UK Pressure Equipment

Pressure Equipment (Safety) Regulations

Global Conformity Assessment
A Guide to Site Installed Assemblies

SAFed publication PEDG1 - Edition 02
EEMUA publication 237 - Edition 02

EEMUA SAFed PECF

Foreword

This document has been developed by the Pressure Equipment Consultation Forum (PECF), Safety Assessment Federation (SAFed) and Engineering Equipment and Materials Users Association (EEMUA) in consultation with LRQA and other stakeholders within the pressure equipment industry to help designers, purchasers, installation contractors, users and other parties achieve their legal requirements to ensure pressure equipment can be correctly certified prior to use in the United Kingdom.

This document has been prepared using technical advice provided by the Health and Safety Executive (HSE).

Within this document are references to UK Legislation, GB Regulations and variations of the two. The document was written in August 2023 and at that time recognition of CE marking was to be phased out by 31 December 2024. The relationships of UK Legislation, GB Legislation and CE marking will likely change as technical and administrative divergence commences. The reader is encouraged to confirm the in-force legislation.

Whilst this document primarily relates to pressure systems containing a relevant fluid as defined under the PSSR, where a relevant fluid is not present, other applicable legislation such as PUWER, COMAH and, DSEAR must be consulted. However, the PSSR is regarded as good practice in most applications.

SAFed Publication – PEDG 1 – Edition 02

EEMUA publication 237 – Edition 02

Imprint reference – 08/2024

First published – 06/2024

ISBN: 978-0-85931-250-9

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1. Introduction

This document has been written following a series of meetings and workshops by a wide range of industry stakeholders. The current revision has taken account of the separation activities of the UK from the EU. The European Union Pressure Equipment Directive (EU PED) is legislated for in the UK as the Pressure Equipment (Safety) Regulations 2016 (PE(S)R). These Regulations are ostensibly the same as the EU PED at the time of writing and indeed EU compliant equipment, CE marked, is acceptable in the UK. This situation will continue until the UK Government ends the coexistence period. The use of UKCA marking is a purely UK marking that is not recognised in the EU or elsewhere. In this document we refer to PE(S)R but until technical divergence between UK and EU, much of the guidance would be valid for PED manufacturing however you are advised to seek advice from an EU recognised Conformity Body.

PEDG1 is about assemblies on site and that will be purely under the UK PE(S)R and therefore UKCA marked but may contain CE marked items of pressure equipment and assemblies. This will be a different situation than those practitioners who are assembling for installation in Europe or selling assemblies which are mobile or skid mounted.

The PE(S)R requires that individual items of pressure equipment undergo conformity assessment where appropriate. This also applies to assemblies of pressure equipment which also need to undergo global conformity assessment (GCA) and UKCA 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 PE(S)R 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).

Note: *Some of these issues are addressed by other guides in this series and that since the UK’s exit from the EU, UK Government have commenced the provision of guides specific to the PE(S)R.*

2. Pressure Equipment Assembly Projects and Global Conformity Assessment

Projects involving the assembly and integration of pressure equipment and systems will vary in size, scope and complexity. Some projects can be successfully delivered by a single manufacturer. Where multiple items of equipment and systems are to be integrated it may be necessary to engage with more than one manufacturer or subcontracting organisation who can provide the necessary range of skills and competencies. The regulations require any assembly of equipment to be assessed under a "global conformity assessment" before final certification.

Global conformity assessment basically comprises of three elements:

1. Confirming that each item of pressure equipment has been conformity assessed in accordance with the Pressure Equipment (Safety) Regulations, PE(S)R, and if not, carrying out the assessment.
2. Assessing that the integration of the various sub-assemblies or items of pressure equipment in the assembly is properly addressed. This refers to the essential safety requirements set out in the PE(S)R and could include, for example, design conditions match throughout, Piping & Instrumentation Diagrams reflect integration, process descriptions cover integrated assemblies, operating procedures, mechanical interactions (loads and thrusts, etc.), inspection and testing of the integration process is covered.
3. Assessment that the protection of the overall assembly has been adequately considered against its permissible operating limits. This could include, for example, that hazard analysis has been carried out and the hazards identified have been addressed with appropriate control systems and safety accessories.

