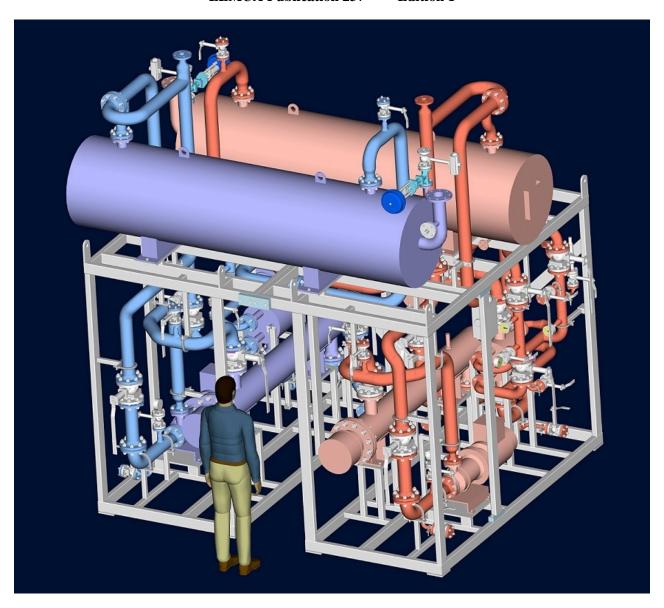
# Pressure Equipment Directive – Global Conformity Assessment

## A Guide to Site Installed Assemblies

SAFed publication PEDG 1 – Edition 1 EEMUA Publication 237 – Edition 1









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#### **Forward**

This document, A Guide to Site Installed Assemblies (PEDG 1), has been developed and written by the Pressure Equipment Consultation Forum (PECF), Safety Assessment Federation (SAFed) and Engineering Equipment and Materials Users Association (EEMUA) in consultation with other stakeholders within the pressure equipment industry to help installation contractors, purchasers, designers and other parties involved in the creation of pressure equipment assemblies to ensure that global conformity assessment can be successfully applied.

The Health and Safety Executive (HSE) was involved with PECF, SAFed and EEMUA in producing this guidance. HSE endorses the guidance, as it follows a sensible and proportionate approach to managing health and safety.

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## **Contents**

<u>1</u> .	Int	roduction	5
2.	Sco	ope	5
3.	Ke	y roles and responsibilities	6
	.1	Economic operator	
	.2	Manufacturer	
	.3	Authorised representative	
	.4	Place on the market	
	.5	Importer	
	.6	Distributer	
	.7	Notified body	
	.8	User Inspectorate	
	.9	End User	
	.10	Common designations for parties involved	9
4.	Cat	tegorisation of assemblies	10
4	.1	An assembly	10
4	.2	Classification of an assembly	10
5.	Gu	idance for the purchaser	12
5.	.1	General requirements	12
5	.2	Conformity assessment	12
5	.3	Regulations applying to use of pressure equipment	13
6.	Gu	idance for the manufacturer - global conformity assessment	13
6	.1	Assemblies and sub-assemblies	13
6	.2	Documentation for the assembly	14
6.	.3	Essential Safety Requirements	15
6	.4	Connection to existing installation	16
6	.5	Commissioning	17
7.	Gu	idance for the end user	18
7.	.1	Assessment of industrial installations under the responsibility of the end user	18
7	.2	Commissioning	18
7.	.3	Repairs – Post installation	19
7	.4	Modifications	20

7.5	Replacements	20
8. Re	eferences	20
Appen	dix – Worked examples of assemblies and industrial installations	21
A1.	Multiple Suppliers/Installers of an Assembly	22
A2.	Categorization of an assembly	23
A3.	Site assembly of a steam generating power plant	24
A4.	Examples of site work carried out under the responsibility of the end user	28
A5.	Assemblies where operator and owner are different parties	30

#### 1. **Introduction**

The Pressure Equipment Directive (PED) requires that individual items of pressure equipment undergo conformity assessment where appropriate. This also applies to assemblies of pressure equipment which need to undergo global conformity assessment (GCA) and CE marking. Experience within the UK indicates that generally this process works well when assemblies are placed on the market as complete, factory supplied products. However when assemblies are created on site at the place of installation the legal process of global conformity assessment is often found to be non-compliant. There are a number of reasons why this can happen:

- Large installations can involve work done by several parties and it becomes unclear who has overall responsibility to ensure global conformity assessment happens
- Sub-contractors appointed by a main contractor may not be aware they have a role to play in the global conformity assessment process
- Industrial Installations under the responsibility of the end user do not have to undergo global conformity assessment but end users are not always clear on what "under the responsibility of" entails.
- New assemblies can be incorporated into existing assemblies or incorporate an existing
  pressure vessel built before the implementation of the PED which leads to uncertainty on
  the extent of global conformity assessment required.

Assemblies which do not have a global conformity assessment when they are handed over to the end user, may require additional verification to confirm their suitability for service under national legislation such as Pressure Systems Safety Regulations (PSSR).

Other than certain Working Party Guidelines published by the European Commission there is no comprehensive guidance to PED currently available to assist the various stakeholders involved in the assembly process.

## 2. Scope

This guidance is aimed at all parties (other than notified bodies or user inspectorates – see note below) who are involved in the design and manufacturer of site installed assemblies in the UK. This includes the following parties:

- End users (including those responsible for procurement of the assembly or appointment of contractors)
- Main contractors
- Site erection contractors
- Design consultants
- Control and instrumentation contractors
- Piping contractors
- Commissioning teams

**Note:** The Conformity Assessment Body Forum (CABF) has published guidance on assemblies aimed at conformity assessment bodies (see CABF PED/SPVD 2014-06-17 on the CIRCA database).

The document is intended to provide the necessary guidance to all parties with responsibilities for the pressure equipment assembly to ensure global conformity assessment can take place.

It applies to the following directives:

- Pressure Equipment Directive (97/23/EC), as implemented by the Pressure Equipment Regulations (PER) 1999
- Pressure Equipment Directive (2014/68/EU), as implemented by the Pressure Equipment (Safety) Regulations (PESR) 2016

**Note:** The PED is transposed into UK law through Pressure Equipment (Safety) Regulations (PESR) 2016 but this document makes reference to the PED throughout.

It excludes assemblies which are placed on the market as complete, factory supplied products. An example of this is a small (bench top) autoclave which is delivered ready for use (ie it is a functional whole with no site based operations required to complete the assembly).

The PED states: "this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations." Guidance on the application of national legislation to industrial installations is beyond the scope of this document but some guidance is included on when and how this exception should be applied.

#### 3. Key roles and responsibilities

The PED provides definitions of all the key players who may have involvement in the supply chain for pressure equipment or assemblies. Key definitions relating to assemblies are repeated in this section along with further explanation focusing on how they are likely to apply to site installed assemblies. Certain parts of the explanations have been taken from "The Blue Guide" version 26 July 2016 (see references section).

### 3.1 Economic operator

'economic operator' means a manufacturer, an importer, authorised representative or a distributor.

"relevant economic operator" means, in relation to pressure equipment or an assembly, an economic operator who has obligations in respect of that pressure equipment or assembly under these Regulations

#### 3.2 Manufacturer

'manufacturer' means any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes.

The definition contains two cumulative conditions: the person has to manufacture (or have a product manufactured) and to market the product under their own name or trademark. So, if the product is marketed under another person's name or trademark, this *named* person will be considered as the manufacturer. In the vast majority of cases there will be a number of parties directly contributing to a site installed assembly (see section 2). However there can only be one party who is the manufacturer for the assembly and that party will be the one who places their name or trademark on the completed assembly. They will also be responsible for the conformity assessment and CE marking. It will need to be agreed at the start of a contract which party is nominated as the manufacturer for the assembly.

