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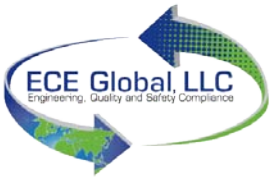

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CE Marking Approval Process

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Design Review

1. Codes and Standards that have been applied for Design, Materials, Inspections, and Testing
2. Design Parameter
    a. Pressure
    b. Temperature
    c. Volume
    d. Fluid
3. Environmental Conditions (Wind, Snow, Earthquake, Excessive Heat or Cold, etc.)
4. Operating Conditions (Potentially Explosive Atmospheres, Pressure Surge (Water Hammer Effect), Maintainability, etc.)
5. Maintenance and Inspection Requirements

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Review of Pressure Bearing Parts

1. Classification according to PED (determination if SEP, Cat. I,II, III or IV applies)
2. Material Suitability
    a. Stress / Strength under all foreseeable conditions
    b. Deterioration Mechanisms (Corrosion, Erosion, H2 or H2S Cracking, etc.)
    c. Hardening over time
    d. Fabrication Suitability (forming ability, welding ability, etc.)
    e. Evidence for Quality Level (affidavit, Inspection Certificates or Material Testing Reports of Specific or Non-Specific Product Controls)

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Determination of the PED Classification based on the Equipment Category

I = Module A
II = Module A1, D1, E1
III = Module B1 + D, B1 + F, B + E, B + C1, H
IV = Module B + D, B + F, G, H1

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Risk Assessment

1. Assessing the pressure equipment / assembly to determine its potential for risk related to all foreseeable conditions during normal operations, malfunctioning, operator errors, maintenance and inspection tasks, others
2. Documenting all steps and evaluating the potential risk
3. Applying the results to the design input phase, manufacturing, operation and inspection & testing, maintenance

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4. When hazardous situations cannot be resolved via design, manufacturing or operations changes, residual conditions must be brought to the attention of the client via warning labels, operation instructions, etc.

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Fabrication

1. Any manufacturing process / step must allow diligent traceability. For category II, III and IV equipment or assemblies, traceability will be audited by a European Notified Body.
2. Welding, Forming and Heat-Treatment requires special attention and approvals, when ever the conditions of the based material can or will be changed due to the applied process. For category II, III and IV equipment or assemblies, traceability will be audited by a European Notified Body.

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Quality Assurance

1. Depending on the Equipment Category per PED (see item 3) and the selected Quality Assurance System Process, the QA System must be audited by a European Notified Body.
2. Module G can be applied to all four categories (I, II, III and IV), since it is a single unit verification and not a QA system based approval process. It allows a manufacturer to get products to their clients, without the time and cost consuming approval of quality systems, however with the required approval according to European Directives for CE Marking.

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PED: Information related to Design Requirements

2 Design

2.1. General

The pressure equipment must be properly designed taking all relevant factors into account in order to ensure that the equipment will be safe throughout its intended life.

The design must incorporate appropriate safety coefficients using comprehensive methods, which are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.

2.2. Design for adequate strength

2.2.1. The pressure equipment must be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors must be taken into account:

- internal/external pressure,
- ambient and operational temperatures,
- static pressure and mass of contents in operating and test conditions,
- traffic, wind, earthquake loading,
- reaction forces and moments which result from the supports, attachments, piping, etc.,
- corrosion and erosion, fatigue, etc.,
- decomposition of unstable fluids.

Various loading, which can occur at the same time, must be considered, raking into account the probability of their simultaneous occurrence.

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2.2.2. Design for adequate strength must be based on:

- as a general rule, a calculation method, as described in 2.2.3, and supplemented if necessary by an experimental design method as described in 2.2.4, or
- an experimental design method without calculation, as described in 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar·L or the product PS·DN less than 3 000 bar.

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2.2.3. Calculation method

(a) Pressure containment and other loading aspects

The allowable stresses for pressure equipment must be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors must be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models and the properties and behaviour of the material.

These calculation methods must provide sufficient safety margins consistent, where applicable, with the requirements of section 7.

The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:

- design by formula,
- design by analysis,
- design by fracture mechanics;

(b) Resistance

Appropriate design calculations must be used to establish the resistance of the pressure equipment concerned.

