the Directive. 5) For components, see PED Guideline G-19. 6) As regards joining materials, see PED Guideline G-10. 7) Previously, the affirmation of compliance was not included in the definition of certificate 3.1.B or 3.1.C according to EN 10204:1991, but is now included in the definition of certificate 3.1 of EN 10204:2004.

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Guideline G-06

Pressure Equipment Directive PED 2014/68/EU
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Guideline related to: Annex I Section 4.3

Question	**The 2nd paragraph of section 4.3 of Annex I gives requirements for the main pressure-bearing parts. How are they defined?**
Answer	The main pressure-bearing parts are the parts, which constitute the envelope under pressure, and the parts which are essential for the integrity of the equipment. Examples of main pressure-bearing parts are shells, ends, main body flanges, tube sheet of exchangers, tube bundles. The materials for these main pressure-bearing parts of equipment of categories II to IV shall have a certificate of specific product control (see PED Guideline G-05). See also PED Guideline G-08 for bolting parts (fasteners).
Reason	
Note [x]	

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Guideline G-07

Pressure Equipment Directive PED 2014/68/EU
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Guideline related to: Annex I Section 4.3

Question	**To what apply the terms “having undergone a specific assessment for materials” of third paragraph of Section 4.3 of Annex I ?**
Answer	It is the quality (assurance) system of the material manufacturer which shall have undergone a specific assessment for materials (and not the competent body).
Reason	
Note 1	See also PED Guideline G-02.

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Guideline G-10

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Sections 3.1.2; 3.1.5; 4.1; 4.2(a) and 4.3 1st paragraph

Question	**What are the requirements for the documentation and traceability of welding consumables:** **- Inspection document** **- Suitable procedures for traceability?**
Answer	Manufacturers of welding consumables shall provide inspection documents affirming compliance with the specification. Based on section 4 of Annex I and PED Guideline G-05 manufacturers of welding consumables shall provide test report "2.2" as an inspection document in accordance with the standard EN 10204. The traceability requirement of Annex I section 3.1.5 applies also for welding consumables. It can be maintained by procedural methods that cover receipt, identification, storage, transfer to production, temporary storage and use in production, availability of correct inspection documents at the final inspection (see also PED Guideline G-04).
Reason	
Note	Welding consumables are defined by trade name, designation and relevant EN classification standard. Inspection documents of welding consumables should give test results, for technical characteristics according to designation and classification standard, such as: - Chemical composition of welding filler metal or all-weld metal as appropriate - Tensile properties of all-weld metal: tensile and yield strength, elongation - Impact properties of all-weld metal at temperature according to designation. Test results are based on non-specific inspection and testing. They can be given for example as typical values based on quality control tests.

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Guideline G-16

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Section 4.3

Question	**The PED considers the case of a material manufacturer who "has an appropriate quality-assurance system, certified by a competent body established within the Union and having undergone a specific assessment for materials". How should this requirement be understood in practice?**
Answer	In practice, this requirement is satisfied when the material manufacturer has a quality assurance system of at least EN ISO 9001 type, certified by a competent body (according to the definition given in PED Guideline G-02) established as a legal entity within the European Community, and when the field of validity of the certification specifies production of material indicating the relevant material types. The specific assessment of the quality system shall properly cover all the relevant processes and material properties referred to in the material specifications, and attested in the material certificates. A single reference to section 4.3 of Annex I of PED is not sufficient to validate the quality assurance system of the material manufacturer. The reference document for quality assurance system which has been used shall be identified. Reference to the PED in the quality assurance system certification is not a mandatory requirement.
Reason	
Note	See also PED Guidelines G-05, G-07 and I-05.

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Guideline G-19

Pressure Equipment Directive PED 2014/68/EU
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Guideline related to: Article 2(1), Annex I, sections 3.1, 4.3 and 7.2

Question	**Which requirements apply to components, such as dished ends, bolts, flanges, welded fittings etc, which are placed on the market as such?**
Answer	To be incorporated into an item of pressure equipment, components which are manufactured from materials such as plates, coils and bars shall meet all the relevant essential safety requirements related to the manufacturing process used ; for instance in the manufacturing of welded dished ends, sections 3.1 and 7.2 of Annex I are relevant in addition to section 4. In order to prove the conformity to the PED of the pressure equipment containing the component the equipment manufacturer will need relevant documents from the component supplier : - Material certificates (of the plates, coils, bars …), and as relevant : - Welding procedure approvals, - Welder/welding operator approvals, - Non Destructive Testing operator qualifications, - Non Destructive Testing reports, - Destructive Testing reports, - Forming and heat treatment information, etc. This information may be in the form of a component certificate. The requirement in Annex I section 4.3 is not however intended for a component manufacturer, who is not a material manufacturer in the context of PED, even if he modifies the mechanical properties of the material. Forgings (including forged flanges), castings and seamless tubes are generally considered to be materials. Fittings made from these “materials” without subsequent welding or other process which could alter the material characteristics are also considered to be materials. As regard welded tubes, see PED Guideline G-25.
Reason	
Note	Current practice may require components to be delivered with certificates based on standard EN 10204 Metallic products. Types of inspection documents or corresponding requirement when they are placed on the market as such. The PED does not preclude supplying such certificates with components. See also PED Guidelines A-09, A-22, D-03, G-05, G-06, G-08, G-18 and G-