The manufacturer may design and manufacture the assembly themselves. As an alternative, they may have it designed, manufactured, assembled, packed, processed or labelled with a view to placing it on the market under their own name or trademark, and thus presenting themselves as a manufacturer. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that they receive all the information that is necessary to fulfil their responsibilities in the conformity assessment. At the start of a contract it should be made clear to other parties/subcontractors of their obligation to provide information to the assembly manufacturer. The manufacturer who subcontracts some or all of their activities may in no circumstances

discharge themselves from their responsibilities, for example to an authorised representative, a distributor, a retailer, a wholesaler, an end user or a subcontractor.

Any organisation who manufactures items of pressure equipment for its own use must assume all of the responsibilities of a manufacturer. However this does not preclude an end user from putting together items of equipment under national legislation to form an industrial installation.

The manufacturer has sole and ultimate responsibility for the conformity of the product to the applicable Union harmonisation legislation, whether they designed and manufactured the product themselves or is considered as a manufacturer because the product is placed on the market under their name or trademark.

#### 3.3 Authorised representative

'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

Whether the manufacturer is established in the EU or not, they may appoint an authorised representative in the Union to act on their behalf in carrying out certain tasks required in the applicable Union harmonisation legislation. A manufacturer established outside the European Union is not obliged to have an authorised representative.

For the purposes of Union harmonisation legislation, to be able to act on behalf of the manufacturer, the authorised representative must be established inside the Union. Commercial representatives of the manufacturer (such as authorised distributors or agents), are not to be confused with the authorised representative in the meaning of Union harmonisation legislation.

This role is not often used in the UK. It may arise where a main contractor appoints a consultancy to assist them with their duties for global conformity assessment of an assembly. However the role must be made clear in the contract for the consultancy to be regarded as the authorised representative.

#### 3.4 Place on the market

- A product is placed on the market when it is made available for the first time on the Union market
- Products made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market (reference 'Blue Guide')

In the context of a site installed assembly it is considered to be placed on the market when a manufacturer, erection contractor, design consultant etc. has completed all manufacturing, testing and commissioning operations, such that it is capable of being put into use.

Note: Placing on the market does not apply to industrial installations.

#### 3.5 Importer

'importer' means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market.

The importer is the economic operator established in the Union who places a product from outside the EU on the Union market. They have important and clearly defined responsibilities under Union

harmonisation legislation. To a large extent, they build on the type of responsibilities to which a manufacturer based in the EU is subjected.

The importer must ensure that the manufacturer has correctly fulfilled their obligations. The importer is not a simple re-seller of products, but has a key role to play in guaranteeing the compliance of imported products.

If an end user or an assembly manufacturer purchases pressure equipment or an assembly directly from outside of the EU then they would become the importer, taking on the associated responsibilities.

#### 3.6 Distributor

'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market.

Along with manufacturers and importers, distributors are the third category of economic operators who are subject to specific obligations. The distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

A distributor acquires products for further distribution either from a manufacturer, from an importer, or from another distributor.

Distributors must act with due care in relation to the applicable requirements. They have to know for instance, which products must bear the CE marking, what information is to accompany the product (for example the instructions for use), what are the language requirements for labelling, user instructions or other accompanying documents, and what is a clear indication of the product being non-compliant.

**Note:** the distributor may also need to consider other applicable product directives in addition to the PED.

## 3.7 Notified Body

A body that performs conformity assessment activities on pressure equipment and assemblies, including testing, certification and inspection. In the UK notified bodies are accredited by United Kingdom Accreditation Service (UKAS) and appointed by the relevant government department.

#### 3.8 User Inspectorate

A body that performs conformity assessment activities on pressure equipment and assemblies under conformity modules A2, C2, F and G within their own organisation, including testing, certification and inspection. In the UK User Inspectorates are accredited by United Kingdom Accreditation Service (UKAS) and appointed by the relevant government department. Equipment and assemblies assessed by a User Inspectorate shall not be CE marked.

#### 3.9 End User

End-users are not defined in Union harmonisation legislation. However many products covered by Union product harmonisation legislation are used at work and thus also subject to Union safety at work legislation.

Union harmonisation legislation does not create obligations for the end-users of the products in their scope. Consequently, the term is not defined in that legislation. It is certain however that the term covers both professional users and consumers. The use of a product as a component to be built into

a new product that again is placed on the market is not considered end-use. The concept of "end use" by a professional or a consumer is intrinsically related to the concept of "intended use".

However if an end-user is the purchaser and is involved in the conceptual design and or specification of the assembly then it will need to provide all necessary information relating to the design/specification to the manufacturer for the purpose of conformity assessment.

The end user is able to assemble appropriated certificated items of pressure equipment without these joining operations complying with PED conformity assessment procedures. Where the end user is taking control of installation and joining operations (as in an "industrial installation"), it will need to understand and manage the integration and joining risks and all relevant legislative requirements and be competent to do so. Further information on end user responsibilities in this context is covered in Section 7.

## 3.10 Common designations for parties involved

In addition to the parties formally defined in the PED there will inevitably be other parties involved in the creation of the assembly who may not fit the definitions covered above but will nevertheless have responsibilities even if they are not a manufacturer.

#### 3.10.1 The purchaser

The purchaser in the context of this guidance is the organisation who obtains/procures equipment incorporating a pressure equipment assembly for the end user. The purchaser could be part of the end user organisation or a separate organisation appointed to operate on their behalf. The references in this document to purchaser means the "technical purchaser" who draws up the technical specifications and or conceptual design used for procurement of the equipment.

#### 3.10.2 Main contractor

The main contractor may not be directly responsible for the design or manufacture of any of the component parts making up the assembly but ultimately they have overall responsibility for the assembly.

#### 3.10.3 Piping contractor

The piping contractor may be appointed to build and install the piping connecting items of pressure equipment in accordance with a design layout and specification provided by others. If the piping is of a size and pressure that requires conformity assessment then the contractor is required to provide all technical documentation relating to the fabrication to whichever party is deemed to be the manufacturer. This technical documentation will include such things as welding qualifications, weld maps, NDT reports, pressure test certificate etc. and it will need to demonstrate that the piping contractor has complied with all of the applicable Essential Safety Requirements of the PED.

## 3.10.4 Design consultant

A design consultant may have been appointed by the main contractor or the end user to design part or the whole of the assembly. In most cases a design consultant would not normally act as the manufacturer of the assembly, unless they are specifically contracted to adopt this role. The design consultant will need to support the manufacturer to ensure all aspects of the design comply with the relevant Essential Safety Requirements of the PED and any other directives that might apply. Technical documentation that demonstrates this will need to be provided to whichever party is deemed to be the manufacturer. The technical documentation will include such things as design drawings, descriptions, results of calculations etc.

## 3.10.5 Erection contractor

An erection contractor (or installer) may be appointed for the purpose of installing items of pressure equipment in accordance with the design drawings/specification or putting together larger items of pressure equipment that have been delivered to site as modules. The erection contractor will have

similar duties and responsibilities as the piping contractor with respect to the supply of technical documentation.

#### 3.10.6 Competent person (PSSR)

The end user of the pressure equipment assembly will have appointed a competent person for the purpose of drawing up written schemes of examination and performing examinations on the assembly once it is in service. The competent person has no duties or responsibilities under the PED.