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In particular:

- the calculation pressures must not be less than the maximum allowable pressures and take into account static head and dynamic fluid pressures and the decomposition of unstable fluids. Where a vessel is separated into individual pressure-containing chambers, the partition wall must be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,
- the calculation temperatures must allow for appropriate safety margins,
- the design must take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
- the maximum stresses and peak stress concentrations must be kept vvithin safe limits,
- the calculation for pressure containment must utilize the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in section 4 together with appropriate safety factors. Material characteristics to be considered, where applicable, include:
- yield strength, 0,2% or 1,0% proof strength as appropriate at calculation temperature,
- tensile strength,
- time-dependent strength, i.e. creep strength,
- fatigue data,

- Young's modulus (modulus of elasticity),
- appropriate amount of plastic strain,
- impact strength,
- fracture toughness,
- appropriate joint factors must be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged;
- the design must take appropriate account of all reasonably foreseeable degradation mechanisms (e.g. corrosion, creep, fatigue) commensurate with the intended use of the equipment. Attention must be drawn, in the instructions referred to in section 3.4, to particular features of the design which are relevant to the life of the equipment, for example:
- for creep: design hours of operation at specified temperatures,
- for fatigue: design number of cycles at specified stress levels,
- for corrosion: design corrosion allowance;

(c) Stability aspects
Where the calculated thickness does not allow for adequate structural stability, the necessary measures must be taken to remedy the situation taking into account the risks from transport and handling.

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2.2.4. Experimental design method

The design of the equipment may be validated, in all or in part, by an appropriate rest program carried out on a sample representative of the equipment or the category of equipment.

The test program must be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.

This program must define test conditions and criteria for acceptance or refusal. The actual values of the essential dimensions and characteristics of the materials, which constitute the equipment tested, shall be measured before the rest.

Where appropriate, during tests, it must be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.

The test program must include:

(a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit significant leaks or deformation exceeding a determined threshold.

The test pressure must be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes; it must take into account the differences between the test and design temperatures;

(b) where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance hold time at specified temperatures, number of cycles at specified stress-levels, etc.;

(c) where necessary, additional tests concerning other factors referred to in 2.2.1 such as corrosion, external damage, etc.

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2.3. Provisions to ensure safe handling and operation

The method of operation specified for pressure equipment must be such as o preclude any reasonably foreseeable risk in operation of the equipment. Particular attention must be paid, where appropriate, to:

- closures and openings,
- dangerous discharge of pressure relief blow-off,
- devices to prevent physical access whilst pressure or a vacuum exists,
- surface temperature taking into consideration the intended use,
- decomposition of unstable fluids.

In particular, pressure equipment fitted with an access door must be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any hazard.

Furthermore, where the opening can be operated quickly, the pressure equipment must be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a hazard.

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2.4. Means of examination

(a) Pressure equipment must be designed and constructed so that all necessary examinations to ensure safety can be carried out;

(b) Means of determining the internal condition of the equipment must be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be carried out safely and ergonomically;

(c) Other means of ensuring the safe condition of the pressure equipment may be applied:

- where it is too small for physical internal access, or
- where opening the pressure equipment would adversely affect the inside, or
- where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.

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2.5. Means of draining and venting

Adequate means must be provided for the draining and venting of pressure equipment where necessary:

- to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions. All stages of operation and testing, particularly pressure testing, must be considered,
- to permit cleaning, inspection and maintenance in a safe manner.

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2.6. Corrosion or other chemical attack

Where necessary, adequate allowance or protection against corrosion or other chemical attack must be provided, taking due account of the intended and reasonably foreseeable use.

2.7. Wear

Where severe conditions of erosion or abrasion may arise, adequate measures must be taken to:

- minimize that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials,
- permit replacement of parts which are most affected,
- draw attention, in the instructions referred to in 3.4, to measures necessary for continued safe use.

2.8. Assemblies

Assemblies must be so designed that:

- the components to be assembled together are suitable and reliable for their duty,
- all the components are properly integrated and assembled in an appropriate manner.

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2.9. Provisions for filling and discharge

Where appropriate, the pressure equipment must be so designed and provided with accessories, or provision made for their fitting, as to ensure safe filling and discharge in particular with respect to hazards such as:

(a) on filling:
  - overfilling or over pressurization having regard in particular to the filling ratio and to vapor pressure at the reference temperature,
  - instability of the pressure equipment;

(b) on discharge: the uncontrolled release of the pressurized fluid;

(c) on filling or discharge: unsafe connection and disconnection.

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2.10. Protection against exceeding the allowable limits of pressure equipment

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment must be fitted with, or provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other protective devices within an assembly.

The suitable device or combination of such devices must be determined on the basis of the particular characteristics of the equipment or assembly.

Suitable protective devices and combinations thereof comprise:

(a) safety accessories as defined in Article 1, section 2.1.3,

(b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2. 11. Safety accessories

2.11.1. Safety accessories must:

- be so designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable,
- be independent of other functions, unless their safety function cannot be affected by such other functions,
- comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.

2.11.2. Pressure limiting devices

These devices must be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; however a short duration pressure surge in keeping with the specifications laid down in 7.3 is allowable, where appropriate.

2.11.3. Temperature monitoring devices

These devices must have an adequate response time on safety grounds, consistent with the measurement function.

2.12. External fire

Where necessary, pressure equipment must be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to its intended use.

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