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Based upon Article 20, paragraph 4 of the Law on product safety (Official Gazette of the Republic of Macedonia No. 33/2006), the Minister of Economy has adopted this

RULEBOOK CONCERNING PRESSURE EQUIPMENT

I. GENERAL PROVISIONS

Article 1

This Rulebook prescribes the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0,5 bar.

Article 2

For the purposes of this Rulebook, the following terms shall mean:

1. 'Pressure equipment` shall mean vessels, piping, safety accessories and pressure accessories.
Where applicable, pressure equipment shall include elements attached to pressurized parts such as: flanges, nozzles, couplings, supports, lifting lugs, etc. ;
2. 'Vessel` shall mean a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment. A vessel may be composed of more than one chamber;
3. 'Piping` shall mean piping components intended for the transport of fluids, when connected together for integration into a pressure system. Piping shall include in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate. Heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping;
4. 'Safety accessories` shall mean devices designed to protect pressure equipment against the allowable limits being exceeded. Such devices include:
 - devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and
 - limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as: pressure switches or temperature switches or fluid level switches and 'safety related measurement control and regulation (SRMCR) devices`;
5. 'Pressure accessories` shall mean devices with an operational function and having pressure-bearing housings;
6. 'Assemblies` shall mean several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;
7. 'Pressure` shall mean pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value;

8. 'Maximum allowable pressure PS` shall mean the maximum pressure for which the equipment is designed, as specified by the manufacturer. It is defined at a location specified by the manufacturer which should be the location of connection of protective and/or limiting devices or the top of equipment or if not appropriate any point specified;
9. 'Maximum/minimum allowable temperature TS` shall mean the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer;
10. 'Volume (V)` shall mean the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts;
11. 'Nominal size (DN)` shall mean a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size. It is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions. The nominal size is designated by DN followed by a number;
12. 'Fluids` shall mean gases, liquids and vapours in pure phase as well as mixtures thereof. A fluid may contain a suspension of solids;
13. 'Permanent joints` shall mean joints which cannot be disconnected except by destructive methods;
14. 'Approval for materials` shall mean a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonized standard developed on the basis of the European harmonised standards (hereinafter: national standard);

Article 3

The provisions of this Rulebook shall not apply for:

1. Pipelines comprising of piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines. This exclusion does not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
2. Networks for the supply, distribution and discharge of water and associated equipment and headraces such as: penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
3. Equipment covered by the regulations on simple pressure vessels;
4. Equipment covered by regulations relating to aerosol dispensers;
5. Equipment intended for the functioning of vehicles (defined by regulations on type-approval):
 - motor vehicles and their trailers,
 - wheeled agricultural or forestry tractors,
 - two or three-wheel motor vehicles.

6. Equipment classified as no higher than category I under the provisions of Article 58 of this Rulebook and covered by one of the following regulations on:
 - machinery safety,
 - placement on the market of lifts and safety devices for lifts,
 - electrical equipment designed for use within certain voltage limits,
 - medical devices,
 - appliances burning gaseous fuels,
 - equipment and protective systems intended for use in potentially explosive atmospheres.
7. Equipment intended for military purposes;
8. Items specially designed for nuclear use, failure of which may cause an emission of radioactivity;
9. Well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure. This comprises the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
10. Equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor. Such equipment may include:
 - engines including turbines and internal combustion engines,
 - steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;
11. Blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel and non-ferrous metals;
12. Enclosures for high-voltage electrical equipment such as: switchgear, control gear, transformers, and rotating machines;
13. Pressurized pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;
14. Ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
15. Pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
16. Exhaust and inlet silencers;
17. Bottles or cans for carbonated drinks for final consumption;
18. Vessels designed for the transport and distribution of drinks having a PS·V of not more than 500 bar·L and a maximum allowable pressure not exceeding 7 bar;

19. Equipment covered by the European Agreement concerning the International Carriage of Dangerous fluids by Road (ADR), the Regulations concerning the International Carriage of Dangerous fluids by Rail (RID), the International Maritime Dangerous fluids Code (IMDG) and the International Civil Aviation Organisation Convention (ICAO);

20. Radiators and pipes in warm water heating systems;

21. Vessels designed to contain liquids with a gas pressure above the liquid of not more than 0,5 bar.

Article 4

The pressure equipment and the assemblies covered by this Rulebook may be placed on the market and put into service only if, when properly installed and maintained and used for their intended purpose, they do not endanger the health and safety of persons and, where appropriate, domestic animals or property.

The provisions of this Rulebook shall not affect the entitlement to lay down such requirements as deemed necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment or assemblies in question provided that this does not mean modifications to such equipment or assemblies in a way not specified in this Rulebook.

Article 5

Pressure equipment or assemblies which are not in conformity with the provisions of this Rulebook may be shown at trade fairs, exhibitions, demonstrations, etc., provided that a visible sign clearly indicates their non-conformity and their non-availability for sale until brought into conformity by the manufacturer or by his authorized representative established within the Republic of Macedonia.

During trade fairs, exhibitions, demonstrations etc., appropriate safety measures shall be taken in order to ensure the safety of persons which requires an appropriate approval from the competent authority designated for technical inspection.

Article 6

All information and instructions essential for right and safe utilization of the pressure equipment and assemblies laid down in the Articles 42 and 43 of this Rulebook, shall be written in Macedonian language and its Cyrillic alphabet, provided such equipment is intended for installation within the Republic of Macedonia.

II. ESSENTIAL SAFETY REQUIREMENTS

1. Technical requirements

Article 7

The pressure equipment referred to in 1, 2, 3 and 4 in this Article should satisfy the essential requirements set out in this Rulebook:

1. Vessels, except those referred to in point 2 in this Article for:

(a) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure, (1 013 mbar) within the following limits:

- for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar·L, or with a pressure PS greater than 200 bar (Appendix I, Table 1),
- for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar·L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus (Appendix I, Table 2),

(b) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

- for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar·L, or with a pressure PS greater than 500 bar (Appendix I, Table 3),
- for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar·L, or with a pressure PS greater than 1 000 bar (Appendix I, Table 4).

2. Fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super-heated water at temperatures higher than 110°C having a volume greater than 2 L, and all pressure cookers (Appendix I, Table 5).

3. Piping intended for:

(a) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure, (1013 mbar) within the following limits:

- for fluids in Group 1 with a DN greater than 25 (Appendix I, Table 6),
- for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Appendix I, Table 7);

(b) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

- for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Appendix I, Table 8),
- for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Appendix I, Table 9).

4. Safety and pressure accessories intended for equipment covered by points 1, 2 and 3 from this Article, including where such equipment is incorporated into an assembly.

Article 8

The assemblies which include at least one item of pressure equipment covered by Article 7 of this Rulebook and which are listed in points 1, 2 and 3 of this Article should satisfy the essential requirements set out by the provisions of this Rulebook:

1. Assemblies intended for generating steam or superheated water at a temperature higher than 110°C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating,

2. Assemblies other than those referred to in point 1, if the manufacturer intends them to be placed on the market and put into service as assemblies,

3. By way of derogation from the introductory paragraph to this Article, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L should comply with the essential requirements referred to in the provisions from the Articles 27, 28, 29, 30, 43 and Article 48, paragraph 2, points 1 to 4 of this Rulebook.

Article 9

Pressure equipment and/or assemblies below or equal to the limits in points 1, 2 and 3 from Article 7 and Article 8 of this Rulebook, respectively should be designed and manufactured in accordance with the sound engineering practice in order to ensure safe use.

Pressure equipment and/or assemblies from paragraph 1 of this Article shall be accompanied by adequate instructions for use and should bear markings to permit identification of the manufacturer or of his authorized representative established in the Republic of Macedonia or EU.

Such equipment and/or assemblies should not bear the conformity marking referred to in Articles 187 to 191 of this Rulebook.

2. Application of essential requirements

Article 10

The obligations arising from the essential requirements listed in this Chapter II for pressure equipment also apply to assemblies where the corresponding hazard exists.

The obligations laid down in these essential requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under conditions which are reasonably foreseeable by the manufacturer.

The manufacturer is under an obligation to analyse the hazards in order to identify those which apply to his equipment on account of pressure in order to later design and construct it taking account of his risk analysis.

The essential requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.

Article 11

Pressure equipment should be designed, manufactured and checked, and if applicable equipped and installed, in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.

In choosing the most appropriate solutions, the manufacturer should apply the principles set out below in the following order:

- eliminate or reduce hazards as far as is reasonably practicable,
- apply appropriate protection measures against hazards which cannot be eliminated,
- where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.

Where the potential for misuse is known or can be clearly foreseen, the pressure equipment should be designed to prevent danger from such misuse or, if that is not possible, adequate warning given that the pressure equipment should not be used in that way.

3. Design

3. 1. Scope

Article 12

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

3. 2. Design for adequate strength

Article 13

The pressure equipment should be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors should 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 loadings which can occur at the same time should be considered, taking into account the probability of their simultaneous occurrence.

Article 14

Design for adequate strength should be based on:

- as a general rule, a calculation method, as described in Articles 15, 16 and 17 from this Rulebook and supplemented if necessary by an experimental design method as described in Articles 18 and 19 from this Rulebook, or
- an experimental design method without calculation, as described in Articles 18 and 19 of this Rulebook when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar·L or the product $PS \cdot DN$ less than 3 000 bar.

3. 2. 1. Calculation method

(a) Pressure containment and other loading aspects

Article 15

The allowable stresses for pressure equipment should be limited having regard to reasonably foreseeable failure modes under operating conditions.

In order to satisfy the requirements from paragraph 1 of this Article, safety factors should 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 should provide sufficient safety margins consistent, where applicable, with the requirements of Articles 50 to 56 of this Rulebook.

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

Article 16

Appropriate design calculations should be used to establish the resistance of the pressure equipment concerned:

1. the calculation pressures should 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 should be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,
2. the calculation temperatures should allow for appropriate safety margins,
3. the design should take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
4. the maximum stresses and peak stress concentrations should be kept within safe limits,
5. the calculation for pressure containment should utilize the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in Articles 44 to 47 of this Rulebook 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,
6. appropriate joint factors should be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged,
7. the design should take appropriate account of all reasonably foreseeable degradation mechanisms (e.g. corrosion, creep, fatigue) commensurate with the intended use of

the equipment. Attention should be drawn, in the instructions referred to in Article 43 of this Rulebook, 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

Article 17

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

3. 2. 2. Experimental design method

Article 18

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

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

The test programme should 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 test.

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

Article 19

The test programme should include:

1. 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 should be determined on the basis of the differences between the values of the geometrical and material characteristics under test conditions and the values used for design purposes; it should take into account the differences between the test and design temperatures.

2. 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.

3. Where necessary, additional tests concerning other factors referred to in Article 13 of this Rulebook such as corrosion, external damage, etc.

3. 3. Provisions to ensure safe handling and operation

Article 20

The method of operation specified for pressure equipment should be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention should 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.

Pressure equipment fitted with an access door should be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any hazard.

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

3. 4. Means of examination

Article 21

Pressure equipment should be designed and constructed so that all necessary examinations to ensure safety can be carried out.

Means of determining the internal condition of the equipment should 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.

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.

3. 5. Means of draining and venting

Article 22

Adequate means should 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, should be considered,
- to permit cleaning, inspection and maintenance in a safe manner.

3. 6. Corrosion or other chemical attack

Article 23

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

3. 7. Wear

Article 24

Where severe conditions of erosion or abrasion may arise, adequate measures should 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 Article 43 of this Rulebook, to measures necessary for continued safe use.