It is a legal requirement of PSSR that the user "shall not operate the system or allow it to be operated unless he has a written scheme for the periodic examination, by a competent person". Furthermore where PSSR applies and if prescribed in a written scheme it will be necessary for the competent person to conduct an examination of the assembly before it is used for the first time. It is therefore important that the end user's competent person becomes involved at an early stage of the project.

## 4. Categorisation of assemblies

## 4.1 An assembly

The directive describes an assembly as being:

composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. Those assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer of an assembly intends to place it on the market and put it into service as an assembly — and not in the form of its constituent non-assembled elements — that assembly should comply with this Directive. However this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.

#### 4.2 Classification of an assembly

Each item making up an assembly must be assessed in order to determine its hazard category for conformity assessment.

The integration of the component parts of the assembly must be assessed according to the highest category applicable to the equipment concerned, disregarding the category of any safety accessories.

The protection of the assembly against exceeding the permissible operating limits must be assessed according to the highest category applicable to the equipment to be protected.

The flow chart in figure 1 provides guidance for this process.

**Note 1** Excluded pressure equipment is covered in Article 1.2 of the PED

**Note 2** The notified body or user inspectorate (when required) should be appointed after the categorisation of the assembly has been ascertained and the conformity assessment module determined.

**Note 3** Further information on classification of an assembly can be found in the Conformity Assessment Body Forum (CABF) guidance document CABF PED/SPVD 2014-06-17.

**Note 4** At the end user's preference it can have the conformity assessment steps carried out by another party or parties (eg main contractor, erection contractor, piping contactor etc.). However if the overall assembly does not follow the global conformity assessment route then responsibilities for an 'industrial installation' will apply to the end user.

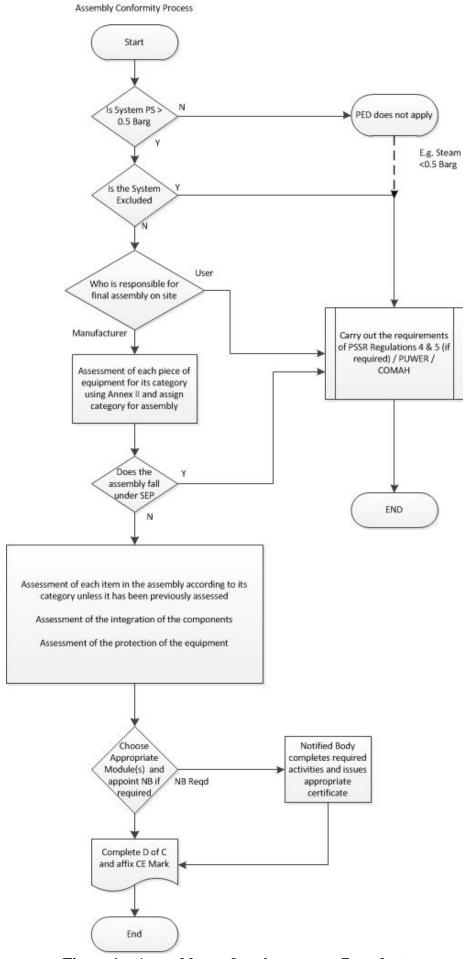


Figure 1 – Assembly conformity process flow chart

## 5. Guidance for the purchaser

## 5.1 General requirements

- 5.1.1 Where the purchaser is independent and is acting on behalf of the end user it will be necessary for that person or organisation to manage the transfer of all necessary information and documentation between parties responsible for the manufacture and installation of assemblies (manufacturers, contractors, sub-contractors, installers) and the end user who is responsible for putting the equipment into service. If not performing this role then purchasers should ensure the duties are performed by another party or organisation and will be fulfilled in an effective manner.
- 5.1.2 Whilst not being directly responsible for the detailed engineering design, generally the purchaser should have an awareness and understanding of the functional design of the equipment, classification of the contained fluids under the PED and PSSR, design pressures and temperatures, materials of construction, the categorisation of the systems comprising an assembly under the PED and the conformity assessment processes to be applied by the nominated parties during the contract.
- 5.1.3 The purchaser will need to ensure that all tender documentation and specifications are produced with the necessary consideration of the PED at the earliest possible stage of the project.
- 5.1.4 The purchaser should understand and ensure that the scope of the assembly, its limits and terminal points are identified and agreed in consultation with the end user, equipment manufacturers and contractors responsible for the manufacture and installation of the assembly. Terminal points between sub-assemblies should be agreed (e.g. golden welds) and specified in contract documentation.
- 5.15 Proof testing of final assemblies should be considered in the contract specification phase by the purchaser. It may be impractical to fully flood a finished assembly due to foundation loadings or similar concerns. In such circumstances a modular approach to testing should be considered and agreed with suppliers, with activities undertaken to provide justification of proof test waivers and the use of comprehensive surface and volumetric NDT as a substitute.
- 5.1.6 Consideration needs to be given to other directives which may be applicable to the assembly, for example, the Machinery Directive, the EMC Directive and, Equipment for Potentially Explosive Atmospheres (ATEX) Directive.

## 5.2 Conformity assessment

5.2.1 For site installed assemblies falling under the requirements of the PED the purchaser should facilitate a coordinated and strategic approach to management of conformity assessment by the responsible parties. This includes consideration of the Global Conformity Assessment process at the beginning and throughout the contract specification, design and manufacturing phases so as to ensure that the equipment can be put into service and operated by the end user in compliance with PSSR, PUWER or COMAH as applicable.

**Note**: Site activities will be subject to the Construction (Design and Management) Regulations (CDM) 2015. All Directives are effectively considered also as part of this Regulation and therefore these guidance notes will be a useful input to the responsible persons under CDM.

- 5.2.2 The purchaser will need to ensure that all parties have taken the necessary steps to effectively engage the services of a notified body in accordance with the conformity assessment process to be applied.
- 5.2.3 The purchaser should be in receipt of documentation outlining how the relevant parties intend to fulfil their duties in compliance with the PED and how the Essential Safety Requirements will be fulfilled. Means to demonstrate Sound Engineering Practice should also be considered.
- 5.2.4 The purchaser should ensure suitable hazard and risk analysis processes are to be applied by all parties, including consideration of the integration of equipment from different suppliers.

5.2.5 Where multiple contracts and parties are involved in a site installation the purchaser should ensure the hierarchical structure of the final assembly and its sub-assemblies are identified. The purchaser should identify which organisation has the overall responsibility for the Global Conformity Assessment of the final assembly on site and ensure such arrangements are contractually specified and known to all parties.

## 5.3 Regulations applying to use of pressure equipment

In order to ensure that requirements of regulations relating to the use of the pressure equipment are addressed (eg PSSR, PUWER, COMAH etc.) consideration needs to be given to the stages of the installation when the end user's competent person (PSSR) or other parties should be involved for the purpose of drawing up written schemes of examination and conducting the initial examination.

When PSSR applies initial inspections and certification need to be performed before putting equipment into service and before any commissioning operations, which normally occur prior to the plant contractual handover. Therefore there needs to be suitable communications and planning between the manufacturer, end user and competent person for drawing up the written scheme of examination (WSE) at an appropriate stage of the installation.

#### 6. Guidance for the manufacturer - global conformity assessment

The term manufacturer in this section refers to the organisation who is responsible for the global conformity assessment of the assembly of pressure equipment. The manufacturer for the assembly is defined in section 3.2, although the organisation may also be responsible for the manufacture of certain items of pressure equipment making up the assembly. For example site fabricated piping joining together items of pressure equipment or pressure vessels manufactured off site. The manufacturer is responsible for classifying the assembly in accordance with section 4.2 and selecting an appropriate conformity assessment module. When applying the conformity module(s) the manufacturer must also consider its own capabilities and competence with respect to the requirement of the module(s) chosen.