The route to successful delivery of a global conformity assessment therefore requires consideration of the optimum contract strategy, nomination of the entity or person who will fulfil the role of manufacturer for global conformity assessment (called the nominated manufacturer in this guidance), understanding of the role and scope of each organisation, their responsibilities and how they will interact with the other parties involved in the delivery of the final integrated assembly and completion of the project.

The following examples of projects help to explain the above.

2.1 Single manufacturer

In its simplest form, a project would involve a single manufacturer making individual items of pressure equipment and then assembling them into the functional whole. The final action would be to place manufactured goods onto the market where it can be procured and put into use by others.

However, before placing the assembly on the market, the manufacturer must declare that it meets the requirements of the PE(S)R and any other applicable Regulations. The single manufacturer is responsible to complete several activities associated with conformity assessment of individual items and the global conformity assessment of the assembly.

The manufacturer's duties for conformity assessment are described in Appendix 1.

Further information on assemblies and global conformity assessment is given in Appendix 2.

2.2 Multiple manufacturers

The project becomes more complex when it involves several manufacturers making individual items of equipment and/or acquiring items of equipment from others that are then all assembled together.

The acquired equipment could be a pressure relief valve, some isolating valves and a complete section of piping. The nominated manufacturer specifies the duty requirements of the pieces of pressure equipment to meet the design requirements. As before, they are responsible for demonstrating that the final assembly meets its conformity assessment. This means that the individual items of pressure equipment, in this case a safety accessory, some pressure accessories and an item of piping, must meet the relevant individual conformity assessment module requirements and the overall assembly must meet the global conformity assessment module requirements.

Pressure equipment is potentially being supplied from several different sources, including other manufacturers, importers and distributors. Whatever the source, the conformity assessment for the final assembly has to be made by the nominated manufacturer.

In this example there are new interfaces to inform and gain documentation from to ensure the conformity process can be completed.

2.3 Multiple sub-assemblies

A project becomes more complex when sub-assemblies from different manufacturers are brought together in one final assembly. This could be a process plant for example.

Whilst each manufacturer is responsible for conformity assessment and global conformity assessment of their own individual sub-assemblies, the nominated manufacturer must be responsible for the overall conformity assessment of the whole assembly - the overall global conformity assessment. The responsibility extends beyond the demonstration that the individual pieces of pressure equipment and assemblies meet conformity requirements; a demonstration that the whole integration of assemblies is safe is needed.

For example, some considerations may be: how operational aspects, instructions, controls and safety systems are integrated across the interacting assemblies to ensure safety of the assembly as a whole; are sufficient safety accessories provided to protect the assembly from exceeding its design conditions under all operational instances.

This is a more onerous responsibility than in the previous examples and requires the nominated manufacturer responsible for the overall global conformity assessment to inform, at an early stage, the other assembly manufacturers of the type and extent of documentation (and knowledge transfer) required of them. It requires a greater degree of forward planning, specifications, agreements, contracts and communications to ensure the nominated manufacturer can complete the overall global conformity assessment in a timely manner.

Figure 1 outlines the process of conformity assessment and global conformity assessment for a new pressure equipment project that involves a number of different manufacturers supplying sub-assemblies. The following sections describe some of the steps in more detail.