3. 8. Assemblies

Article 25

Assemblies should 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.

3. 9. Provisions for filling and discharge

Article 26

Where appropriate, the pressure equipment should 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:

1. on filling:

- overfilling or overpressurization having regard in particular to the filling ratio and to vapour pressure at the reference temperature,
- instability of the pressure equipment,

2. on discharge: the uncontrolled release of the pressurized fluid;

3. on filling or discharge: unsafe connection and disconnection.

3. 10. Protection against exceeding the allowable limits of pressure equipment

Article 27

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment should 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 should be determined on the basis of the particular characteristics of the equipment or assembly.

Suitable protective devices and combinations thereof comprise:

1. safety equipment as defined in Article 2, point 4 of this Rulebook,
2. 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.

3.11. Safety accessories

Article 28

Safety accessories should:

- 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,
- 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.

Article 29

Pressure limiting devices should 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 Article 54 of this Rulebook is allowable, where appropriate.

Article 30

Temperature monitoring devices should have an adequate response time on safety grounds, consistent with the measurement function.

3.12. External fire

Article 31

Where necessary, pressure equipment should 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.

4. Manufacturing

4.1. Manufacturing procedures

Article 32

The manufacturer should ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the manufacturing aspects set out in Articles 33 to 43 of this Rulebook.

4.1.1. Preparation of the component parts

Article 33

Preparation of the component parts (e.g. forming and chamfering) should not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.

4.1.2. Permanent joining

Article 34

Permanent joints and adjacent zones should be free of any surface or internal defects detrimental to the safety of the equipment.

The properties of permanent joints should meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations.

For pressure equipment, permanent joining of components which contribute to the pressure resistance of equipment and components which are directly attached to them should be carried out by suitably qualified personnel according to the national standards.

For pressure equipment in categories II, III and IV, operating procedures and personnel should be approved by a competent independent legal persons which, at the manufacturer's discretion and in accordance with the national standards, may be:

- legal persons for assessment of conformity;
- a recognized independent (third-party) organization as provided for in Article 68 of this Rulebook.

To carry out these approvals referred to in paragraph 4 of this Article the independent legal persons should perform examinations and tests as set out in the appropriate national standards or equivalent examinations and tests.

4.1.3. Non-destructive tests

Article 35

For pressure equipment, non-destructive tests of permanent joints should be carried out by suitable qualified personnel in accordance with the national standards.

For pressure equipment in categories III and IV, the personnel should be approved by a recognized independent (third-party) organization pursuant to Article 68 of this Rulebook.

4.1.4. Heat treatment

Article 36

Where there is a risk that the manufacturing process will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment should be applied at the appropriate stage of manufacture.

4.1.5. Traceability

Article 37

Suitable procedures should be established and maintained for identifying the material making up the components of the equipment which contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.

4.2. Final assessment

Article 38

Pressure equipment should be subjected to final assessment pursuant Articles 39, 40 and 41 of this Rulebook.

4.2.1. Final inspection

Article 39

Pressure equipment should undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of this Rulebook.

As far as is necessary on safety grounds, the final inspection should be carried out internally and externally on every part of the equipment, where appropriate in the course of manufacture (e.g. where examination during the final inspection is no longer possible).

4.2.2. Proof test

Article 40

Final assessment of pressure equipment should include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value laid down in Article 55 of this Rulebook.

For category I series-produced pressure equipment, the test referred to in paragraph 1 may be performed on a statistical basis.

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognized value may be carried out.

For tests other than the hydrostatic pressure test, additional measures, such as non-destructive tests or other methods of equivalent validity, should be applied before those tests are carried out.

4.2.3. Inspection of safety devices

Article 41

For assemblies, the final assessment should also include a check of the safety devices intended to check full compliance with the requirements referred to in Article 27 of this Rulebook.

4.3. Marking and labelling

Article 42

In addition to the CE conformity marking, the following information should be provided:

1. for all pressure equipment:

- the name and address or name and headquarters or other means of identification of the manufacturer and, where appropriate, of his authorized representative established within the Republic of Macedonia;
- the year of manufacture;
- identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number;
- essential maximum/minimum allowable limits;

2. depending on the type of pressure equipment, further information necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection such as:

- the volume V of the pressure equipment in L,
- the nominal size for piping DN,
- the test pressure PT given in bar and date,
- safety device set pressure in bar,
- output of the pressure equipment in kW,
- supply voltage in V (volts),

- intended use,
- filling ratio kg/L,
- maximum filling mass in kg,
- tare mass in kg,
- the product group;

3. where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

The conformity marking and the required information should be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:

- where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly. This applies to conformity marking and other marking and labelling referred to in Chapter II of this Rulebook;
- where the pressure equipment is too small, e.g.: accessories, the information referred to in point 2, paragraph 1 of this Article may be given on a label attached to that pressure equipment;
- labelling or other adequate means may be used for the mass to be filled and the warnings referred to in point 3, paragraph 1 of this Article, provided it remains legible for the appropriate period of time.

4.4. Operating instructions

Article 43

When pressure equipment is placed on the market, it should be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:

- mounting including assembling of different pieces of pressure equipment,
- putting into service,
- use,
- maintenance including checks by the user.

Instructions from paragraph 1 from this Article should cover information affixed to the pressure equipment in accordance with Article 42 of this Rulebook, with the exception of serial identification, and should be accompanied, where appropriate, by the technical documents, drawings and diagrams necessary for a full understanding of these instructions.

If appropriate, instructions laid down in paragraph 1 from this Article should also refer to hazards arising from misuse in accordance with Article 11, paragraph 3 from this Rulebook and particular features of the design in accordance with Articles 15 to 17 of this Rulebook.

5. Materials

Article 44

Materials used for the manufacture of pressure equipment should be suitable for such application during the scheduled lifetime unless replacement is foreseen.

Welding consumables and other joining materials need fulfil only the relevant requirements of Article 45, paragraph 1 of Article 46, and paragraphs 1 and 2 of Article 47 from this Rulebook, in an appropriate way, both individually and in a joined structure.

Article 45

Materials for pressurized parts should:

1. have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and tough. Where appropriate, the characteristics of the materials should comply with the requirements of Article 56 from this Rulebook. Moreover, due care should be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures should be taken;
2. be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety should not be significantly affected within the scheduled lifetime of the equipment;
3. not be significantly affected by ageing;
4. be suitable for the intended processing procedures;
5. be selected in order to avoid significant undesirable effects when the various materials are put together.

Article 46

The pressure equipment manufacturer should define in an appropriate manner the values necessary for the design calculations referred to in Articles 15 to 17 from this Rulebook and the essential characteristics of the materials and their treatment referred to in Article 45 from this Rulebook.

The manufacturer should provide in his technical documentation elements relating to compliance with the materials specifications of the Rulebook in one of the following forms:

- by using materials which comply with the requirements from the national standards;
- by using materials covered by an approval of pressure equipment materials in accordance with Article 63 from this Rulebook;
- by a particular material appraisal.

For pressure equipment in categories III and IV, particular appraisal as referred to in the third indent of paragraph 2 should be performed by the notified body in charge of conformity assessment procedures for the pressure equipment.

Article 47

The equipment manufacturer should take appropriate measures to ensure that the material used conforms with the required specification.

In particular, documentation prepared by the material manufacturer affirming compliance with a specification should be obtained for all materials.

For the main pressure-bearing parts of equipment in categories II, III and IV, the documentation referred to in paragraph 2 of this Article should take the form of a certificate of specific product control.

Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body and having undergone a specific assessment for materials, certificates issued by the manufacturer are presumed to certify conformity with the relevant requirements laid down in this Article.

6. Specific pressure equipment requirements

Article 48

In addition to the applicable requirements of Article 10 of this rulebook, the following requirements applies.

Fired or otherwise heated pressure equipment with a risk of overheating as referred to in article 7 of this Rulebook include:

- steam and hot-water generators as referred to in Article 7, point 2 of this Rulebook, such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, together with their accessories and where applicable their systems for treatment of feedwater and for fuel supply, and
- process-heating equipment for other than steam and hot water generation falling under Article 7, point 1 of this Rulebook, such as heaters for chemical and other similar processes and pressurized food-processing equipment.

This pressure equipment from paragraph 1 of this Article should be calculated, designed and constructed so as to avoid to minimize risks of a significant loss of containment from overheating. In particular it should be ensured, where applicable, that:

1. appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off and, where applicable, fluid level so as to avoid any risk of local and general overheating,
2. sampling points are provided where required to allow evaluation of the properties of the fluid so as to avoid risks related to deposits and/or corrosion,
3. adequate provisions are made to eliminate risks of damage from deposits,
4. means of safe removal of residual heat after shutdown are provided,
5. steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.

Article 49

Piping as referred to in Article 7, point 3 of this Rulebook should be designed and constructed in order to ensure that:

1. that the risk of overstressing from inadmissible free movement or excessive forces being produced, e.g. on flanges, connections, bellows or hoses, is adequately controlled by means such as support, constraint, anchoring, alignment and pre-tension,
2. that where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion,
3. that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of Article 24 are applicable,
4. that due consideration is given to the risk of fatigue due to vibrations in pipes;
5. that, where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate 'take-off' pipes the size of which represents a significant risk;
6. that the risk of inadvertent discharge is minimized; the take-off points should be clearly marked on the permanent side, indicating the fluid contained;
7. that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

7. Specific quantitative requirements for certain pressure equipment

Article 50

Where the provisions from Articles 51 to 56 of this Rulebook are not applied, including in cases where materials are not specifically referred to and no national standards are applied, the manufacturer should demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

The provisions laid down in Articles 51 to 56 of this Rulebook shall supplement the essential requirements of the provisions for the pressure equipment to which they apply.

7. 1. Allowable stresses

7. 1. 1. Symbols

Article 51

$R_{e/T}$, yield limit, indicates the value at the calculation temperature of:

- the upper flow limit for a material presenting upper and lower flow limits,
- the 1,0% proof strength of austenitic steel and non-alloyed aluminium,
- the 0,2% proof strength in other cases.

$R_{M/20}$ indicates the minimum value of the ultimate strength on 20°C.

$R_{M/T}$ designates the ultimate strength at the calculation temperature.

Article 52

The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant should not exceed the smaller of the following values, according to the material used:

1. in the case of ferritic steel including normalized (normalized rolled) steel and excluding fine-grained steel and specially heat-treated steel, of $\frac{2}{3}$ of $R_{e/T}$ and $\frac{5}{12}$ of $R_{M/20}$;
2. in the case of austenitic steel:
 - if its elongation after rupture exceeds 30%, $\frac{2}{3}$ of $R_{e/T}$;
 - or, alternatively, and if its elongation after rupture exceeds 35%, $\frac{5}{6}$ of $R_{e/T}$ and $\frac{1}{3}$ of $R_{M/T}$;
 - in the case of non-alloy or low-alloy cast steel, $\frac{0}{19}$ of $R_{e/T}$ and $\frac{1}{3}$ $R_{M/20}$;
 - in the case of aluminium, $\frac{2}{3}$ of $R_{e/T}$;
 - in the case of aluminium alloys excluding precipitation hardening alloys, $\frac{2}{3}$ of $R_{e/T}$ and $\frac{5}{12}$ of $R_{M/20}$.