#### 6.1 Assemblies and sub-assemblies

A large and complex assembly can be divided into smaller assemblies referred to as sub-assemblies, although this is not a term used in the PED. For any given assembly there can only be one manufacturer, even if it incorporates sub-assemblies. Such "sub-assemblies" can be manufactured by different manufacturers and assessed not only separately but also at different stages (sold not CE marked, for example ie compliant but not certified). They may not necessarily include the protective devices required for protecting the final assembly.

An overall assessment shall be performed when interacting sub-assemblies are joined together to form a larger assembly. In particular the operating instructions of sub-assemblies shall be considered.

Figure 2 provides an example of an assembly for a new plant containing sub-assemblies and involving three manufacturers AA, BB and CC:

Description of the assemblies	Manufacturer for GCA		
Boiler house containing boilers and ancillary equipment	AA		
Steam Distribution system connecting to various heat exchangers	ВВ		
Compressed air system including compressors, distribution pipework and air receivers	CC		
Nitrogen system including liquid nitrogen vessel, evaporator and distribution pipework to various process vessels	ВВ		
The overall assembly for the new plant incorporating all of the above plus connecting process pipework, controls and instrumentation	To be agreed at start of project (see notes 1, 2 & 3)		

Fig 2 – Sample assemblies and sub-assemblies

- **Note 1:** The overall global conformity assessment does not necessarily have to include all assemblies located on a site. It is only those assemblies or sub-assemblies which interact that need to be included in the overall global conformity assessment. Thus, there may be more than one final global conformity assessment per installation.
- **Note 2:** The manufacturer responsible for the overall global conformity assessment could be a separate organisation from the manufacturers referred to in the table, such as a principal contractor or a design consultancy.
- **Note 3:** The global conformity assessment could be carried out by any of the three parties providing they have the necessary competence to do so.

#### 6.2 Documentation for the assembly

The global conformity assessment will include compiling technical documentation for the assembly. Where a notified body is involved in the assessment it will be required to review this documentation. In most situations there will be a submission of technical documentation at the design stage followed a further submission at the manufacturing or final assessment stage.

#### Design stage

- General description of the assembly including the terminal points a description of the process, intended use and other applied directives)
- List of all individual items of pressure equipment in the assembly with all relevant information (allowable pressure (PS), allowable temperature (TS), volume (V)/nominal diameter (DN), content, fluid, category, etc.)
- Information on which items are to be purchased from suppliers with CE marking and which, if any, are manufactured by the manufacturer of the assembly (e.g. the assembly piping).
- Hazard and risk analysis of the assembly, considering both named hazards in the ESR such
  as protection against over pressure/over temperature, fire, misuse, etc. and any other
  identified hazards such as loss of coolant system, power failure and ones related to erection
  and integration in the assembly.

- Global conformity assessment strategy: a description including whether the assembly is to be divided into smaller units for assessment.
- Diagrams and descriptions such as process flow diagrams and Piping & Instrumentation diagrams (PID)
- Protection philosophy and method of protection eg
  - o Safety valve set pressure, capacity, maximum flow of fluid
  - o Information relating control and safety loops e.g.
  - o Details of PLC control systems which incorporate safety functions
- List of the design and construction standards used for the integration and protection.
- An ESR checklist is required describing how the applicable ESRs are addressed.
- Additional documents as necessary to enable assessment e.g. piping stress analysis reports, nozzle loads on connecting equipment, pump curves, safety valve reaction loads.

#### Manufacturing or final assessment stage

- Declarations of conformity (DoC) of all pressure equipment making up the assembly (and which have been subjected to a conformity assessment procedure by the manufacturer, resulting in CE marking).
- The corresponding documentation for equipment classified as Sound Engineering Practice (SEP)
- Documentation supporting any permanent joining operations on site, joining items of pressure equipment to form the assembly
- Records of any inspection and testing during the forming of the assembly
- Operating instructions for each item of pressure equipment
- Declarations of conformity of all other equipment that is essential for the safety of the assembly, and which is covered by another directive.
- For functional safety controls: Written proof of performed functional tests of the hardware and/or software of the safety functions (manufacturer validation, FAT)
- As built documentation (e.g. drawings, P&IDs, equipment list)
- DoC for the assembly (draft)
- Operating Instructions of the assembly (draft)

## **6.3** Essential Safety Requirements

The PED outlines the obligation on manufacturers to assess and identify which hazards apply to their equipment on account of pressure, regardless of whether these are individual items of equipment or complex assemblies. In addition to ESR 2.8 which specifically addresses assemblies, there is also the requirement to consider all the other ESRs as part of the integration process. Normally this activity would be carried out from conception of a project through to the detailed design and engineering phases as part of the design hazard and risk analysis. Whilst these activities may be carried out independently of the specific considerations and content of any design codes and the PED, it should be ensured that assessments are structured and documented in such a way as to address all of the Essential Safety Requirements, as laid out by the PED. Hazard and risk analysis should consider all reasonably foreseeable operation scenarios and the conditions the finished assembly is likely to encounter. Where necessary the manufacturer should inform and discuss with their notified body at an early stage in this process to ensure the approach by the manufacturer is adequate and supports their requirements for the final Global Conformity Assessment.

Whilst each item of equipment or sub-assembly comprising a finished assembly may have been individually assessed to ensure it has been placed onto the market in compliance with the PED, it should be assumed that no assessment or consideration will have been made with regards to its integration into any proposed assembly or the additional hazards this may present.

#### Additional considerations of ESRs for assemblies:

- Suitability of equipment (including existing equipment) for integration (design pressure, design temperature, fluid inventory, operation under vacuum conditions, hot and cold filling, flashing of vessel contents).
- Suitability and adequate sizing of pressure relieving devices for combined systems.
- Allowable limits/conditions at the terminal points of the assembly.
- Hazards associated with egress/ingress of fluid inventories from different parts of an assembly combining with each other.
- Material compatibility issues (chemical attack, galvanic corrosion etc.).
- Nozzle loadings onto vessels.
- Pipework flexibility assessments.
- Vibration induced fatigue due to connections to rotating plant.
- Transient conditions associated with start/stop of pumps and fast closure of valves.
- Accumulation of pressure in pipework and vessels and adequate sizing/positioning of relief valves.
- Static head of fluid inventories.
- Safety of procedures for hydraulic testing of final assemblies (foundation loads due to increased fluid content, means of adequate isolation, venting and draining etc.).
- Access for non-destructive testing of final connections.
- Functional safety of electrical/electronic programmable safety related systems
- SIL ratings of components forming critical control and safety loops.
- Content and scope of operating instructions.
- Safety information relating to commissioning, operation and maintenance.

#### 6.4 Connection to existing installation

The situation commonly arises where a new assembly has to be "bolted on" to an existing installation. The PED requires that all pressure equipment making up the assembly undergoes conformity assessment.

In the vast majority of cases for existing non CE marked equipment it may not comply with all of the applicable essential safety requirements. However it should be possible to do a limited assessment of the existing installation against certain applicable essential safety requirements covered in 6.3. In particular the hazard and risk analysis should be extended to the existing installation to determine whether there are any hazards and risks that could impact on the resulting assembly when the old and the new are integrated. For example if a new assembly takes steam from an existing supply it will need to be determined whether the supply is adequately protected at source. Other risks to the new assembly could be associated with other factors such as varying pressures, interruption in the supply or impurities in the steam.

The responsibility for conducting the hazard and risk analysis on the existing installation will be the organisation that joins the assembly to the existing installation. If it is performed by the manufacturer it needs to form part of the global conformity assessment for the new assembly. If it is performed by the end user then it will follow the requirements of PSSR Regulation 4 (if PSSR applies).