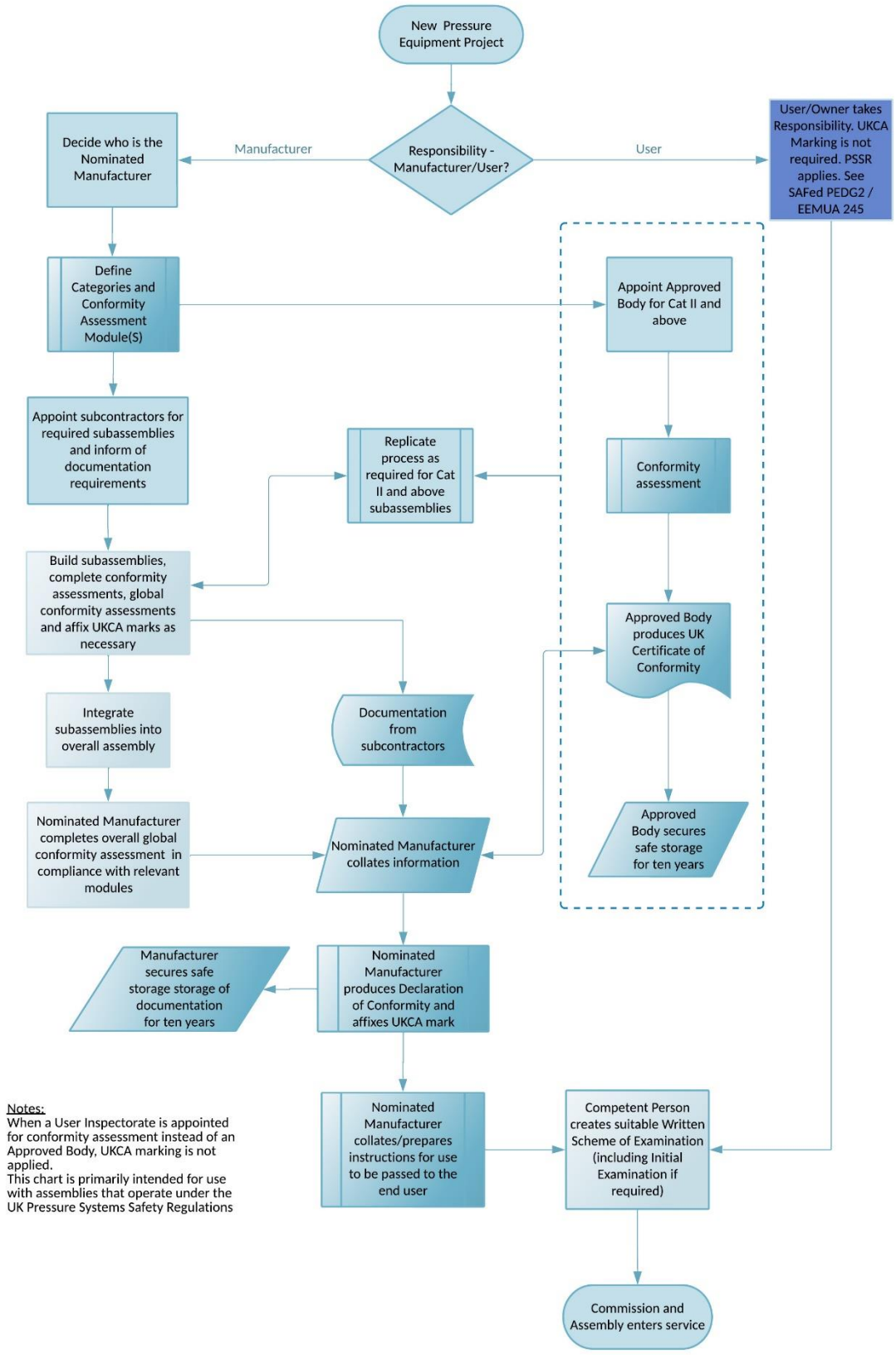

Figure 1: Outline conformity assessment and global conformity assessment processes for a new pressure equipment project involving a number of manufacturers.

3 Sub-Contracting

3.1 Managing Subcontractors

Any manufacturer who is subcontracting work will need to ensure that the conformity assessment is maintained to meet the requirements of the PE(S)R. The supply of information, in both directions, is extremely important.

The nominated manufacturer cannot delegate overall responsibility to subcontractors.

Depending on the hazard category and quality module being followed for manufacture, the involvement of a conformity assessment body may be needed and this may require inspections during manufacture, review of design and manufacturing parameters, and the approval, for example, of welding personnel and procedures, and NDT personnel.

For overall global conformity assessment, subcontractors need to be fully aware of the role they have and the documentation and information they are required to supply to the nominated manufacturer. Depending on the subcontracting arrangements, the nominated manufacturer may not be directly involved in design or manufacture of some of the component parts or sub-assemblies, however, they have overall responsibility for the complete assembly.

3.2 Examples of commonly subcontracted services

A **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 and has contents 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 nominated manufacturer.

A **design consultant** may be appointed by the nominated manufacturer to design part of or the whole of the assembly. The design consultant must be able to support the nominated manufacturer to ensure all aspects of the design comply with the relevant Essential Safety Requirements of the PE(S)R and any other Regulations that might apply. Technical documentation that demonstrates this will need to be provided to the nominated manufacturer.