7. 2. Joint coefficients

Article 53

For welded joints, the joint coefficient should not exceed the following values:

- for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects: 1,
- for equipment subject to partial (random) non-destructive testing: 0,85,
- for equipment not subject to non-destructive testing other than visual inspection: 0,7.

If necessary, the type of stress and the mechanical and technological properties of the joint should also be taken into account.

7. 3. Pressure limiting devices, particularly for pressure vessels

Article 54

The momentary pressure surge referred to in Article 29 of this Rulebook should be kept to 10% of the maximum allowable pressure.

7. 4. Hydrostatic test pressure

Article 55

For pressure vessels, the hydrostatic test pressure referred to in Article 40 of this Rulebook should be no less than:

- that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1,25, or
- the maximum allowable pressure multiplied by the coefficient 1,43.

7. 5. Material characteristics

Article 56

Unless other values are required in accordance with other criteria that should be taken into account, a steel is considered as sufficiently ductile to satisfy point 1 of Article 45 from this Rulebook if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14% and its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature not greater than 20°C but not higher than the lowest scheduled operating temperature.

III. CONFORMITY ASSESSMENT

1. Presumption of conformity

Article 57

Pressure equipment and assemblies bearing the CE marking and the EC declaration of conformity shall be regarded as conforming to the provisions of this Rulebook, including the conformity assessment procedures.

Pressure equipment and assemblies which conform to the national standards shall be presumed to conform to the essential requirements referred to in Articles 7, 8 and 9 of this Rulebook.

Republic of Macedonia and member states shall ensure that appropriate measures are taken to enable both sides of industry to have an input at national level in the process of preparing and monitoring the harmonized standards.

2. Classification of the pressure equipment

Article 58

Pressure equipment referred to in Article 7 of this Rulebook shall be classified by category in accordance with Conformity assessment tables (Appendix I) enclosed to this Rulebook, according to ascending level of hazard.

For the purposes of classification referred to in paragraph 1, fluids shall be divided into two groups as follows:

1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or preparation defined as:

- explosive,
- extremely flammable,
- highly flammable,
- flammable (where the maximum allowable temperature is above flashpoint),
- very toxic,
- toxic,
- oxidizing.

2. Group 2 comprises all other fluids not covered in point 1 of this paragraph.

Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

3. Conformity assessment procedures

Article 59

Before placing pressure equipment on the market, the manufacturer shall subject each item of equipment to one of the CE conformity assessment procedures described in the provisions of this Rulebook, according to the conditions given in this Article.

The conformity assessment procedures to be applied to an item of pressure equipment with a view to affixing the CE conformity marking shall be determined by the category, as defined in Article 58 in this Rulebook, in which the equipment is classified.

The conformity assessment procedures to be applied for the various categories are as follows:

- Category I
Module A

- Category II
Module A1
Module D1
Module E1

- Category III
Module B1 + D
Module B1 + F
Module B + E
Module B + C1
Module H

- Category IV
Module B + D
Module B + F
Module G
Module H1

Pressure equipment shall be subjected to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which it is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

In the framework of quality assurance procedures for equipment in Categories III and IV referred to in Article 7, point 1 subpoint (a), subpoint (b), indent 1 and point 2 of this Rulebook, the legal person which designate to assess the conformity, when performing unexpected visits, take a sample of equipment from the manufacturing or storage premises in

order to perform, or have performed, the final assessment as referred to in Article 40 of this Rulebook.

In cases of paragraph 5 of this Article, the manufacturer shall inform the notified body of the intended schedule of production.

The legal person shall carry out at least two visits during the first year of manufacturing. The frequency of subsequent visits shall be determined by the legal person designated to assess the conformity on the basis of the criteria set out in the system for control visits of the relevant modules.

In the case of one-off production of vessels and equipment in Category III referred to in Article 7, point 2 of this Rulebook, under the module H procedure, the legal person which assesses the conformity shall perform or have performed the final assessment, as referred to in Article 40 of this Rulebook, for each unit.

In cases of paragraph 8, the manufacturer shall communicate the intended schedule of production to the legal person which assesses the conformity.

Article 60

Assemblies referred to in Article 8 of this Rulebook shall be subjected to a global conformity assessment procedure comprised of:

1. assessment of each item of pressure equipment making up the assembly and referred to in Article 7 of this Rulebook which has not been previously subjected to a conformity assessment procedure and to a separate conformity marking; the assessment procedure shall be determined by the category of each item of equipment;
2. the assessment of the integration of the various components of the assembly as referred to in Articles 20, 25 and 26 of this Rulebook which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;
3. the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in Articles 27 and 40 of this Rulebook shall be conducted in the light of the highest category applicable to the items of equipment to be protected.

Article 61

By way of derogation from paragraphs 59 and 60 of this Rulebook, where justified, placing on the market and putting into service of individual pressure equipment items and assemblies may be allowed, in respect of which the conformity assessment procedures have not been applied and the use of which is in the interests of experimentation.

Article 62

Records and correspondence which refer to the conformity assessment procedures shall be written in Macedonian language and on its Cyrillic alphabet.

4. Approval for materials

Article 63

European Approval for materials shall be issued at the request of one or more manufacturers of materials or equipment, by the legal person which performs the conformity assessment, specifically designated for that task.

The legal person referred to in paragraph 1 of this Article shall determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of this Rulebook.

Before issuing European approval for materials, the notified body shall inform the Member States and the Commission by sending them the appropriate information. Within

three months, a Member State or the Commission may refer the matter to the Standing Committee set up by Article 5 of Directive 83/189/EEC, giving its reasons. In that case, the Committee shall issue an opinion as a matter of urgency. The notified body shall issue the European approval for materials taking into account, where appropriate, the opinion of the Committee and the comments submitted.

A copy of the European approval for pressure equipment materials shall be sent to the Member States, the notified bodies and the Commission. The Commission shall publish and keep up to date a list of European approvals for materials in the Official Journal of the European Communities.

The materials used for the manufacture of pressure equipment conforming with European approvals for materials, the references of which have been published in the Official Journal of the European Communities, shall be presumed to conform to the applicable essential requirements of Article 10 of this Rulebook.

The legal person referred to in paragraph 1 of this Article which issued the European Approval for pressure equipment materials shall withdraw that approval if it finds that it should not have been issued for if the type of materials is covered by a national standard.

5. Legal persons which perform the assessment of conformity

Article 64

The legal person authorized to perform the assessment of conformity of pressure equipment materials and assemblies (hereinafter: notified body) shall meet the criteria for performing the assessment of conformity, listed in Chapter IV of this Rulebook.

Article 65

The notified body shall meet the criteria for performing the assessment of conformity, listed in Chapter IV of this Rulebook, may be authorized to perform one or few of the following conformity assessment procedures for pressure equipment and assemblies:

- internal production control (Module “A”), in accordance with the provisions from Chapter B, Subchapter 1 of this Rulebook,
- internal manufacturing checks with monitoring of the final assessment (Module “A1”), in accordance with the provisions from Chapter B, Subchapter 2 of this Rulebook,
- type-examination (Module “B”), in accordance with the provisions from Chapter B, Subchapter 3 of this Rulebook,
- design-examination (Module “B1”), in accordance with the provisions from Chapter B, Subchapter 4 of this Rulebook,
- conformity to type (Module “C1”), in accordance with the provisions from Chapter B, Subchapter 5 of this Rulebook,
- production quality assurance (Module “D”), in accordance with the provisions from Chapter B, Subchapter 6 of this Rulebook,
- production quality assurance (Module “D1”), in accordance with the provisions from Chapter B, Subchapter 7 of this Rulebook,
- product quality assurance (Module “E”), in accordance with the provisions from Chapter B, Subchapter 8 of this Rulebook,
- product quality assurance (Module “E1”), in accordance with the provisions from Chapter B, Subchapter 9 of this Rulebook,
- product verification (Module “F”), in accordance with the provisions from Chapter B, Subchapter 10 of this Rulebook,
- unit verification (Module “G”), in accordance with the provisions from Chapter B, Subchapter 11 of this Rulebook,
- full quality assurance (Module “H”), in accordance with the provisions from Chapter B, Subchapter 12 of this Rulebook,

- full quality assurance with design examination and special surveillance of the final assessment (Module “H1”), in accordance with the provisions from Chapter B, Subchapter 13 of this Rulebook.

The notified body which performs the assessment of conformity of pressure equipment materials and assemblies shall be assigned with a unique identification number of the body.

Article 66

The notified body which performs the conformity assessment procedures for pressure equipment and assemblies shall fulfil the corresponding criteria in Chapter IV of this Rulebook and shall be able to perform the specific tasks from the national standards.

Article 67

The designation (notification) procedure of the notified body in the European Commission shall be executed in accordance with product safety regulations.

6. Recognised independent (third party) organisations

Article 68

Recognised independent (third-party) organizations, for the purposes of this Rulebook, shall be a legal person recognized pursuant to product safety regulations and which performs qualifications and approval of:

- working procedure for permanent joining in accordance with Article 34 of this Rulebook,
- permanent joining personnel in accordance with Article 34 of this Rulebook,
- non-destructive testing personnel in accordance with Article 35 of this Rulebook.

The recognized independent (third-party) organization as provided for in paragraph 1 of this Article shall permanently satisfy the criteria provided for in Chapter IV of this Rulebook and it shall be able to perform the specific tasks from the national standards.

7. User inspectorates

Article 69

The pressure equipment and assemblies may be used only in establishments operated by the group of which the inspectorate is part. The user inspectorate has assess the conformity of the pressure equipment and assemblies with the essential requirements.

Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall not bear the conformity marking.

The pressure equipment and assemblies subject to conformity assessment may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies.

The user inspectorates shall act exclusively for the group of which they are part.

The conformity assessment procedures applicable by user inspectorates shall be modules A1, C1, F and G, in accordance with the provisions from Chapter B of this Rulebook.

The user inspectorate shall at any time fulfill the conditions given in Chapter IV of this Rulebook and meet the criteria from paragraph 3 of this Article.

8. Declaration of conformity

Article 70

The declaration of conformity shall have printed form, certified and written in Macedonian language and in its Cyrillic alphabet.

The declaration of conformity shall contain the following particulars:

- name, surname and address or name and the headquarters of the manufacturer or his authorized representative established in the Republic of Macedonia;
- description of the pressure equipment and assemblies,
- conformity assessment procedure followed,
- in case of assemblies, description of pressure equipment constituting the assembly and applied conformity assessment procedures,
- name and headquarters of the notified body which carried the inspection (where appropriate),
- reference to type-examination certificate, design-examination certificate and conformity certificate, (where appropriate),
- name and address of the headquarters of the authorized body which performs the producers' quality assurance system, (where appropriate),
- applied national standards, (where appropriate),
- other applied technical standards and specifications, (where appropriate),
- other applied regulations, (where appropriate),
- data for the person authorized to sign the legally binding declaration from the manufacturer or his authorized representative established in Republic of Macedonia.

IV. CONDITIONS TO BE MET BY THE LEGAL PERSONS WHICH PARTICIPATE IN THE CONFORMITY ASSESSMENT PROCEDURES

1. Notified bodies and Recognised independent (third party) organisations

Article 71

The notified body, the recognized independent (third party) organization, their responsible personnel (director, manager, head etc.) and expert personnel responsible for carrying out the assessment and verification operations may not be the designer, manufacturer, supplier, installer or user of the pressure equipment or assemblies which that body inspects, nor the authorized representative of any of those parties.

The notified body, the recognized independent (third party) organization, their responsible personnel (director, manager, head etc.) and expert personnel may not become directly involved in the design, construction, marketing or maintenance of the pressure equipment or assemblies, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of pressure equipment or assemblies and those bodies.