The figure 3 provides an example of delineation of responsibility between in-service modification and new 'CE' System. The final connection between 'user responsibility' and 'manufacturer responsibility' can be made by either the end user or the manufacturer. If it is performed by the end

user then it does not infer any responsibility on the part of the end user for global conformity assessment of the assembly.

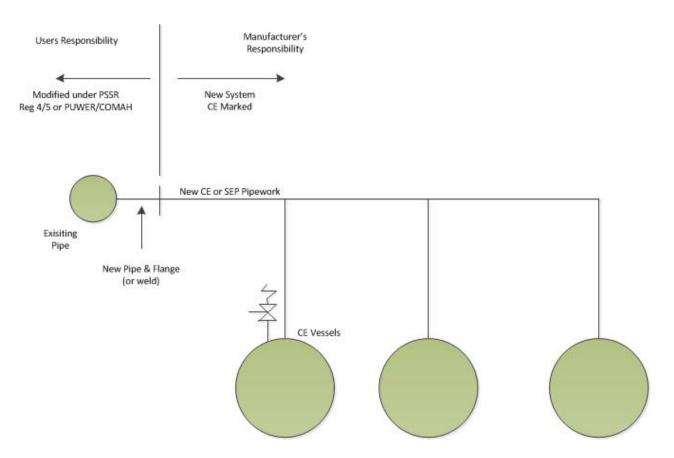


Fig 3 – How a new assembly should be treated when being added as an extension to an existing installation

#### 6.5 Commissioning

During the final stage of forming an assembly or sub-assembly it is often necessary to actually operate the system in order to complete all processes of the final assessment. This usually forms part of the commissioning process and includes verification that safety accessories function correctly and that controls and instrumentation are correctly set and calibrated.

Such operations should be for a defined period, just sufficient to perform the necessary tests and complete the final assessment. It is recommended that a plan for commissioning is drawn up such that the period of operation is clearly defined. Operating the assembly for any longer periods eg operation trials are regarded as going into service. As such the manufacturer will need to assume all or at least some of the responsibilities of the "user" or "operator" within PSSR, PUWER or COMAH as applicable.

When PSSR applies, in order to operate the plant legally the manufacturer will need a suitable written scheme of examination (WSE) for the assembly, certified by a competent person (CP). The system would also normally require an initial examination by a competent person. To enable the CP to complete this examination it will need sufficient information/document relating to the design and construction made available to confirm the safe operating limits of the assembly.

In order to ensure a smooth handover of the assembly to the end user the manufacturer should engage a CP at the start of the site installation. This is to allow sufficient time to draw up the WSE. The CP may also require to witness the functional testing of the safety accessories. The end user's appointed competent person is normally best placed to perform these functions.

#### 7. Guidance for the end user

#### 7.1 Assessment of industrial installations under the responsibility of the end user

7.1.1 User responsibility - Where an end user takes responsibility for the final assembling and integration of items of pressure equipment on its own site, or a subcontractor under the overall direct control of the end user performs this function, it constitutes an industrial installation and the PED does not apply. Instead national legislation shall apply eg HSWA, PSSR etc. The end user therefore takes responsibility not just for the method and nature of the jointing operation, but for consideration of the design integration and operation of the systems being connected in fulfilment of all relevant health and safety legislation not just aspects relating to the pressure equipment. The end user will need to have the necessary competence to fulfil these obligations.

The PED still applies to individual items of pressure equipment and sub-assemblies forming part of the industrial installation (except where they are specifically excluded from PED). The end user should therefore ensure the equipment purchased to form the industrial installation is compliant with the PED where appropriate but there is no requirement for such equipment to undergo any further conformity assessment. It should be noted that where equipment is acquired from outside of the EU, the end user or purchaser will assume the duties of an importer.

7.1.2 Legislation - Where PSSR applies the user (as defined in PSSR) will need to comply with regulations 4, 5 and 6. This will follow a similar approach to the PED global conformity assessment to confirm that parts are properly integrated and adequately protected where appropriate. Sufficient documentation concerning the industrial installation will need to be produced to meet the requirements of regulation 5 and to allow the user's competent person to confirm the safe operating limits. The Competent Person will also need to confirm that individual items of equipment to be included in the WSE are compliant with the PED as appropriate, and that the industrial installation is safe as a functional whole. The user should engage with the competent person at an early stage in the project. The timing of engagement will depend on individual circumstances but typically before site operations commence.

If the user cannot produce sufficient documentary evidence to confirm the adequacy of the industrial installation then a fitness for purpose assessment may need to be carried out.

7.1.3 Exceptions - An erection contractor, design consultant, pipework erector, (i.e. someone other than the end user) may be appointed by the purchaser/end user for the purpose of assembling and integrating items of pressure equipment to form a functional whole, using the appointed contractor's own direction and control. This contractor then effectively becomes the manufacturer of the assembly and the PED applies. When applicable, conformity assessment and CE marking must be applied to the assembly by whoever is deemed to be the manufacturer.

Where items of pressure equipment are manufactured in-situ by the end user or under the end user's control, for example welding pipe/pipework sections together to form a new piping system, then the PED applies. When applicable, conformity assessment and CE marking must be applied to this equipment by whoever is deemed to be the manufacturer (see definition of manufacturer).

**Note:** Where a User Inspectorate is involved then the equipment would not be CE marked.

#### 7.2 Commissioning

During the commissioning stage of a complex project involving a global conformity assessment of an assembly under the scope of PED, several parties are likely be engaged. Where this applies the

end user should check to ensure all requirements for conformity assessment are met for the assembly and its constituents (items of pressure equipment or sub-assemblies) by the various parties involved. Conformity assessment will need to be addressed at the appropriate stages of the project and not at the end. Retrospective conformity assessment is unlikely to be successful and it is therefore important that responsibilities of the various parties are agreed at the start of the project.

7.2.1 The manufacturer, or economic operator of the assembly shall be identified. This organisation should have addressed the global conformity assessment process and engaged a notified body (where appropriate) and should have addressed the relevant essential safety requirements, drawn up a declaration of conformity and affixed a nameplate bearing the CE mark and other relevant details by the end of the commissioning period at the latest.

**Note:** The manufacturer, or economic operator for the assembly may have sub-contracted certain tasks, but should have retained overall control / responsibility for the assembly.

- 7.2.2 If permanent joining (e.g. welding of pipework) of the assembly has been performed on site, the manufacturer of the assembly should be able to demonstrate compliance with the essential safety requirements relating to joining, testing and final assessment as part of the global conformity assessment.
- 7.2.3 During the completion phase the assembly or sub-assemblies may need to be put into service for commissioning purposes. These sub-assemblies are regarded as an assembly in their own right under the PED and the manufacturer should have applied the global conformity assessment process as referred to in 7.2.1.

Note: It is important to note that this procedure does not absolve the manufacturer, or economic operator of the overall assembly from performing global conformity assessment.

- 7.2.4 The end user's design specification communicated to the manufacturer by the purchaser shall provide sufficient technical information to ensure the manufacturer of the assembly is able to address all of the applicable Essential Safety Requirements in the PED (see section 6.3).
- 7.2.5 Where the PSSR apply then prior to putting an assembly into service the end user is responsible for establishing safe operating limits (PSSR Reg. 7), ensuring a written scheme of examination is drawn up (PSSR Reg. 8) and that appropriate examinations are carried out by a competent person in accordance with the scheme. The Global Conformity assessment documentation (or equivalent as may apply) can be used as evidence that the assembly has been properly designed and constructed. The end user is responsible for ensuring all relevant documentation concerning the assembly is made available to the competent person.