A **construction 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 construction contractor will have similar duties and responsibilities as the piping contractor with respect to the supply of technical documentation.

4 Assemblies on the site of and under the responsibility of the user

If a user procures several items of pressure equipment and assembles them, or has them assembled, under their responsibility on their site and puts them into service, the PE(S)R does not apply. This is often referred to as an installation. However, these installations should comply with the requirements of national legislation – in Great Britain this would be the Pressure Systems Safety Regulations 2000 (PSSR). If, however, the user creates a piece of pressure equipment on their site (such as a vessel, steam generator or complete piping) then they will become a manufacturer and have to fulfil the associated duties under the PE(S)R.

Note: *Reference should be made to PEDG2 / EEMUA 245 in these circumstances.*

5 Equipment Review and Select Hazard Category

Pressure equipment designed and manufactured to the PE(S)R is categorised according to the level of hazard should failure occur. The categories range from sound engineering practice (SEP), the lowest, to category IV, the highest. The category is a function of the stored energy (e.g. pressure x volume (barg x litres) or pressure x nominal diameter (barg x DN)) and the nature of the contents. The PE(S)R provides charts to determine the categorisation of individual items of pressure equipment.

For successful completion of Global Conformity Assessment, knowledge of the conformity assessment completed for all parts of the assembly is needed. The requirements for the GCA depend upon the hazard category for the items comprising the assembly.

5.1 Categorisation of an assembly and conformity assessment

It should be noted that for all categories (I to IV), the responsibilities of the manufacturer are predominately the same. The involvement of an Approved Body [1], User Inspectorate or Recognised Third-Party Organisation (RTPO) commences from Category II. For assemblies classified according to sound engineering practice (SEP), the manufacturer still has obligations before placing equipment on the market. There is however, no formal requirement to undertake a global conformity assessment in this instance, but it is considered good practice to follow the principles of global conformity assessment.

Note: *Although PE(S)R does not formally require a global conformity assessment for pressure assemblies categorised under Sound Engineering Practice (SEP), it would be expected that the nominated manufacturer provides sufficient information to the user, so as to ensure the basis of safety is clearly understood for the limitations of the intended application(s). In other words, a design risk assessment should still be undertaken by the nominated manufacturer, following the guidelines contained in this document.*

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 also be assessed according to the highest category applicable to the equipment to be protected.

- The Approved Body or User Inspectorate should be appointed after the categorisation of the assembly has been confirmed by the manufacturer and the conformity assessment module determined.
- For information regarding requirements for pressure equipment and assemblies to comply with sound engineering practice (SEP) reference should be made to the PE(S)R.
- The overall assembly must be conformity assessed either under PE(S)R (global conformity assessment) or similarly assessed by the end user to meet in-service requirements (e.g. Pressure Systems Safety Regulations) when on the user's site and under their control, in the case of an industrial installation (refer to EEMUA 245 / SAFed PEDG2).

[1] The term Approved Body relates to the UK PE(S)R. In the EU the term Notified Body is used as the nearest equivalent to the UK term.

5.2 Components or sub-assemblies

The category of each item of equipment including pressure accessories and piping is determined by its manufacturer. That category cannot be changed and is not re-assessed for integration into an assembly. The assembly integration follows a conformity route suitable for the highest category for the equipment (excluding the safety devices) and one of the activities is to ensure the compatibility of each item with the service conditions of the assembly.

As part of the assessment of the equipment making up the assembly, the following documentation and verification will likely be required:

- Declarations of conformity to show that the components or sub-assemblies are in compliance with applicable legal requirements and have been correctly brought onto the market.
- The required marking (allowable limits, etc.), Original Equipment Manufacturer (OEM) operating instructions, maintenance schedules and warnings for the equipment.
- Components or sub-assemblies to be checked for signs of damage during transport or installation (and paperwork provided to acknowledge this has been undertaken).
- Where any damage has been rectified, validation of the repairs would normally include the appropriate documentation (Non-Destructive Testing reports, Welding qualifications / procedures, etc.).

Further information is provided in Appendix 3.