Article 72

The notified body, the recognized independent (third party) organization and their expert personnel should carry out the assessments and verifications with the highest degree of professional integrity and technical competence and should be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

Article 73

The notified body, the recognized independent (third party) organization should have at its disposal the necessary personnel to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations.

The notified body shall have at least three expert full time employees who will be involved in the conformity assessment process, as follows:

- a mechanical engineer with a continuous experience of minimum five years in operations related to conformity assessment of pressure equipment and assemblies,
- a mechanical engineer with a continuous experience of minimum three years in operations related to inspections of pressure equipment and assemblies,
- a high school degree mechanical technician with a continuous experience of minimum three years in operations related to testing of pressure equipment and assemblies.

Recognised independent (third party) organisation should have minimum three full time employees, as follows:

- a mechanical engineer with a continuous experience of minimum five years in performing operations defined in Article 68 of this Rulebook,
- a mechanical engineer with a continuous experience of minimum three years in performing operations defined in Article 68 of this Rulebook,
- a high school degree mechanical technician with a continuous experience of minimum three years in performing operations defined in Article 68 of this Rulebook.

The full time employees in the notified body and in the recognized independent (third party) referred to in paragraphs 2 and 3 of this Article should have appropriate qualifications in accordance with the national standards.

Article 74

The personnel responsible for inspections should have:

- sound technical and professional training and qualification in accordance with the national standards,
- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

Article 75

The notified body and the recognized independent (third party) organization should have access to the equipment required to perform the technical operations covered by the national standards.

The notified body and the recognized independent (third party) organization should also have access to the equipment required to perform special verifications.

Article 76

The notified body and the recognized independent (third party) organization should ensure the impartiality of its expert personnel when performing the inspections and their remuneration should not depend on number of performed inspections nor on the results from such inspections.

The notified body and the recognized independent (third party) organization should have adequate liability insurance.

The notified body and the recognized independent (third party) organization should respect the professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent national authorities) under this Rulebook or any provision of national law related to the conformity assessment procedures for pressure equipment and assemblies.

2. User inspectorate

Article 77

The user inspectorate should be organizationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality.

The user inspectorate shall not be responsible for the design, manufacture, supply, installation, operation or maintenance of the pressure equipment or assemblies, and should not engage in any activities that might conflict with its independence of judgment and integrity in relation to its inspection activities.

Article 78

The user inspectorate and their expert personnel should carry out the assessments and verifications with the highest degree of professional integrity and technical competence and should be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

Article 79

The user inspectorate should have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations, it should also have access to the equipment required to perform special verifications.

The user inspectorate shall have at least three expert full time employees who will be involved in the conformity assessment process, as follows:

- a mechanical engineer with a continuous experience of minimum five years in operations related to conformity assessment of pressure equipment and assemblies,
- a mechanical engineer with a continuous experience of minimum three years in operations related to inspections of pressure equipment and assemblies,
- a high school degree mechanical technician with a continuous experience of minimum three years in operations related to testing of pressure equipment and assemblies.

Full time employees in the user inspectorate referred to in paragraph 2 of this Article shall have the appropriate qualifications in accordance with the national standards.

Article 80

The expert personnel responsible for inspections should have:

- sound technical and professional training and qualification in accordance with the national standards,
- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,
- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

Article 81

User inspectorate should ensure the impartiality of its expert personnel when performing the inspections and their remuneration should not depend on number of performed inspections nor on the results from such inspections.

The user inspectorate should take out liability insurance unless its liability is assumed by the group which the inspectorate is part of.

The user inspectorate, its responsible persons and expert personnel should respect the professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent national authorities) under this Rulebook or any provision of national law related to the conformity assessment procedures for pressure equipment and assemblies.

C. CONFORMITY ASSESSMENT PROCEDURES

Article 82

The obligations arising from the conformity assessment procedures for pressure equipment listed in Chapter C of this Rulebook shall also apply to the assemblies.

1. Internal production control (Module “A”)

Article 83

For the purposes of this Rulebook (Module “A”) the internal production control is a procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia, who carries out the obligations laid down in Article 84 of this Rulebook, shall ensure and declare that the pressure equipment satisfies the relevant requirements set out in the provisions of this Rulebook.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

Article 84

The manufacturer should draw up the technical documentation described in Article 85 of this Rulebook and either the manufacturer or his authorized representative established within the Republic of Macedonia should keep it at the disposal of the relevant national authorities for inspection purposes for a period of 10 years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in the Republic of Macedonia, the obligation to keep the technical documentation available shall be the responsibility of the natural or legal person who places the pressure equipment on the market.

Article 85

The technical documentation should enable an assessment to be made of the conformity of the pressure equipment with the requirements of this Rulebook which apply to it.

Provided necessary to assess the conformity, the technical documentation referred to in this article, paragraph 1, it shall cover the design, manufacture and operation of the pressure equipment and contain the following:

- description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Rulebook where the standards referred to in Article 57 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 86

The manufacturer or its authorized representative established in the Republic of Macedonia, shall keep a copy of the declaration of conformity with the technical documentation.

Article 87

The manufacturer shall take all necessary measures to ensure that the manufacturing process requires that the manufactured pressure equipment is in compliance with the technical documentation referred to in Article 84 of this Rulebook and with the relevant requirements laid down in the provisions of this Rulebook and refer to that equipment.

2. Internal manufacturing checks with monitoring of the final assessment (Module “A1”)

Article 88

In addition to the requirements of module A, the following applies.

Final assessment should be performed by the manufacturer and monitored by means of unexpected visits by a notified body chosen by the manufacturer.

During the unexpected visits, the notified body should:

- establish that the manufacturer actually performs final assessment in accordance with Articles 38 to 41 of this Rulebook,
- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

Should one or more of the items of pressure equipment not conform, the notified body should take appropriate measures.

Upon an approval from the notified body, the manufacturer should affix the former's identification number on each item of pressure equipment.

3. Type-examination (Module “B”)

Article 89

For the purposes of this Rulebook, type-examination (Module “B”) shall be the part of the procedure by which a notified body ascertains and attests that a representative example of the production in question meets the provisions of the Rulebook which apply to it.

Article 90

The application for type-examination should be lodged by the manufacturer or by his authorized representative established within the Republic of Macedonia with a single notified body of his choice.

The application referred to in paragraph 1 should include:

- name, surname and address or name and the headquarters of the manufacturer; or if the application is lodged by the authorized representative established in the Republic of Macedonia, his name, surname and address of the headquarters,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in Article 91 of this Rulebook.

The applicant should place at the disposal of the notified body a representative example of the production envisaged, (hereinafter: ‘type’). The notified body may request further examples should the test programme so require.

A type may cover several versions of pressure equipment provided that the differences between the versions do not affect the level of safety.

Article 91

The technical documentation should enable an assessment to be made of the conformity of the pressure equipment with the requirements of this Rulebook which apply to it.

Provided necessary to assess the conformity, the technical documentation referred to in this Article, paragraph 1, it shall cover the design, manufacturing and operation of the pressure equipment and contain the following:

- a general description of the type,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Rulebook where the national standards referred to in Article 57 of this Rulebook have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports,
- information concerning the tests provided for in manufacture,
- information concerning the qualifications or approvals required under Articles 34 and 35 of this Rulebook.

Article 92

When performing the type-examination the notified body should:

1. examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the national standards referred to in Article 57 of this Rulebook, as well as those designed without applying the provisions of those standards.

When performing the type-examination the notified body should, in particular:

- examine the technical documentation with respect to the design and the manufacturing procedures;
- assess the materials used where these are not in conformity with the relevant national standards or with an approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with Article 47 of this Appendix;
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with Article 34 of this Rulebook;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with Articles 34 and 35 of this Rulebook;

2. perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential requirements of this Rulebook where the national standards referred to in Article 57 have not been applied;

3. perform or have performed the appropriate examinations and necessary tests to establish whether, where the manufacturer has chosen to apply the relevant national standards, these have actually been applied;

4. agree with the applicant the location where the examinations and necessary tests are to be carried out.

Article 93

Where the type satisfies the provisions of this Rulebook which apply to it, the notified body should issue an type-examination certificate to the applicant.

The certificate referred to in paragraph 1 of this Article, which should be valid for 10 years and be renewable, should contain the name, surname and address of the manufacturer's headquarters, the conclusions of the examination and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation should be annexed to the certificate referred to in paragraph 1 and a copy kept by the notified body.

If the notified body refuses to issue an type-examination certificate to the manufacturer or to his authorized representative established within the Republic of Macedonia, that body should provide detailed reasons for such refusal.

If the notified body refuses to issue an type-examination certificate to the manufacturer or to his authorized representative established within the Republic of Macedonia, they could object to the notified body.

Article 94

The applicant should inform the notified body that holds the technical documentation concerning the type-examination certificate of all modifications to the approved pressure equipment; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment.

This additional approval referred to in paragraph 1 should be given in the form of an addition to the original type-examination certificate.

Article 95

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn type-examination certificates, and,
- on request, type-examination certificates it has issued.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn type-examination certificates, or
- refused type-examination certificates.

Article 96

The other notified bodies may receive copies of the type-examination certificates and/or their additions. The appendices to the certificates should be held at the disposal.

Article 97

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep with the technical documentation copies of type-examination certificates and their additions for a period of ten years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in the Republic of Macedonia, the obligation to keep the technical documentation available shall be the responsibility of the natural or legal person who places the pressure equipment on the market.

4. Design-examination (Module “B1”)

Article 98

For the purposes of this Rulebook, design-examination (Module “B1”) shall be the part of the procedure by which a notified body ascertains and attests that the design of an item of pressure equipment meets the provisions of this Rulebook which apply to it.

The experimental design method provided for in Articles 18 and 19 of this Rulebook are not applied in the context of this module referred to in paragraph 1 of this Article.

Article 99

The application for design-examination should be lodged by the manufacturer or by his authorized representative established within the Republic of Macedonia with a single notified body of his choice.

The application referred to in paragraph 1 should include:

- name, surname and address or name and the headquarters of the manufacturer; or if the application is lodged by the authorized representative established in the Republic of Macedonia, his name, surname and address of the headquarters,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in Article 100 of this Rulebook.

The application may cover several versions of pressure equipment provided that the differences between the versions do not affect the level of safety.

Article 100

The technical documentation should enable an assessment to be made of the conformity of the pressure equipment with the requirements of this Rulebook which apply to it.

Provided necessary to assess the conformity, the technical documentation referred to in this Article, paragraph 1, it shall cover the design, manufacture and operation of the pressure equipment and contain the following:

- general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Rulebook where the national standards referred to in Article 57 of this Rulebook have not been applied,
- the necessary supporting evidence for the adequacy of the design solution, in particular where the standards referred to in Article 57 of this Rulebook have not been applied in full; this supporting evidence should include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,
- results of design calculations made, examinations carried out, etc.,
- information concerning the qualifications or approvals required under Articles 34 and 35 of this Rulebook.

Article 101

When performing the design-examination the notified body should:

1. examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the national standards referred to in Article 57 of this Rulebook, as well as those which have been designed without applying the relevant provisions of those standards.

When performing the design-examination the notified body should, in particular:

- assess the materials where these are not in conformity with the relevant national standards or with an approval for pressure equipment materials,
- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with Article 34 of this Rulebook;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with Articles 34 and 35 of this Rulebook;

2. perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential requirements of this Rulebook where the national standards referred to in Article 57 have not been applied;

3. perform or have performed the appropriate examinations and necessary tests to establish whether, where the manufacturer has chosen to apply the relevant national standards, these have actually been applied.