#### 7.3 Repairs – Post installation

European Commission Working Party Guideline A-03 provides guidance on subsequent repairs to pressure equipment once they have been put into use. Repairs are covered by national legislation and not the PED. In the vast majority of cases in the UK this will be Regulation 13 of the Pressure System Safety Regulations (PSSR), PUWER or COMAH as applicable. The competent person appointed under PSSR may need to be involved either during or after the repair process. In the few cases where the pressure equipment is outside of the scope of PSSR then the Provision and Use of Work Equipment Regulations will apply.

- **Note 1**: According to A-03 an entire change i.e. the complete replacement of an item of pressure equipment by a new one is covered by the PED.
- **Note 2:** The PED also applies to repairs carried out on pressure equipment prior to completion of conformity assessment and CE marking; for example of a repair a weld defect.

The original global conformity assessment carried out on the assembly containing the repaired or replaced item of pressure equipment will still remain valid.

#### 7.4 Modifications

Guideline A-03 also provides guidance where pressure equipment in use is subsequently modified. Generally simple modifications that do not change the original characteristics, purpose and/or type of the equipment will be subject to national legislation, as in the case of repairs. Examples of simple modifications would be installing an additional nozzle on a pressure vessel or connecting a new autoclave to an existing steam main. Examples of important modifications that need to be covered by the PED are converting a steam boiler to operate as a high pressure hot water boiler or converting a pressure vessel designed and constructed to contain refrigerant R404A for use on ammonia. In both of these examples the important modification will affect various items making up the assembly and therefore global conformity assessment would need to be repeated. Modifications will need to be assessed on a case by case basis and it may be necessary to seek clarification on their significance from someone knowledgeable on the PED such as a notified body or user inspectorate.

#### 7.5 Replacements

The PED will apply to a replacement part which constitutes a complete item of pressure equipment. For example a spare shell and tube heat exchanger, complete with tube bundle and channels is a complete item of pressure equipment but a spare tube bundle on its own is just a component of pressure equipment. It is not required to undergo conformity assessment and CE marking. However it will need to be manufactured on a 'like for like' basis, otherwise it may be considered to be an important modification to the pressure equipment.

Where replacement components are to be incorporated into an assembly or industrial installation and are not considered to be a complete item of pressure equipment, users should be aware that in order to satisfy any legal obligations under national legislation (e.g. PSSR) they may need to be able to demonstrate compliance with the Essential Safety Requirements of the PED. It may therefore be necessary to make the provision of appropriate information and documentation subject to contract with the supplier.

As a general rule any replacement pressure retaining component of an item of CE marked pressure equipment will need to be manufactured applying the same essential safety requirements that were applicable to the original component. For example the material for spare tubes for a shell and tube heat exchanger will need to be of the same specification as the original tubes or an equivalent specification that complies with the essential safety requirements relating to materials.

Replacement components will need to be supplied with documentation that confirms their identity and where applicable their suitability for the intended pressure equipment. PED Working Party Guideline A-03 provides further information on documentation. The competent person appointed under PSSR where applicable may require to see this documentation in order to confirm fitness for further service for the item of equipment that has been repaired.

#### 8. References.

The 'Blue Guide' on the implementation of EU products rules 2016

CABF PED/SPVD 2014-06-17 Principles for the Assessment of Assemblies

CABF N17/036 Assemblies according to the Pressure Equipment Directive

Pressure Equipment Directive (97/23/EC), as implemented by the Pressure Equipment Regulations (PER) 1999

Pressure Equipment Directive (2014/68/EU), as implemented by the Pressure Equipment (Safety) Regulations (PESR) 2016

Pressure Systems Safety Regulation (PSSR) 2000

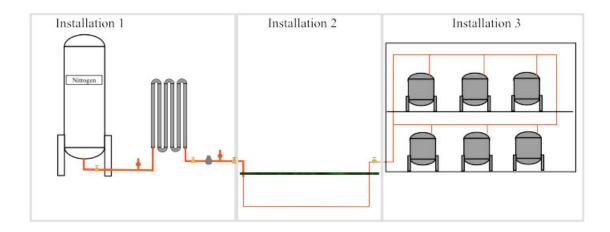
## Appendix – Worked examples of assemblies and industrial installations

The following practical examples have been compiled to outline approaches to managing responsibilities to achieve compliance with the PED. Other means of achieving compliance may also be equally valid. The overall aim is to ensure that consideration is given to providing a robust strategy and ensuring processes are in place at an early stage of projects to designate key responsibilities and manage the interfaces between various stakeholders.

#### A1. Multiple Suppliers/Installers of an Assembly

An end user requires Nitrogen to supply a new facility. There are three separate installers involved in the assembly:

- A gas supplier supplies and installs a vacuum insulated nitrogen storage vessel and associated vaporizers' etc.
- A pipework contractor installs the underground pipework to the new facility.
- Another installer supplies a number of vessels, and pipes them to the underground pipework.



Each Installed Section is CE Marked Appropriately

Functional Whole = Installation 1 + Installation 2 + Installation 3

Who is Responsible for CE marking the complete Assembly?

#### Responsibility.

In this case it would depend on the contract, this means that the procurement department for the site owner needs to be careful when placing multiple contracts to ensure that one party has the overall responsibility to CE mark the final assembly. This would be similar to the principal contractor/designer role in the Construction Design and Management regulations 2015.

Within the PED there can only be one "Manufacturer of the Assembly".

The party taking the responsibility of the manufacturer for global conformity assessment and CE marking of the assembly should be agreed before the work commences. This party must be aware of their responsibilities and should be suitably competent to fulfil them.

If you are in a position where there are multiple "installers" on a contract, as in this example, then it would be advisable to check with the owner who is taking responsibility as the "Manufacturer" for the whole assembly.

It is never a simple task to try to carry out Global Conformity assessment at the end of a project and can be time consuming. The costs of completing the process should not be underestimated.

#### A2. Categorization of an assembly

The manufacturer should compile a list of all pressure equipment making up the assembly along with relevant technical information required to determine PED hazard categories. Typical assembly XYZ comprises:

## Piping and valves

Line No	Service	Line size (DN)	Design Temp (TS)	Design Press (PS)	PS x DN	Fluid Group	Fluid state	PED Chart	PED Haz. Cat.
A-80	Dowtherm J <sup>1</sup>	80	200	10	800	1	Gas	6	1
C-80	Steam	80	184	10	800	2	Gas	7	SEP
D-40	Steam / Cond	40	100	10	400	2	Gas/Liq	$7/9^2$	SEP
E-80	Water	80	80	10	800	2	Liq	9	SEP
F-80	Ethylene Glycol	80	50	10	800	1	Liq	9	SEP
G-25	Nitrogen	25	50	10	250	1	Gas	7	SEP
H-25	Dowtherm J <sup>1</sup> / Nitrogen	25	200	10	250	1	Gas	6/7 <sup>2</sup>	SEP
456	DN 80 valves	N/A	200	10	800	1	Gas	6	I

## **Equipment**

Item No	Service	Internal Volume	Design Temp	Design Press	PS x V	Fluid Group	Fluid state	PED Chart	PED Haz.
	Dowtherm J <sup>1</sup>	(litres)	(TS)	(PS)					Cat.
123	Thermowell <sup>3</sup>	0	200	10	0	1	Gas	N/A	Excl
589	DN 80 pump <sup>4</sup>	4.5	200	10	45	1	Gas	$1/6^2$	I
789	DN 80 Filter	14	200	4	56	1	Gas	$1/6^2$	II
101	Vessel jacket <sup>5</sup>	48	200	4	192	1	Gas	1	II
111	Safety valve	N/A	200	4	N/A	1	Gas	N/A	IV
120	Expansion Tank	240	200	4	960	1	Gas	1	III

<sup>&</sup>lt;sup>1)</sup> Vapour pressure of the thermal fluid Dowtherm J at  $200^{\circ}$ C = 1.58 bar

The item of pressure equipment incorporated into the assembly with the highest hazard category (excluding the safety accessory) is the Expansion Tank. The manufacturer responsible for making the assembly will therefore need to carry out global conformity assessment using one of the conformity modules for hazard category III.