6 Global Conformity Assessment

As already discussed, an assembly of pressure equipment undergoes global conformity assessment. Details are provided in Appendix 2. The complexity of the project determines the complexity of the assessment. For a simple assembly there will be one global conformity assessment. Where sub-assemblies are brought together, each sub-assembly will undergo global conformity assessment by its manufacturer (before a Declaration of Conformity can be made) and the final integration of sub-assemblies will undergo an overall global conformity assessment by the nominated manufacturer (see Figure 1).

Often, in complex projects, protection against identified hazards is provided not in every sub-assembly, but in the overall assembly. Where this is the case, it is important to ensure it is accounted for in the project planning and overall design concept. Where this applies to a sub-assembly it should be identified as an exclusion on that declaration of conformity. The nominated manufacturer can address the overall protection in the overall global conformity assessment.

6.1 Connection to an existing installation

This situation commonly arises where a new assembly has to be “bolted on or otherwise connected” to an existing installation. The suitability of the existing system for the addition must form part of the global conformity assessment of the new assembly.

In particular the hazard and risk analysis should consider 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). Figure 2 provides an example of delineation of responsibility between in-service modification and new 'UKCA' 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.

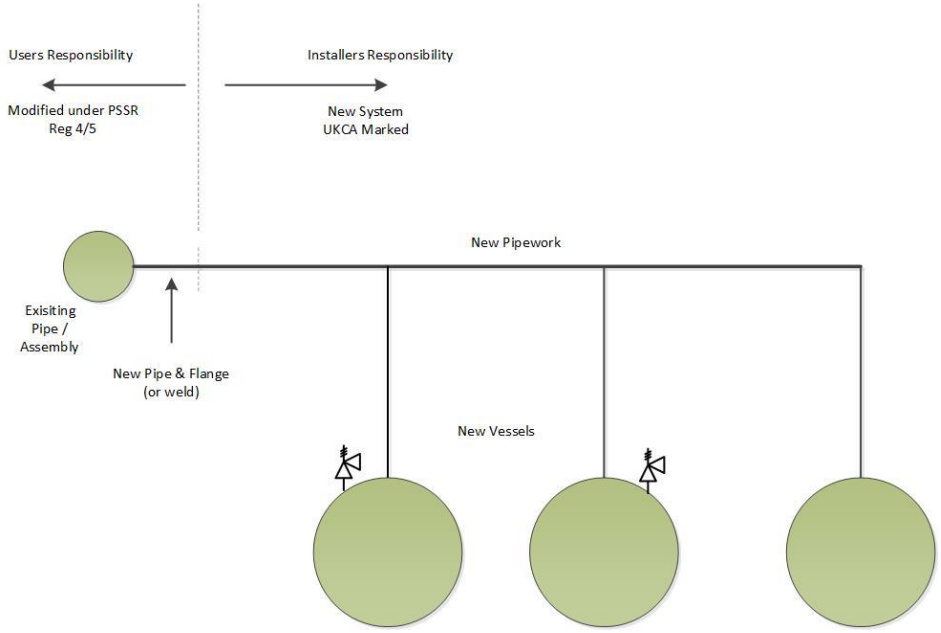

Figure 2: How a new assembly should be treated when being connected as an extension to an existing installation.

7 Application of the UKCA Marking / Declaration of Conformity

Once the global conformity assessment has been completed, and the assembly complies with the provisions of the PE(S)R, the nominated manufacturer will be required to affix the UKCA marking to the overall assembly and draw up a declaration of conformity. The UKCA marking will need to be accompanied by the identification number of the Approved Body which was involved at the production control phase (i.e. monitoring of the final assessment, product verification or surveillance of an approved quality assurance system).

By affixing the UKCA to the assembly the nominated manufacturer is demonstrating that their equipment conforms with the regulatory requirements (as applicable).

The nominated manufacturer must produce the technical documentation and draw up a written declaration of conformity, both shall be retained for 10 years after the assembly has been placed on the market.

8 Supply of Original Equipment Manufacturers Operation Instructions

Anyone who supplies a pressure system or its component parts (including those manufactured on-site) should provide sufficient information to allow the pressure assembly to be operated safely.

Instructions for use (including the limitations of use) must be provided by the nominated manufacturer who is responsible for the overall co-ordination of documentation. Instructions should be compiled within an Operating and Maintenance (O&M) manual.

The O&M Manual is a written document that will be issued at the handover stage of the site assembly. They are written to exchange critical information from the various pressure equipment suppliers and those integrating the parts as a functional whole, with detailed information on the equipment and systems that have been designed, installed, and commissioned/set to work.