Article 102

Where the type satisfies the provisions of this Rulebook which apply to it, the notified body should issue a design-examination certificate to the applicant.

The certificate, referred to in paragraph 1 of this Article, should contain the name, surname and address of the manufacturer's headquarters, the conclusions of the examination the validity conditions and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation should be annexed to the certificate referred to in paragraph 1 and a copy kept by the notified body.

If the notified body refuses to issue a design-examination certificate to the manufacturer or to his authorized representative established within the Republic of Macedonia, that body should provide for them detailed reasons for such refusal.

If the notified body refuses to issue a design-examination certificate to the manufacturer or to his authorized representative established within the Republic of Macedonia, they could object to the notified body.

Article 103

The applicant should inform the notified body that holds the technical documentation concerning the design-examination certificate of all modifications to the approved design; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of such equipment.

This additional approval referred to in paragraph 1 should be given in the form of an addition to the original design-examination certificate.

Article 104

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn design-examination certificates, and
- on request, design-examination certificates it has issued.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn design-examination certificates or
- refused design-examination certificates.

Article 105

The other notified bodies may on request obtain the relevant information concerning:

- the design-examination certificates and additions granted,
- the design-examination certificates and additions withdrawn.

Article 106

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep with the technical documentation copies of design-examination certificates and their additions for a period of 10 years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in the Republic of Macedonia, the obligation to keep the technical documentation available shall be the responsibility of the natural or legal person who places the pressure equipment on the market.

5. Conformity to type (Module “C1”)

Article 107

For the purposes of this Rulebook, conformity to type (Module “C1”) is a procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia, shall ensure and declare that the pressure equipment is in conformity to the type described in the type-examination certificate and satisfies the requirements from the provisions of this Rulebook which apply to it.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

Article 108

The manufacturer shall take all measures necessary to ensure that the manufacturing process requires the manufactured pressure equipment to comply with the type as described in the type-examination certificate and with the requirements as prescribed in the provisions of this Rulebook which apply to it.

Article 109

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep a copy of the declaration of conformity for a period of 10 years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in the Republic of Macedonia, the obligation to keep the technical documentation available shall be the responsibility of the natural or legal person who places the pressure equipment on the market.

Article 110

Final assessment should be subject to monitoring by means of unexpected visits by a notified body chosen by the manufacturer.

During the unexpected visits, the notified body should:

- establish that the manufacturer actually performs final assessment in accordance with Articles 38 to 41 of this Rulebook,
- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

Should one or more of the items of pressure equipment not conform, the notified body should take appropriate measures.

On the responsibility of the notified body, the manufacturer should affix the former's identification number on each item of pressure equipment.

6. Production quality assurance (Module “D”)

Article 111

For the purposes of this Rulebook, production quality assurance (Module “D”) is a procedure whereby the manufacturer who satisfies the obligations of Article 112 of this Rulebook ensures and declares that the pressure equipment concerned is in conformity with the type described in the type-examination certificate or design-examination certificate and satisfies the requirements from the provisions of this Rulebook which apply to it.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

The conformity marking, referred to in paragraph 2 of this Article should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 117 to 120 of this Rulebook.

Article 112

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 113 to 116 of this Rulebook and be subject to surveillance as specified in Articles 117 to 120 of this Rulebook.

6. 1. Quality system

Article 113

The manufacturer should lodge an application for assessment of his quality system with a notified body of his choice.

The application referred to in paragraph 1 of this Article should include:

- all relevant information on the pressure equipment concerned,
- the documentation concerning the quality system,
- the technical documentation for the approved type and a copy of the type-examination certificate or design-examination certificate.

Article 114

The quality system should ensure compliance of the pressure equipment with the type described in the type-examination certificate or design-examination certificate and with the requirements of this Rulebook which apply to it.

All the elements, requirements and provisions adopted by the manufacturer should be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation should permit a consistent interpretation of the quality programmes, plans, manuals and records.

The documentation on the quality system referred to in paragraph 2 of this Article should, especially include an appropriate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with Article 34 of this Rulebook,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with Articles 34 and 35 of this Rulebook,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

Article 115

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 114 of this Rulebook.

The elements of the quality system which conform to the relevant national standard are presumed to comply with the corresponding requirements referred to in Article 114 of this Rulebook.

The auditing team should have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure should include an inspection visit to the manufacturer's premises.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision. In case of a negative result the manufacturer may make an appeal to the notified body.

Article 116

The manufacturer should undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body should assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Article 114 of this Rulebook or whether a reassessment is required.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

6. 2. Surveillance under the responsibility of the notified body

Article 117

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Article 118

The manufacturer should allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- quality system documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

Article 119

The notified body should carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report.

The frequency of periodic audits referred to in paragraph 1 of this Article should be such that a full reassessment is carried out every three years.

Article 120

In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors should be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly.

The notified body should provide the manufacturer with a visit report and, if a test has taken place, with a test report.

6. 3. Keeping the documentation and communication of information

Article 121

The manufacturer should, for a period of 10 years after the last of the pressure equipment has been manufactured, hold at the disposal of the competent national authorities:

- the documentation referred to in the second indent, paragraph 2 of Article 113 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 116 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 4 of Article 115 and paragraph 4 of Article 116 and in Article 119 and 120 of this Rulebook.

Article 122

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn quality system approvals and
- issued quality system approvals, on request.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn quality system approvals or
- refused quality system approvals.

7. Production quality assurance (Module “D1”)

Article 123

For the purposes of this Rulebook (Module “D1”) is a procedure whereby the manufacturer satisfies the obligations from Article 125 of this Rulebook and ensures and declares that the items of pressure equipment concerned satisfy the requirements of this Rulebook which apply to them.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

The conformity marking, referred to in paragraph 2 of this Article should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 130 to 133 of this Rulebook.

Article 124

The manufacturer should draw up the technical documentation in order to enable an assessment to be made of the conformity of the pressure equipment with the requirements of this Rulebook which apply to it.

Provided necessary to assess the conformity, the technical documentation referred to in this Article, paragraph 1, shall cover the design, manufacture and operation of the pressure equipment and contain the following:

- general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Rulebook, where the national standards referred to in Article 57 of this Rulebook have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 125

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 126 to 129 of this Rulebook and be subject to surveillance as specified in Articles 130 to 133 of this Rulebook.

7. 1. Quality system

Article 126

The manufacturer should lodge an application for assessment of his quality system with a notified body of his choice.

The application referred to in paragraph 1 of this Article should include:

- all relevant information on the pressure equipment concerned,
- the documentation concerning the quality system.

Article 127

The quality system should ensure compliance of the pressure equipment with the requirements of this Rulebook which apply to it.

All the elements, requirements and provisions adopted by the manufacturer should be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation should permit a consistent interpretation of the quality programmes, plans, manuals and records.

The documentation on the quality system referred to in paragraph 2 of this Article should, especially include an appropriate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with Article 34 of this Rulebook,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with Articles 34 of this Rulebook,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

Article 128

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 127 of this Rulebook.

The elements of the quality system which conform to the relevant national standard are presumed to comply with the corresponding requirements referred to in Article 127 of this Rulebook.

The auditing team should have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure shall include an inspection visit to the manufacturer's premises.

The result should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision. In case of a negative result the manufacturer may make an appeal to the notified body.

Article 129

The manufacturer should undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body should assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Article 127 of this Rulebook or whether a reassessment is required.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

7. 2. Surveillance under the responsibility of the notified body

Article 130

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Article 131

The manufacturer shall allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- quality system documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

Article 132

The notified body should carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report.

The frequency of periodic audits referred to in paragraph 1 of this Article should be such that a full reassessment is carried out every three years.

Article 133

In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors should be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly.

The notified body should provide the manufacturer with a visit report and, if a test has taken place, with a test report.

7. 3. Keeping the documentation and communication of information

Article 134

The manufacturer should, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the competent national authorities:

- the technical documentation described in Article 124 of this Rulebook;
- the documentation referred to in the second indent, paragraph 2 of Article 126 of this Rulebook,
- the adjustments referred to in the second paragraph of Article 129 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 4 of Article 128 and paragraph 4 of Article 129 and in Articles 132 and 133 of this Rulebook.

Article 135

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn quality system approvals and
- issued quality system approvals, on request.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn quality system approvals or
- refused quality system approvals.

8. Production quality assurance (Module “E”)

Article 136

For the purposes of this Rulebook, product quality assurance (Module “E”) is a procedure whereby the manufacturer who satisfies the obligations of Article 137 from this Rulebook ensures and declares that the pressure equipment is in conformity with the type as described in the type-examination certificate and satisfies the requirements from the provisions of this Rulebook which apply to it.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item and draw up a written declaration of conformity.

The conformity marking, referred to in paragraph 2 of this Article should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 142 to 145 of this Rulebook.

Article 137

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 138 to 141 of this Rulebook and be subject to surveillance as specified in Articles 142 to 145 of this Rulebook.

8. 1. Quality system

Article 138

The manufacturer should lodge an application for assessment of his quality system for the pressure equipment with a notified body of his choice.

The application referred to in paragraph 1 of this Article should include:

- all relevant information on the pressure equipment concerned,
- the documentation concerning the quality system,
- the technical documentation for the approved type and a copy of the type-examination certificate.

Article 139

Under the quality system, each item of pressure equipment should be examined and appropriate tests as set out in the relevant national standard referred to in Article 57 of this Rulebook, or equivalent tests, particularly final assessment as referred to in Articles 38 to 41 of this Rulebook, should be carried out in order to ensure its conformity with the requirements of the provisions of this Rulebook which apply to it.

All the elements, requirements and provisions adopted by the manufacturer should be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation should permit a consistent interpretation of the quality programmes, plans, manuals and records.

The documentation on the quality system referred to in paragraph 2 of this Article should, especially include an appropriate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the examinations and tests to be carried out after manufacture,
- the means of monitoring the required effective operation of the quality system,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with Articles 34 and 35 of this Rulebook.

Article 140

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 139 of this Rulebook.

The elements of the quality system which conform to the relevant national standard are presumed to comply with the corresponding requirements referred to in Article 139 of this Rulebook.

The auditing team should have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure shall include an inspection visit to the manufacturer's premises.

The result should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

Article 141

The manufacturer should undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body should assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Article 139 of this Rulebook or whether a reassessment is required.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

8. 2. Surveillance under the responsibility of the notified body

Article 142

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Article 143

The manufacturer shall allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

Article 144

The notified body should carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report.

The frequency of periodic audits referred to in paragraph 1 of this Article should be such that a full reassessment is carried out every three years.

Article 145

In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors should be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly.

The notified body should provide the manufacturer with a visit report and, if a test has taken place, with a test report.

8. 3. Keeping the documentation and communication of information

Article 146

The manufacturer should, for a period of 10 years after the last of the pressure equipment has been manufactured, hold at the disposal of the competent national authorities:

- the documentation referred to in the second indent, paragraph 2 of Article 138 of this Rulebook,
- the adjustments referred to in the second paragraph of Article 141 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 4 of Article 140 and paragraph 4 of Article 141 and in Articles 144 and 145 of this Rulebook.

Article 147

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn quality system approvals and
- issued quality system approvals, on request.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn quality system approvals or
- refused quality system approvals.