<sup>&</sup>lt;sup>2)</sup> Chart returning the highest hazard category to be used in evaluation

<sup>&</sup>lt;sup>3)</sup> Item is not pressure equipment as it has no volume (see PED Working Party Guideline A-40)

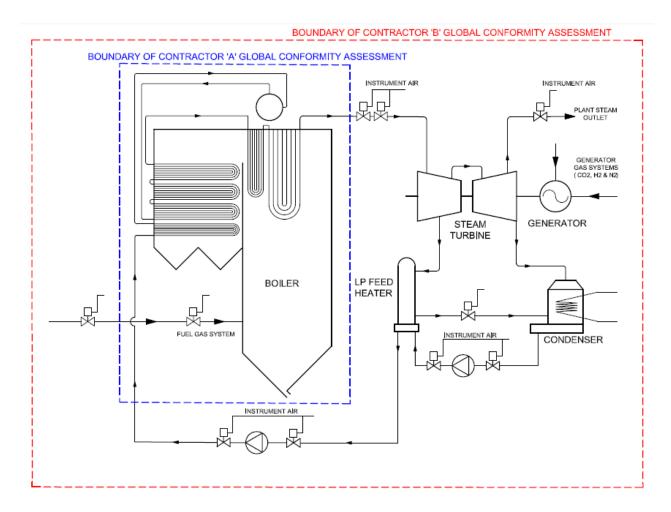
<sup>&</sup>lt;sup>4)</sup> Item CE marked under the Machinery Directive and in hazard category I, therefore excluded from PED

<sup>&</sup>lt;sup>5)</sup> The process side of vessel is less than 0.5 bar design pressure

#### A3. Site assembly of a steam generating power plant

#### Scenario A3-1

An end user places a contract for the manufacture and installation of a new biomass thermal power plant. The biomass boiler, fuel handling systems and ancillary systems internal to the boiler house are to be provided by Contractor 'A'. Contractor 'B' provides the steam turbine, high energy steam pipework and balance of plant (condensers, feed system vessels and pipework, control instrument air system, fuel gas systems, Carbon Dioxide, Hydrogen and Nitrogen systems).



#### Responsibility.

During the contractual negotiations and tendering phase of the project it is agreed that Contractor A will perform Global Conformity Assessment for the boiler and associated systems in its supply. Contractor B will be responsible for performing Global Conformity Assessment for the power plant as a completed assembly (functional whole) and will be responsible for the safe integration of the components across the site. Contractor B performs global conformity assessment on the full steam/water circuit using documentation/information on the boiler assembly part of the circuit provided by contractor A. Contractor B then carries out separate global conformity assessment on each of the ancillary services (ie the fuel gas system, control air, Carbon Dioxide, Hydrogen and Nitrogen pipework and vessels)

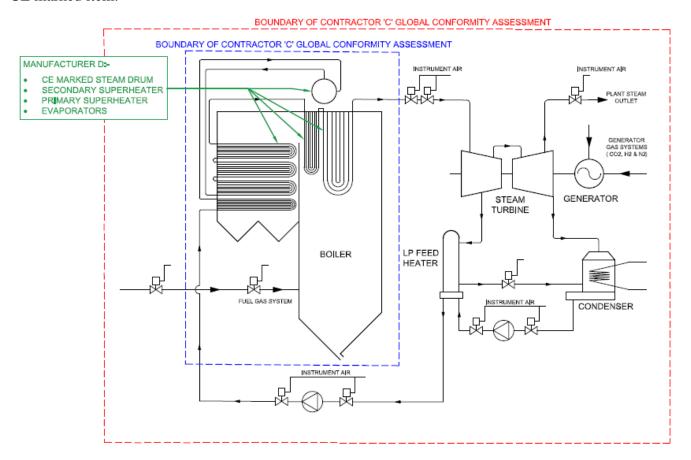
Whilst there is no specific guidance within the PED relating to what constitutes a supporting system, the requirement and logic to apply separate global conformity assessment for systems which operate in isolation of one another should be taken into account when developing a methodology for the Conformity Assessment process and contractual responsibilities.

#### Scenario A3-2

As in the previous scenario an end user places a contract for the manufacture and installation of a new biomass thermal power plant with a site main Engineering Procurement Contractor (EPC). The site contractor responsible for the delivery of the plant, contractor C, subcontracts the design of the boiler to a manufacturer D in the USA, who agrees to supply the boiler design, the boiler components but not any transportation to site, erection, site installation, or commissioning. Contractor D builds components in the USA under Module G with a notified body. It supplies a steam drum CE marked, primary and secondary super heater modules, and evaporator modules all CE marked, together with interconnecting pipework and detailed design calculations and assembly drawings.

Contractor C carries out the site build of the supplied components. It employs a notified body to carry out a Global Conformity Assessment of the boiler assembly under module G. The notified body reviews the calculations and assembly drawings (supplied originally from Contractor D), witnesses welding and NDT results (if appropriate) of the boiler interconnecting pipework and after witnessing the pressure test(s) checks the installation of the safety relief valves. Contractor C then CE marks the boiler assembly (under the PED Contractor C is responsible for the assembly). Contractually it still holds the manufacturer D responsible for the design and the boiler performance.

Later Contractor C, who has provided the steam turbine, high energy steam pipework and balance of plant (condensers, feed system vessels and pipework, control instrument air system, fuel gas systems, etc.) completes a global conformity assessment on the full steam/water circuit using the boiler assembly as one CE marked item.

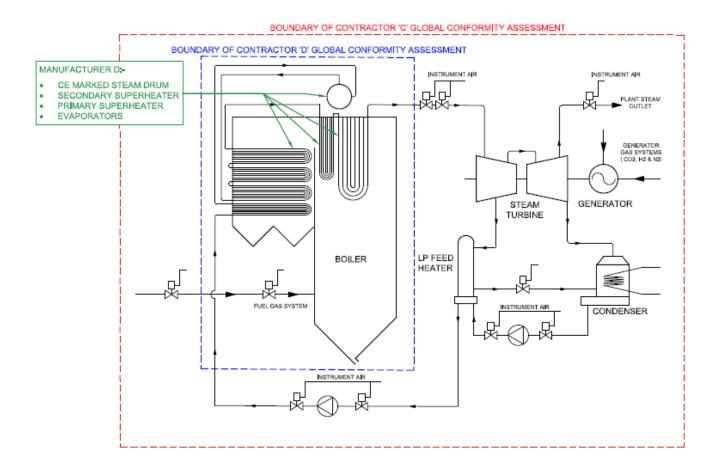


#### Scenario A3-3

As in the previous scenario an end user places a contract for the manufacture and installation of a new biomass thermal power plant with a main site contractor (EPC). The site contractor responsible for the delivery of the plant, contractor C, subcontracts the design of the boiler to a manufacturer D in the USA, who agrees to supply the boiler design, the boiler components and site installation. Contractor D builds components in the USA under Module G with a notified body. It supplies a steam drum CE marked, primary and secondary super heater modules, and evaporator modules all CE marked, together with interconnecting pipework. Contractor/manufacturer D places a subcontract on the main Contractor C to carry out the erection, welding, NDT and pressure testing of the boiler on site under his technical supervision.