The manuals will provide the end-user with up to date, as-built information relating to how the pressure equipment and systems have been designed, installed, commissioned, and set to work, allowing an efficient understanding of the operation, safety protection and maintenance requirements.

The O&M instructions compile all the information on the operation, maintenance, decommissioning of the assembly. It is recommended that the instructions for use include:

- Details and description about the pressure assembly construction
- Health and safety information
- Comprehensive details of important operating procedures and parameters.
- Process flow diagrams
- Piping & Instrumentation diagrams
- Information relating to protection, e.g. safety valve set pressure, capacity, maximum flow of fluid
- Drawings and specifications about the components forming the assembly together with details of spare parts
- Corrective and recommended preventive maintenance programs, including schedules, procedures, and test requirements
- Emergency procedures that outline the safety measures, the people, organisations, and agencies that need to be notified in case of failure
- Manufacturer and/or supplier’s contact details
- Conformity certification
- Commissioning and testing results
- Guarantees and warranties, test certificates
- Requirements for equipment and asset decommission, demolition, and disposal

Note: *The PE(S)R has a minimum requirement for the content of instructions (Ref: Schedule 2, Part 3, Paragraph 30).*

9 Pressure Testing

Pressure testing is usually a requirement of the manufacture of pressure equipment. It may require to be witnessed by an Approved Body as part of conformity assessment.

The pressure testing of assemblies should be considered when drawing up the contract for the final assembly, clarifying who will carry out this work and whether this is part of the final assembly, commissioning or handover phase.

Each item of pressure equipment shall be subject to a pressure test and the integration of items of pressure equipment should be assessed as part of the global conformity assessment.

A hydraulic pressure test should always be carried out in preference to a gas pressure test or other tests, wherever practicable. The hydraulic pressure test may only be replaced by other appropriate tests, if it is detrimental to the equipment or not feasible.

Where a final pressure test is not possible, other tests must be shown by the manufacturer in a test concept and defined in a test plan. To confirm the measures planned, the test plan should be approved by an Approved Body. Other tests usually include an increase in the amount and/or type of inspection (e.g. additional NDT) and higher quality requirements in the area of specification and production.

The pressure test normally takes place as part of the commissioning phase of a pressure system.

Note: *Pressure testing carries inherent safety issues, suitable safety measures must be in place before during and after testing. Reference should be made to:*

- *HSE Publication GS4 Safety requirements for pressure testing - HSE Publication GS4*
- *EEMUA Publication 168 Guide to pressure testing of equipment*
- *SAFed PSG-21 Guidance for Competent Persons witnessing pressure tests*

10 Commissioning

Commissioning work should be undertaken formally, by following a commissioning plan. This needs to be documented, together with ensuring the results of the commissioning phase are recorded. Communication, co-ordination and planning are critical to ensure safety during commissioning because:

a) commissioning can involve many people, sometimes from different disciplines and different companies; and

b) the behaviour of the pressure assembly might not have been fully validated, therefore mistakes in the design, installation or software can cause unexpected behaviour. Any discrepancies found during commissioning should be fed back to ensure that the hazards from the use of pressure equipment are reduced.

c) protection systems may not be fully tested or calibrated.

d) a commissioning plan effectively identifies the tasks to be completed, the order in which they are to be carried out and the agreed method and interaction with others on how the work is to be undertaken - refer to Clause 7.6.2 of BS 14100 for further information.

The documentation required for commissioning can be used in developing the initial Written Scheme of Examination required under the Pressure Systems Safety Regulations.

It is important to ensure that only persons with the necessary competence are able to carry out work activities involving placing the pressure system into service. Establishing competency will be based on the type of pressure assembly and the learning gained

during commissioning. Competence will involve consideration of the knowledge, skills and experience of all persons involved.

Under the Pressure Systems Safety Regulations, the safe operating limits of the pressure system should be clearly established by the end user, referring to data from the original pressure equipment manufacturer, or information established as part of commissioning - to ensure the assembly is operated within the confines of the specified limitations of use. It will require the end user to have carried out an adequate assessment on how the risks are controlled as a result of the fluid, pressure, volume and temperature applied to the structural and safety integrity of the pressure components forming the overall assembly.