9. Product quality assurance (Module “E1”)

Article 148

For the purposes of this Rulebook, product quality assurance (Module “E1”) is a procedure whereby the manufacturer who satisfies the obligations of Article 150 of this Rulebook, ensures and declares that the pressure equipment satisfies the requirements of the provisions from this Rulebook which apply to it.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

The conformity marking, referred to in paragraph 2 of this Article should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 155 to 158 of this Rulebook.

Article 149

The manufacturer should draw up the technical documentation in order to enable an assessment to be made of the conformity of the pressure equipment with the requirements of this Rulebook which apply to it.

Provided necessary to assess the conformity, the technical documentation referred to in this Article, paragraph 1, shall cover the design, manufacture and operation of the pressure equipment and contain the following:

- general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of this Rulebook where the national standards referred to in Article 57 of this Rulebook have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 150

The manufacturer should operate an approved quality system for final inspection and testing as specified in Articles 151 to 154 of this Rulebook and be subject to surveillance as specified in Articles 155 to 158 of this Rulebook.

9. 1. Quality system

Article 151

The manufacturer should lodge an application for assessment of his quality system with a notified body of his choice.

The application referred to in paragraph 1 of this Article should include:

- all relevant information on the pressure equipment concerned,
- the documentation concerning the quality system.

Article 152

Under the quality system, each item of pressure equipment should be examined and appropriate tests as set out in the relevant national standard referred to in Article 57 of this Rulebook, or equivalent tests, particularly final assessment as referred to in Articles 38 to 41 of this Rulebook, should be carried out in order to ensure its conformity with the requirements of the provisions of this Rulebook which apply to it.

All the elements, requirements and provisions adopted by the manufacturer should be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation should permit a consistent interpretation of the quality programmes, plans, manuals and records.

The documentation on the quality system referred to in paragraph 2 of this Article should, especially include an appropriate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the procedures used for the permanent joining of parts as approved in accordance with Article 34 of this Rulebook,
- the examinations and tests to be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with Article 34 of this Rulebook.

Article 153

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 152 of this Rulebook.

The elements of the quality system which conform to the relevant national standard are presumed to comply with the corresponding requirements referred to in Article 152 of this Rulebook.

The auditing team should have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure shall include an inspection visit to the manufacturer's premises.

The result should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision. In case of a negative result the manufacturer may make an appeal to the notified body.

Article 154

The manufacturer should undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body should assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Article 152 of this Rulebook or whether a reassessment is required.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

9. 2. Surveillance under the responsibility of the notified body

Article 155

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Article 156

The manufacturer shall allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- quality system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

Article 157

The notified body should carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report.

The frequency of periodic audits referred to in paragraph 1 of this Article should be such that a full reassessment is carried out every three years.

Article 158

In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors should be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly.

The notified body should provide the manufacturer with a visit report and, if a test has taken place, with a test report.

9. 3. Keeping the documentation and communication of information

Article 159

The manufacturer should, for a period of 10 years after the last of the pressure equipment has been manufactured, hold at the disposal of the competent national authorities:

- the technical documentation described in Article 149 of this Rulebook,
- the documentation referred to in the second indent, paragraph 2 of Article 151 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 154 of this Rulebook;
- the decisions and reports from the notified body which are referred to in paragraph 4 of Article 153 and paragraph 4 of Article 154 and in Articles 157 and 158 of this Rulebook.

Article 160

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn quality system approvals and
- issued quality system approvals, on request.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn quality system approvals or
- refused quality system approvals.

10. Product verification (Module “F”)

Article 161

For the purposes of this Rulebook, product verification (Module “F”) is a procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia, shall ensure and declare that the pressure equipment subject to the procedure set out in the Article 163 of this Rulebook is in conformity with the type described:

- in the type-examination certificate, or
 - design-examination certificate
- and satisfies the requirements of this Rulebook which apply to it.

Article 162

The manufacturer should take all measures necessary to ensure that the manufacturing process requires the pressure equipment to comply with the type described:

- in the type-examination certificate, or
 - design-examination certificate
- and with the requirements of this Rulebook which apply to it.

The manufacturer, or his authorized representative established within the Community, should affix the conformity marking to all pressure equipment and draw up a declaration of conformity.

Article 163

The notified body should perform the appropriate examinations and tests in order to check the conformity of the pressure equipment with the relevant requirements of this Rulebook by examining and testing every product in accordance with with the provisions of Articles 164 to 166 of this Rulebook.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep a copy of the declaration of conformity for a period of 10 years after the last of the pressure equipment has been manufactured.

10.1. Verification by examination and testing of each item of pressure equipment

Article 164

Each item of pressure equipment should be individually examined and should undergo appropriate examinations and tests as set out in the relevant national standards referred to in Article 57 or equivalent examinations and tests in order to verify that it conforms to the type and the requirements of this Rulebook which apply to it.

In cases of paragraph 1 of this Article, the notified body should in particular:

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with Articles 34 and 35 of this Rulebook,
- verify the certificate issued by the materials manufacturer in accordance with Article 47 of this Rulebook,
- carry out or have carried out the final inspection and proof test referred to in Article 38 to 41 of this Rulebook and examine the safety devices, if applicable.

Article 165

The notified body should affix its identification number or have it affixed to each item of pressure equipment and draw up a written certificate of conformity relating to the tests carried out.

Article 166

The manufacturer, or his authorized representative established within the Republic of Macedonia, should ensure that the certificates of conformity issued by the notified body can be made available on request.

11. Unit verification (Module “G”)

Article 167

For the purposes of this Rulebook, unit verification shall describe the procedure whereby the manufacturer ensures and declares that pressure equipment which has been issued with the certificate referred to in Article 171 of this Rulebook satisfies the requirements set out in the provisions of this Rulebook which apply to it.

The manufacturer shall affix the conformity marking to pressure equipment which he manufactures and draw up a written declaration of conformity.

Article 168

The manufacturer should apply to a notified body of his choice for unit verification.

The application referred to in paragraph 1 of this Article should include:

- name, surname and address or name and the headquarters of the manufacturer and the location of the pressure equipment,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation.

Article 169

The technical documentation should enable the conformity of the pressure equipment with the requirements of this Rulebook which apply to it to be assessed and the design, manufacture and operation of the pressure equipment to be understood.

The application referred to in paragraph 1 of this Article should include:

- general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the national standards referred to in Article 57 of this Rulebook, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Rulebook where the national standards referred to in Article 57 of this Rulebook have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports;
- appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with Articles 34 and 35 of this Rulebook.

Article 170

The notified body should examine the design and construction of each item of pressure equipment and during manufacture perform appropriate tests as set out in the relevant national standards referred to in Article 57 of this Rulebook, or equivalent examinations and tests, to ensure its conformity with the provisions of this Rulebook which apply to it.

In cases of paragraph 1 of this Article, the notified body should in particular:

- examine the technical documentation with respect to the design and the manufacturing procedures,
- assess the materials used where these are not in conformity with the relevant national standards or with an approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with Article 47 of this Rulebook,
- approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with Article 34 of this Rulebook,
- verify the qualifications or approvals required under Article 35 of this Rulebook,
- carry out the final inspection referred to in Article 39 of this Rulebook, perform or have performed the proof test referred to in Article 40 of this Rulebook and examine the safety devices, if applicable.

Article 171

The notified body should affix its identification number or have it affixed to the pressure equipment and draw up a certificate of conformity for the tests carried out.

The certificate referred to in paragraph 1 of this Article should be kept for a period of ten years.

Article 172

The manufacturer, or his authorized representative established within the Republic of Macedonia, should ensure that the declaration of conformity and certificate of conformity issued by the notified body can be made available on request.

12. Full quality assurance (Module “H”)

Article 173

For the purposes of this Rulebook, full quality assurance (Module “H”) describes the procedure whereby the manufacturer who satisfies the obligations of Article 174 ensures and declares that the pressure equipment in question satisfies the requirements of this Rulebook which apply to it.

The manufacturer or its authorized representative established in the Republic of Macedonia, shall affix the conformity marking to each item of pressure equipment and draw up a written declaration of conformity.

The conformity marking, referred to in paragraph 2 of this Article should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 179 to 182 of this Rulebook.

Article 174

The manufacturer should implement an approved quality system for design, manufacture, final inspection and testing as specified in Articles 175 to 178 of this Rulebook and be subject to surveillance as specified in Articles 179 to 182 of this Rulebook.

12. 1. Quality system

Article 175

The manufacturer should lodge an application for assessment of his quality system with a notified body of his choice.

The application referred to in paragraph 1 of this Article should include:

- all relevant information on the pressure equipment concerned,

- the documentation concerning the quality system.

Article 176

The quality system should ensure compliance of the pressure equipment with the provisions of this Rulebook which apply to it.

All the elements, requirements and provisions adopted by the manufacturer should be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation should permit a consistent interpretation of the procedural and quality measures such as programmes, plans, manuals and records.

The documentation on the quality system referred to in paragraph 2 of this Article should, especially include an appropriate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality,
- the technical design specifications, including the national standards, that will be applied and, where the national standards referred to in Article 57 of this Rulebook are not applied in full, the means that will be used to ensure that the essential requirements of this Rulebook which apply to the pressure equipment will be met,
- the design control and design verification techniques, processes and systematic measures that will be used when designing the pressure equipment, particularly with regard to materials in accordance with Articles 44 to 47 of this Rulebook,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with Article 34 of this Rulebook,
- the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with Articles 34 and 35 of this Rulebook,
- the means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the quality system.

Article 177

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 176 of this Rulebook.

The elements of the quality system which conform to the relevant national standard are presumed to comply with the corresponding requirements referred to in Article 176 of this Rulebook.

The auditing team should have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure shall include an inspection visit to the manufacturer's premises.

The result should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision. In case of a negative result the manufacturer may make an appeal to the notified body.

Article 178

The manufacturer should undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body should assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in Article 176 of this Rulebook or whether a reassessment is required.

The decision should be notified to the manufacturer. The notification should contain the conclusions of the examination and the reasoned assessment decision.

12. 2. Surveillance under the responsibility of the notified body

Article 179

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Article 180

The manufacturer should allow the notified body access for inspection purposes to the locations of design, manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- quality system documentation,
- the quality records provided for in the design part of the quality system, such as: results of analyses, calculations, tests, etc.,
- the quality records provided for in the manufacturing part of the quality system, such as: inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc:

Article 181

The notified body should carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report.

The frequency of periodic audits referred to in paragraph 1 of this Article should be such that a full reassessment is carried out every three years.

Article 182

In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors should be considered in the visit control system:

- the category of the equipment,
- the results of previous surveillance visits,
- the need to follow up corrective action,
- special conditions linked to the approval of the system, where applicable,
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly.

The notified body should provide the manufacturer with a visit report and, if a test has taken place, with a test report.

12. 3. Keeping the documentation and communication of information

Article 183

The manufacturer should, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the competent national authorities:

- the documentation referred to in the second indent, paragraph 2 of Article 175 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 178 of this Rulebook;
- the decisions and reports from the notified body which are referred to in paragraph 4 of Article 177 and paragraph 4 of Article 178 and in Articles 181 and 182 of this Rulebook.

Article 184

Each notified body should communicate to the competent national bodies the relevant information concerning:

- withdrawn quality system approvals and
- issued quality system approvals, on request.

Each notified body should communicate to the other competent bodies the relevant information concerning:

- withdrawn quality system approvals or
- refused quality system approvals.