Manufacturer D employs a notified body to carry out a Global Conformity Assessment of the Boiler assembly under module G. The notified body reviews the calculations and assembly drawings, witnesses welding and NDT results (if appropriate) of the boiler interconnecting pipework carried out by C under supervision of D and after witnessing the pressure test(s) checks the installation of the safety relief valves. The USA manufacturer D then CE marks the boiler assembly under the global conformity assessment and takes responsibility for the design and manufacture.

Later contractor C, who has provided the steam turbine, high energy steam pipework and balance of plant (condensers, feed system vessels and pipework, control instrument air system, fuel gas systems, etc.) completes a global conformity assessment on the full steam/water circuit using the boiler assembly as one CE marked item.



#### Discussion of Scenarios A3-1, A3-2 &A3-3

In scenario A3-1 the end user places two separate orders for different parts of the plant and therefore the <u>end user</u> needs to make clear in its contracts the responsibilities of each party and who is responsible for the global conformity assessment of the boiler and the whole plant.

In the A3-2 and A3-3 the end user places one contract on the site Contractor C, and it is Contractor C who needs to ensure that the subcontract on D is clear in terms of a global conformity assessment for the boiler.

In both A3-2 and A3-3 the same organisation carries out the boiler design and supply of the main components to site already CE marked. The site assembly and welding of the boiler components into an assembly is carried in both scenarios by Contractor C. The difference is who takes responsibility for the global conformity assessment of the boiler and so who employs the notified body. Both scenarios are acceptable and common ways that occur on major construction sites.

The importance of agreeing and understanding at the outset, who takes the responsibility for the different global conformity assessments needed on large sites to ensure a legally functioning assembly, cannot be over emphasised.

## A4. Examples of site work carried out under the responsibility of the end user

This section provides some examples of scenarios where items of pressure equipment are put together or installed under the responsibility of the end user, as in the case of industrial installations. This situation will apply to an installation put together on an end user's own site and under their control.

Example	Description	Note 1	Note 2
Attachment of additional instrument connections onto a vessel.	A row of flanged instrument branches are attached by welding on to a reactor vessel to provide additional connections to measure process conditions.	The attachment of new branches is considered to be a minor modification and does not require assessment under the PED.	Work should be carried out in accordance with Regulations 5 and 13 of the PSSR.
Installation of new/replacement valves.	New large diameter (DN400) valves are installed on the HP (120barg) bypass system at a power generating station.	Installation of new valves on a like for like basis is categorised as a repair under the PED. The replacement valve does not have an impact on the overall functionality or design of the system.	New valve and pipe assemblies (valve tails) to be supplied CE marked. PSSR (Regulation 13) applies to installation works and Competent Person updates Written Schemes of Examination where necessary.
Installation of a prefabricated steam distribution manifold assembly.	A steam manifold is replaced as the original is considered to be creep/fatigue life expired. The plant was commissioned in the 1970's prior to the implementation of the PED.	Contract for manufacture is awarded to a fabrication specialist who is not the OEM for the plant, however the design is like for like based on a paper copy of the original manufacturing drawing. Original design and materials standards are no longer in use and have been superseded by a Euro Norm equivalents. Third party design approval is required for the new design and the manufacturer undertakes a Conformity Assessment of the new manifold assembly under module G of the PED. The new assembly is supplied CE marked.	Installation of the manifold on site is carried out under the PSSR (Regulations 4 & 5, & 13) and no assessment of existing systems beyond the limits of the new connection welds is carried out.

Example	Description	Note 1	Note 2
Installation of a Gas Turbine anti- icing system	A steam to air heat exchanger system is installed to prevent icing of GT compressor blades during operation when ambient conditions are below freezing. The systems consists of a steam system with plate heat exchangers to heat a secondary glycol loop flowing through tubular air heater.	All new equipment is supplied CE marked. A Global Conformity Assessment is carried out by the piping installer for the new steam pipework and integration of components to form the anti-icing system. Overall responsibility for assembly, installation and integration with the existing station systems is carried out under end user control.	PSSR regulations 4 and 5 apply to new installation. Written Schemes of Examination are created and updated for existing systems accordingly.
On-site fabrication of a new piping system forming part of an industrial installation	End user appoints a piping contractor to fabricate and install connecting pipework between items of new pressure equipment. End user takes responsibility for site assembling the other items of equipment which make up the assembly of which the piping is part.	The end user has designed the piping layout and carried out a pipe stress analysis in accordance with a recognised pipe standard. Piping contractor builds and installs piping to end user's arrangement drawings	The piping constitutes a new item of pressure equipment within the industrial installation and will therefore require conformity assessment as appropriate. However the resulting assembly consisting of the pipework and the other new items of pressure equipment constitutes an industrial installation under the responsibility of the end user, and therefore does not require conformity assessment.
On-site fabrication of a piping system forming part of an industrial installation	An end user who also operates as a User Inspectorate installs a new system of pipework connecting items of pressure equipment. The pipework falls within PED hazard classification II.	The end user has designed the pipework to a suitable harmonised standard and the pipework is fabricated and installed on site by subcontractors in accordance with the supplied drawings. The end user has chosen to assume responsibility as the manufacturer. The User Inspectorate carries out inspections in accordance with conformity module A2.	The piping constitutes a new item of pressure equipment within the industrial installation and will therefore require Conformity Assessment under the appropriate module. As the end user/manufacturer also operates as a User Inspectorate it is not necessary to employ the services of a notified body and CE marking shall not be applied.

#### A5. Assemblies where the operator and owner are different parties

An owner of a factory employs a facilities management (FM) company to operate and maintain the factory steam system. The owner places an order on the FM company to procure and install a new energy from waste facility to provide additional steam capacity to the factory.

#### Responsibility – scenario 1

The FM company draws up specifications for the boiler and ancillary plant. Orders are placed with a boiler manufacturer and a piping contractor, both of whom assume responsibility for conformity assessment of the items of pressure equipment within their supply. The boiler manufacturer controls and directs the site assembly of the boiler parts, piping, controls and instrumentation, including connecting to the existing steam system.

The boiler manufacturer takes responsibility for global conformity assessment of the assembly as stipulated in the contract. In this situation the FM company has to fulfil the responsibilities of the distributer because it forms the supply chain between the manufacturers and the factory owner. Responsibilities will include ensuring all of the relevant documentation relating to operation, maintenance and conformity assessment of the energy from waste facility are passed to the owner.

#### Responsibility – scenario 2

The FM company draws up specifications for the boiler and ancillary plant. Orders are placed with a boiler manufacturer and a piping contractor, both of whom assume responsibility for conformity assessment of the items of pressure equipment within their supply. The FM company controls and directs the site assembly of the boiler parts, piping, controls and instrumentation, including connecting to the existing steam system.

The FM company is still acting in the capacity of the distributer between the manufacturers and the factory owner and the exclusion relating to assembly of pressure equipment on the site and under the responsibility of a user will not apply. Unless the FM company has a contractual agreement with one of the appointed manufacturers to undertake global conformity assessment of the assembly then the responsibility will lie with the FM company.





Pressure Equipment Consultation Forum



Safety Assessment Federation

Unit 4, First Floor

70 South Lambeth Road Vauxhall

London SW8 1RL

www.safed.co.uk

www.pecf.org.uk

Engineering Equipment

& Materials Users' Association

63 Mark Lane London EC3R 7NQ

www.eemua.org