11 Written Scheme of Examination (as applicable)

Before putting the pressure assembly into service under the Pressure Systems Safety Regulations, the user must ensure that the Safe Operating Limits are established and a Written Scheme of Examination (WSE) is produced that applies to the particular pressure system. This WSE should be drawn up and/or certified by a Competent Person as appropriate. Typically, this is required before the “relevant fluid” is introduced for the first time (e.g. hot testing).

To enable the WSE to be drawn up, OEM documentation, details of design standards, construction drawings and safe operating limits should be made available.

Reference should be made to PEDG3 / EEMUA 248 (to be issued shortly) for further information.

Appendix 1 - Conformity Assessment - Manufacturer's Duties

i. Analyse the hazards and risks the equipment presents in order to identify those which apply on account of pressure, and then, design and construct it taking account of that analysis and to meet the essential safety requirements of the Regulations.

ii. Assign the PE(S)R hazard category for the equipment, which is a function of pressure, fluid state, fluid threat, and defining equipment dimensions. The categories range from Sound Engineering Practice (SEP), the lowest category, then upwards through I, II, III and IV. The higher the hazard category the more extensive will be the quality assurance requirements.

iii. Select a conformity assessment module, appropriate to the hazard category, that will be followed to validate the design, materials, production, inspection, and testing (the quality assurance requirements).

iv. Appoint an Approved Body (for hazard category II and above).

v. Fulfil all the requirements of the conformity assessment module throughout the design, material procurement, manufacture and assembly, inspection, and testing, engaging with the Approved Body as and when required.

vi. Draw up the relevant technical documentation required to demonstrate conformity, referred to in the conformity assessment module (often referred to as the technical file).

vii. Produce a Declaration of Conformity once the Approved Body has issued a Certificate of Conformity (for Category II and above).

viii. Affix the UKCA marking as appropriate (not SEP).

ix. Provide appropriate instructions and safety information.[2]

In this example, all the fabrication / manufacturing has been considered to be contained within one organisation and the production of all documentation is self-contained.

[2] The Instructions are an important input to the PSSR, or other in-use Regulations and must be relevant to the actual assembly.

Appendix 2 - Assemblies and Global Conformity Assessment of Assemblies [PE(S)R - Regulation 45]

Definition of an assembly

Items of pressure equipment form an assembly if:

- They are integrated *(designed and connected to be compatible with each other).*
- They are functional *(together, they achieve specific overall objectives and could be put into operation).*
- They form a whole *(all the items which are necessary for the assembly to function and be safe are present).*
- The resulting assembly is placed on the market, in which case the nominated manufacturer shall have subjected the assembly to a global assessment procedure.

Note: *It is irrelevant whether completion of the assembly takes place at the manufacturer's workshop or by the manufacturer on site.*

Application and limits of an assembly

The Regulations do not limit the extent of an assembly, which can range from simple standard products up to large complex industrial plants.

Note: *An assembly itself can be composed of other assemblies and further items of pressure equipment*

For the Final (or overall) Assembly / Global Assembly, there are two possible cases:

- When a *"Manufacturer"* places on the market a product as a final assembly consisting of assemblies and items of pressure equipment, intended to be put into service as such, he has to perform the global conformity assessment resulting in the *"UKCA marking"* of the final assembly.[3]

  Note: *If some of the constituent sub-assemblies are not "UKCA marked", the individual items of pressure equipment shall be included in the overall global conformity assessment.*
- When a *"User"* / "Duty Holder" takes the responsibility for the final assembly, it constitutes as an *"installation".*

  [3] Reference to UKCA marking includes the acceptable product conformity marking in the UK

Global conformity assessment of assemblies

Assemblies of pressure equipment shall be subjected to the following three-stage global conformity assessment procedure comprising:

a) Assessment of each item of pressure equipment making up the assembly *[as referred to in Regulation 6 (i.e. a component that requires application of the essential safety requirements)]* which has not already been previously subjected to a conformity assessment procedure and to a separate UKCA marking [3]; the assessment procedure shall be determined by the category of each item of equipment:

   - A check shall be made that all items are appropriately marked and have been issued with a Declaration of Conformity (you are advised to request

the Declaration of Conformity since there is no obligation for the manufacture to supply one contractually).