13. Full quality assurance with design examination and special surveillance of the final assessment (Module “H1”)

Article 185

In addition to the requirements of module H, the following apply:

(a) The manufacturer should lodge an application for examination of the design with the notified body.

(b) The application should enable the design, manufacture and operation of the pressure equipment to be understood, and enable conformity with the relevant requirements set out in the provisions of this Rulebook to be assessed.

The application referred to in paragraph 1 of this point should include:

- the technical design specifications, including standards, which have been applied,
- the necessary supporting evidence for their adequacy, in particular where the national standards referred to in Article 57 of this Rulebook have not been applied in full. This supporting evidence should include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;

(c) the notified body should examine the application and where the design meets the provisions of this Rulebook which apply to it issue a design-examination certificate to the applicant. The certificate should contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories;

(d) the applicant should inform the notified body that has issued the design-examination certificate of all modifications to the approved design. Modifications to the approved design should receive additional approval from the notified body that issued the design-examination certificate where they may affect conformity with the essential requirements of the provisions of this Rulebook or the prescribed conditions for use of the pressure equipment. This additional approval should be given in the form of an addition to the original design-examination certificate;

(e) each notified body should also communicate to the other notified bodies the relevant information concerning the design-examination certificates it has withdrawn or refused.

Article 186

Final assessment as referred to in Article 38 to 41 of this Rulebook is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body should conduct examinations on the pressure equipment.

VI. 'CE' CONFORMITY MARKING

Article 187

The CE marking consists of the initials 'CE'. CE conformity shall consist of the CE abbreviation in accordance with the model given in Annex 2 enclosed to this Rulebook.

The CE marking should be accompanied by the identification number, as referred to in Articles 64 to 67 of this Rulebook, of the notified body involved at the production control phase.

Should the 'CE'-marking be reduced or enlarged the proportions given in the Appendix 2.

Various components of the 'CE'-marking shall have, in essence, the same vertical dimensions, which may not be less than 5 mm.

Article 188

The CE marking shall be affixed in a visible, easily legible and indelible fashion to each:

- item of pressure equipment referred to in Article 7 of this Rulebook, or
- assembly referred to in Article 8 of this Rulebook,

which is complete or is in a state permitting final assessment as described in Articles 38 to 41 of this Rulebook.

Article 189

It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly as referred to in Article 8 of this Rulebook. Individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.

Article 190

Where the pressure equipment or assembly is subject to other regulations covering other aspects which provide for the affixing of the CE marking, the latter shall indicate that the pressure equipment or assembly in question is also presumed to conform to the provisions of those other regulations.

Should one or more of those regulations allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the regulations applied by the manufacturer.

In cases of paragraph 2 of this Article, the particulars of the said regulations should be given in the documents, notices or instructions required by those regulations, accompanying the pressure equipment or assembly.

Article 191

The affixing of markings on pressure equipment or assemblies which are likely to mislead the natural and legal persons as to the meaning or form of the CE marking shall be prohibited.

Any other marking may be affixed to pressure equipment or assemblies provided that the visibility and legibility of the CE marking is not thereby reduced.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 192

The provisions from this Rulebook, which refer to 'CE'-marking, shall apply after the accession of the Republic of Macedonia in the European Union or after the entry into force of an appropriate Protocol with the European Community on conformity assessment and after the designation (notification) of a notified body of Republic of Macedonia in the European Commission.

Article 193

Before the period of the accession of the Republic of Macedonia in the European Union, the manufacturer or its authorized representative established in the Republic of Macedonia may permit the placing on the market of pressure equipment and assemblies which bear the conformity marking complying with the essential requirements as laid down in the provisions of this Rulebook.

In case of paragraph 1 of this Article, the manufacturer of pressure equipment and assemblies, his authorized representative established in the Republic of Macedonia shall provide for declaration of conformity for each pressure equipment and assembly in accordance with the conformity assessment procedure as set by the provisions of this Rulebook.

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep a copy of the declaration of conformity issued in accordance with the paragraph 2 of this Article for a period of 10 years after the last of the pressure equipment or assembly has been manufactured. Documentation for each product verified by the producer shall be accompanied by a copy of the certificate.

Article 194

Before the period of the accession of the Republic of Macedonia in the European Union or before entrance into force of an appropriate Protocol for conformity assessment with the European Union or before entrance into force of an appropriate bilateral agreement for mutual document recognition, any pressure equipment and assemblies imported and placed on the market within the Republic of Macedonia shall possess a conformity certificate issued by notified body identified in European commission or **authorized** body established in the Republic of Macedonia. **The certificate of conformity shall be followed with CE marking issued by manufacturer or its representative in time of importing it in the Republic of Macedonia.** The certificate of conformity referred to in paragraph 1 of this Article shall be issued based upon declaration of conformity from the manufacturer, certificate for conformity for pressure equipment and assemblies in accordance with procedure on conformity assessment used to carry out the assessment, issued by the notified body, upon results from the conducted tests and after an analysis on the level of conformity with the essential requirements as set out in the provisions from this Rulebook.

The certificate of conformity referred to in the first paragraph of this Article, shall be issued for each type of pressure equipment or assembly and it shall be accompanied by documentation for each individual item of pressure equipment or assembly.

Where non-conformity of the pressure equipment or assemblies with the requirements set out in the provisions of this Rulebook is established, a conformity certificate shall not be issued. In accordance with the law, the notified body shall forthwith inform the Commission for product safety thereof.

Article 195

Before the accession of the Republic of Macedonia in the European Union or before entrance into force of an appropriate Protocol for conformity assessment with the European Union, the manufacturer or his authorized representative established **in the Republic of Macedonia or EU**, should receive an European approval for the material issued by the notified body established in the Republic of Macedonia **or EU**, where a material with an European approval for material is implanted.

Article 196

After the accession of the Republic of Macedonia in the European Union or after the entry into force of an appropriate Protocol with the European Community, for the purposes of this Rulebook, the following terms shall apply:

- "
- "EC-declaration of conformity" instead of "declaration of conformity",
- "EC" type examination" instead of "type examination"
- "EC type examination certificate" instead of "type examination certificate",
- "EC design examination" instead of "design examination"
- "EC design examination certificate" instead of "design examination certificate",
- "EC unit verification" instead of "unit verification",
- "EC unit verification certificate" instead of "unit verification certificate",
- "EC-marking" instead of "conformity marking",
- "notified body" instead of "authorized body",
- "identification number of the notified body" instead of "identification number of the authorized body". Identification number of the notified body is the number granted by the European Commission, and the identification number of the authorised body is the number granted by the Minister of Economy.

Article 197

The provisions of the Rulebook on technical norms for stable pressure vessels (Official Gazette of SFR Yugoslavia No. 16/83) which regard to pressure vessels up to the moment of their implantation, shall cease to apply as from the date of entrance into force of this Rulebook.

Article 198

This Rulebook shall enter into force on the 8th day following its publication in the "Official Gazette of the Republic of Macedonia".

Number
_____ 2007
Skopje

MINISTER,
Vera Rafajlovska, signed

Appendix I

CONFORMITY ASSESSMENT TABLES

1. The references in the tables to categories of modules are the following:

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

2. The safety accessories defined in Article 2, point 4, and referred to in Article 7, point 4 of this Rulebook, are classified in Category IV. However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.

3. The safety accessories defined in Article 2, point 5, and referred to in Article 7, point 4 of this Rulebook, are classified on the basis of:

- their maximum allowable pressure PS, and
- their volume V or their nominal size DN, as appropriate, and
- the group of fluids for which they are intended,

and the appropriate table for vessels or piping is to be used to determine the conformity assessment category.

Where both the volume and the nominal size are considered appropriate in the second indent, the pressure accessory should be classified in the highest category.

4. The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

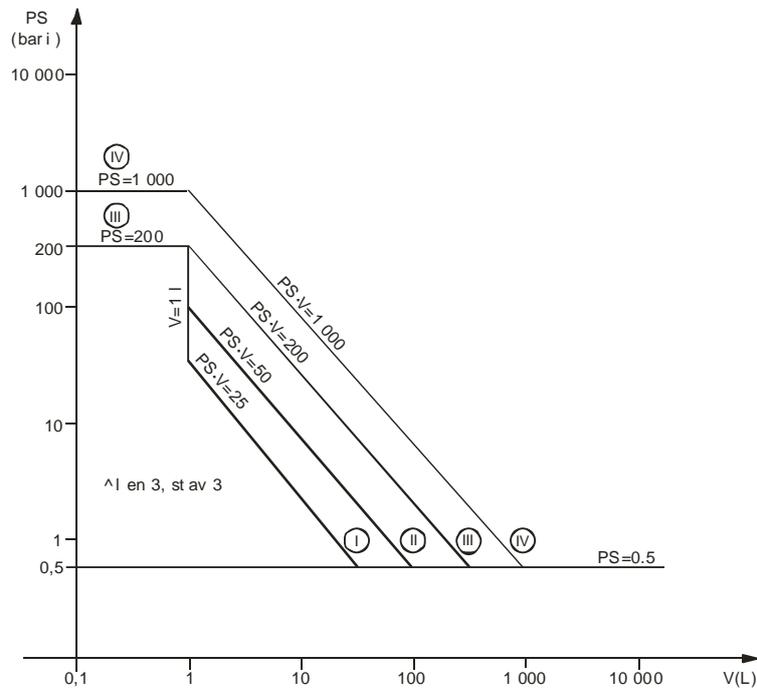


Table 1. Vessels referred to in Article 7, point 1, subpoint (a), first indent of this Rulebook

Exceptionally, vessels intended to contain an unstable gas and falling within Categories I or II on the basis of table 1 should be classified in Category III.

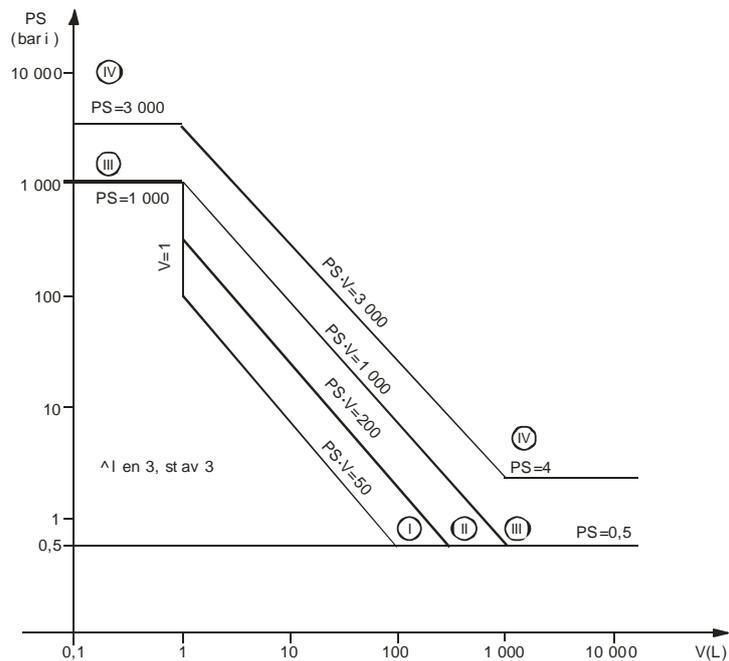


Table 2. Vessels referred to in Article 7, point 1, subpoint (a), second indent of this Rulebook

Exceptionally, portable extinguishers and bottles for breathing equipment should be classified at least in Category III.