Guideline G-24

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I **S**ections 2.2.3 and 4.3

Question	**Annex I Section 4.3 of the Pressure Equipment Directive (PED) requires that the material manufacturer must prepare documentation affirming compliance with the specification required by the equipment manufacturer.** **Does this requirement mean that material properties used in the design of the pressure equipment must be based on those affirmed (guaranteed) by the material manufacturer?**
Answer	Yes, the material properties used in design of the equipment, e.g. yield strength and impact properties, must be based on those of the specification which are affirmed by the material manufacturer.
Reason	
Note 1	This does not mean that the values of the specification need to be written on the certificate. It is sufficient for the material manufacturer's certificate to make reference to the specification where the appropriate values are included. See also PED Guideline G-17 for the need of verification testing of specified impact properties.
Note 2	See also PED Guideline G-18 for the relationship between the essential safety requirements and the properties of the base material.

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Guideline G-27

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Section 4.3

Question	**When an equipment manufacturer receives a certificate type 3.1 according to EN 10204:2004 by the material manufacturer, in pursuance of the third paragraph of section 4.3 of Annex I, what evidence of compliance with these requirements shall be recorded in the technical documentation?**
Answer	The equipment manufacturer shall be able to confirm that the material manufacturer's quality system certificate meets the requirements of the third paragraph of section 4.3 of Annex I (field of validity of the certification, range of validity of certification, establishment of the competent body as a legal entity within the European Union, accreditation). The equipment manufacturer should keep track of such information which may be requested by the market surveillance authority. To fulfil this requirement the equipment manufacturer should keep in its technical documentation the appropriate quality system certificate of the material manufacturer or other equally objective evidence. See also PED Guideline G-02 and PED Guideline G-16.
Reason	
Note [x]	

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Guideline G-29

Pressure Equipment Directive PED 2014/68/EU
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Guideline related to: Annex I section 3.2.1 and section 4.3

Question	**Based on data contained in a certificate issued by a material manufacturer (EN 10204:2004 3.1-certificate) material has been supplied in accordance with a material specification.** **May a pressure equipment manufacturer perform additional mechanical or non-destructive testing or have them performed to affirm that the material meets all the requirements specified by the equipment manufacturer?**
Answer	No, unless in exceptional circumstances, as outlined below: The extent of additional testing shall be specified by the equipment manufacturer and it should be at least equivalent to the tests specified in the harmonized standard, if available, for a similar type of material and representative of the entire batch of the material used for the equipment. The testing shall be supplementary to the original certificate. It shall not have the purpose to "improve" properties already included in the certificate. It does not justify an increase in the allowable design stress over the values of the base material specification. The equipment manufacturer takes full responsibility for all additional tests being carried out. The certificate issued by the material manufacturer who has a certified quality-assurance system is presumed to certify conformity with the requirements but only to the extent that is specified in the inspection certificate. No new material certificate shall be issued for the additional tests carried out by the equipment manufacturer. However the results shall form part of the records in the technical documentation. This does not apply to EN 10204:2004 3.2-certification where the specified additional tests shall be carried out by the material manufacturer.
Reason	In certain circumstances the equipment manufacturer may require properties of the material that are not normally affirmed by the material manufacturer. If material with these required additional properties is not available, the equipment manufacturer must take appropriate measures to ensure that his equipment complies by undertaking additional tests.
Note 1	The pressure equipment manufacturer shall compile a hazard analysis for the pressure equipment, on the basis of which the essential safety requirements for the equipment are determined, including the required materials properties. The results of the analysis have to be taken into account in design and manufacture of the equipment, as well as in determining possible additional material testing.

Note 2	A particular material appraisal (PMA) shall be drawn up for a pressure equipment material if the material is not in accordance with a harmonized standard or the European approval of materials (EAM). In that case, the additional material testing shall be made in accordance with the PMA document PE-03-28, appendix 2. The document is available on the EU Commission's PED website.
Note 3	The testing laboratory and its personnel performing additional material tests shall be suitably qualified for the tests in question, and the equipment used for the tests shall be calibrated. Accreditation is the most common way to demonstrate the testing laboratory's qualification. See also PED Guidelines G-24, G-30, H-04 and I-13.

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Guideline G-30

Pressure Equipment Directive PED 2014/68/EU
Commission's Working Group "Pressure"

Guideline related to: Annex I Section 4.3

Question	**A manufacturer produces material only to a chemical analysis without mechanical testing and without affirmation of compliance to a material specification and/or grade.** **An entity intends to purchase the material and affirm compliance to a material specification by performing the mechanical tests as required by that material specification. There will be no further processing, other than cutting to size. Is this procedure acceptable and may this material be used in pressure equipment under the PED?**
Answer	No, even if the mechanical tests are recorded in an EN 10204 inspection certificate which describes the testing entity as the manufacturer of the material.
Reason	Section 4.3 Annex I of the PED requires the material manufacturer to affirm the compliance with a specification. Any entity who is not involved in the material manufacturing process cannot be considered as a material manufacturer.
Note [x]	

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