- Items of pressure equipment not UKCA marked [3] shall each be subject to a conformity assessment procedure appropriate to their own individual category *(which may be based on the conditions of the assembly).*

b) The integration of the component parts of the assembly *[as referred to in paragraphs 14 and 28 of Schedule 2 (e.g. the essential safety requirements)]* will need to be assessed according to the highest category applicable to the equipment concerned:

- Hazard analysis to identify any additional hazards arising from the integration of component parts over and above those already determined.
- Provisions for safe handling and operation.
- Assemblies of pressure equipment should be so designed that:
  - The components to be assembled are suitable and reliable for their intended application / duty.
  - All the components are properly integrated and assembled in an appropriate manner.
- Provisions for filling and discharge.
- Correct assembly / installation of the pressure equipment.

c) The protection of the assembly against exceeding the permissible operating limits *[as referred to in paragraphs 7, 12 and 13 of Schedule 2 (e.g. the essential safety requirements)]* must be assessed according to the highest category applicable to the equipment to be protected:

- The global assembly should be fitted with, or provision made for, suitable protective devices, unless the equipment is intended to be protected by other protective devices within the global assembly.
- Suitable device(s) or combination of devices should be determined on the characteristics of the equipment within the global assembly.
- Suitable protective devices and combinations thereof comprise:
  - Regulating devices *(Control Valves).*
  - Safety devices *(e.g. Pressure Safety Valves, Bursting Discs).*
  - Control systems which either activate the means for correction or provide for shutdown or shutdown and lockout *(eg Trips / Interlocks, Safety Instrumented Systems (SIS) / Emergency Shutdown (ESD), High Integrity Pressure Protection System (HIPPS)).*

The minimum required information during the conformity assessment process (typically during the design phase) is detailed in Appendix 3.

Appendix 3 - Required Information During the Conformity Assessment Stages

Note: *this list is not exhaustive, and the levels of information may differ depending on the potential risks from the assembly.*

1. General description of the scope of the pressure assembly including:
    - Description of the process.
    - Process Flow Schemes/ Process Engineering Flow Schemes (PFS/ PEFS).
    - Piping and Instrumentation Diagrams (P&IDs) on which the systems will be manufactured.
    - The terminal points.
    - Other relevant legislation within scope of contract.
2. Details of how Essential Safety Requirements (ESRs) in PE(S)R for the assembly, will be addressed:
    - List of standards by which the integration and protection has been designed and constructed.
    - Where designated standards are not used, sufficient written description on how the applicable ESRs are addressed.
3. List of all individual items of equipment in the overall pressure assembly to include:
    - Relevant process information (Design Pressure (PS), Design Temperature (TS), Volume (V) / Nominal Piping size (DN), content, fluid, category, etc.).
    - Which items are to be purchased from suppliers with UKCA marking [3], partial assemblies or those to be manufactured by the manufacturer of the assembly (e.g. the assembly pipework).
    - Details of the intended provisions to ensure all items will be:
        i) correctly specified, and
        ii) checked to ensure compliance with all applicable legislation.
4. Reasonably Foreseeable Hazard analysis of the assembly (part of the ESR's):
    - Assessment of the intended use and foreseeable misuse of the pressure system
    - Consideration of circumstances such as fire, loss of coolant system, power failure, etc. to identify the possible failure modes.
    - Pipework stress analysis reports.
    - Pump curves detailing the intended performance ranges.
    - Safety systems.
5. The Global Conformity Assessment (GCA) strategy must be based on the highest safety category of any included component. The GCA strategy can address the system as a whole or may be based on individual parts of that overall assembly, so long as these are assessed against the highest category of the overall system.

    Where additional plant is to be tied into an existing system then the responsibility for any tie-in to the existing pressure systems will be part of the GCA for the new assembly.

6. Protection philosophy (sometimes referred to as Safety Narratives) including, Information relating to protection, e.g. safety valve set pressure, capacity, maximum flow of fluid.
7. Information relating to control and safety loops, e.g.:
    - Circuit and logic diagrams
    - Device list, e.g. temperature, pressure limiters
    - Safety Integrity Levels (SIL) classification and SIL report
    - Assignment of safety levels for the protection functions
    - User program (logic diagram)
    - Device and system manual

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Pressure Equipment Consultation Forum

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