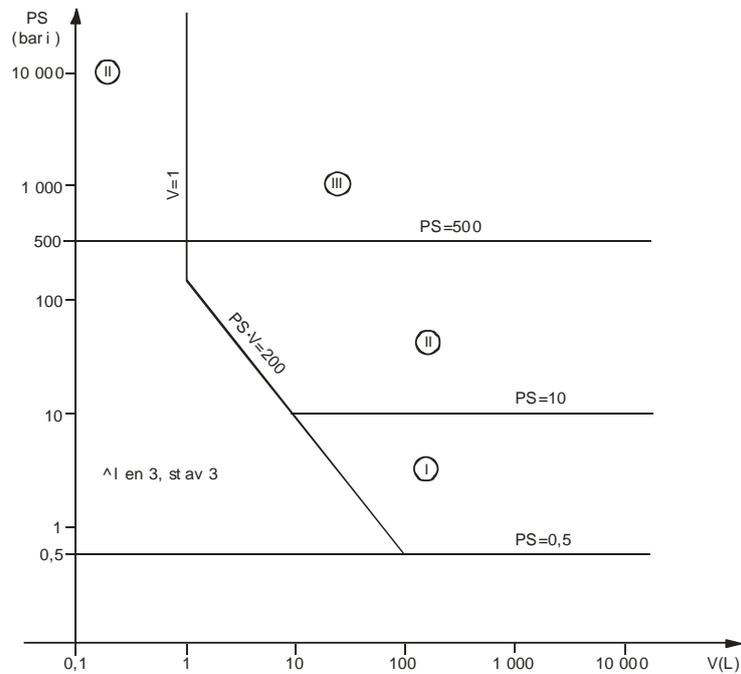


Table 3. Vessels referred to in Article 7, point 1, subpoint (b), first indent of this Rulebook

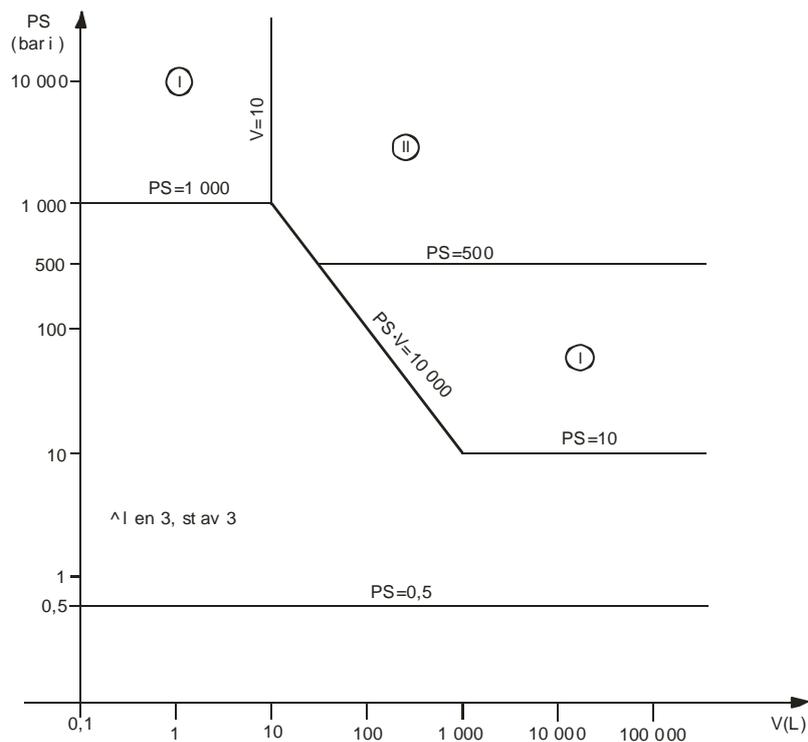


Table 4. Vessels referred to in Article 7, point 1, subpoint (b), second indent of this Rulebook

Exceptionally, assemblies intended for generating warm water as referred to in Article 8, point 3 of this Rulebook, should be subject either to an design examination (Module B1) with respect to their conformity with the essential requirements referred to in Articles 27 to 30, 43 and 48, paragraph 2, points 1 and 4 of this Rulebook, or to full quality assurance (Module H).

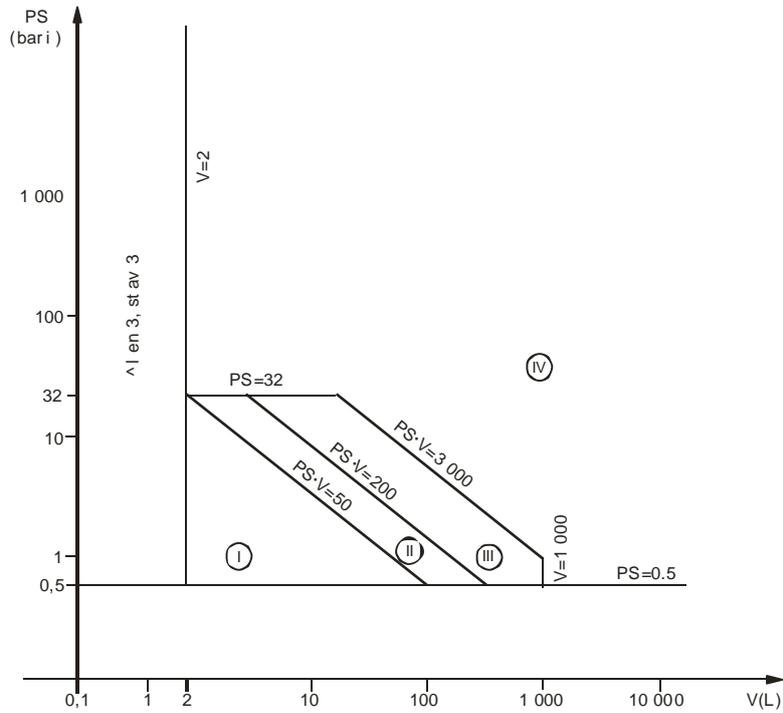


Table 5. Pressure equipment referred to in Article 7, point 2 of this Rulebook

Exceptionally, the design of pressure-cookers should be subject to a conformity assessment procedure equivalent to at least one of the Category III modules.

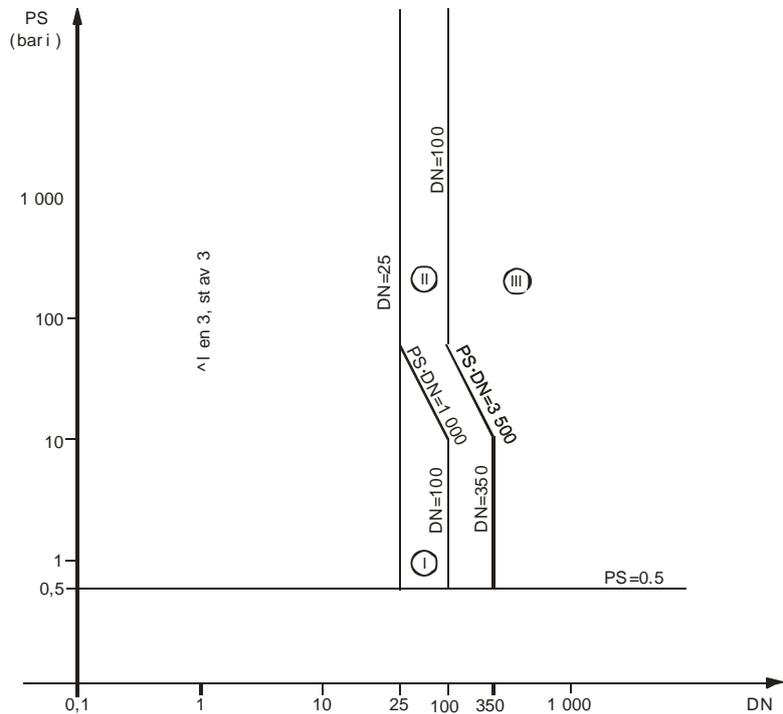


Table 6. Piping referred to in Article 7, point 3, subpoint (a), first indent of this Rulebook

Exceptionally, piping intended for unstable gases and falling within Categories I or II on the basis of Table 6 should be classified in Category III.

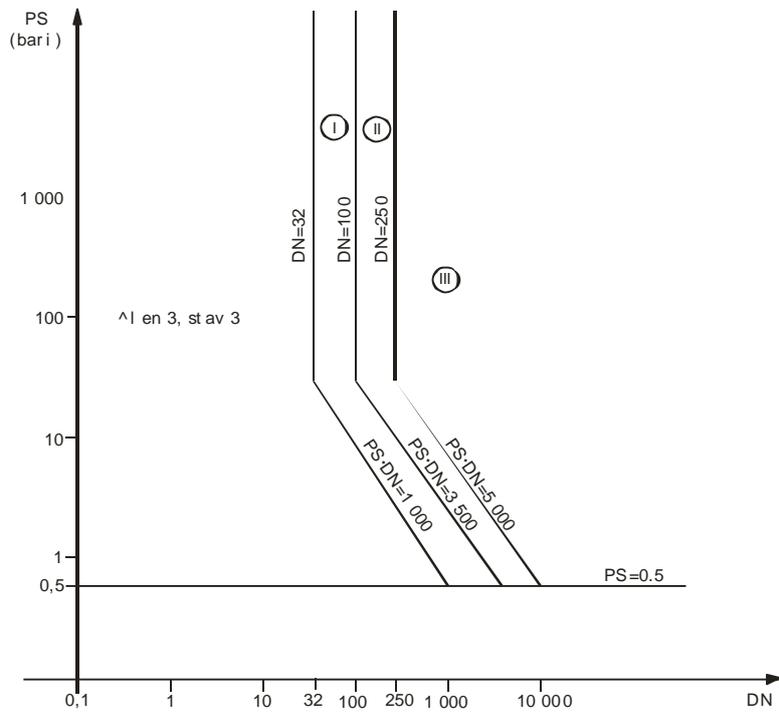


Table 7. Piping referred to in Article 7, point 3, subpoint (a), second indent of this Rulebook

Exceptionally, all piping containing fluids at a temperature greater than 350°C and falling within Category II on the basis of Table 7 should be classified in Category III.

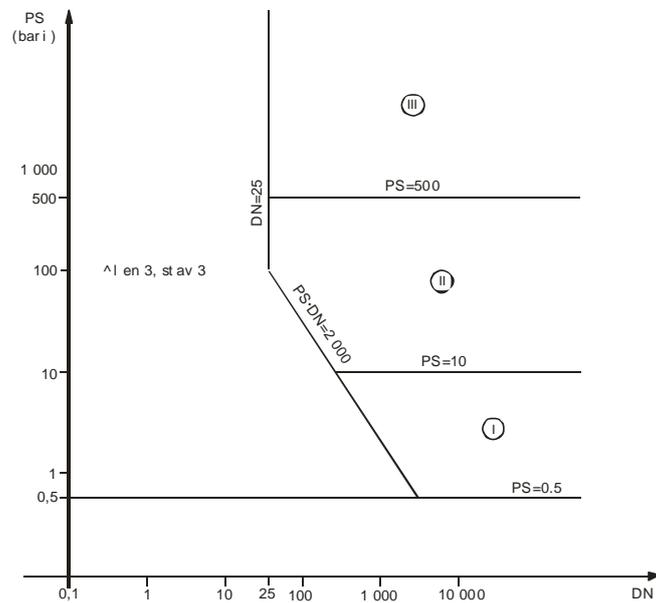


Table 8. Piping referred to in Article 7, point 3, subpoint (a), first indent of this Rulebook

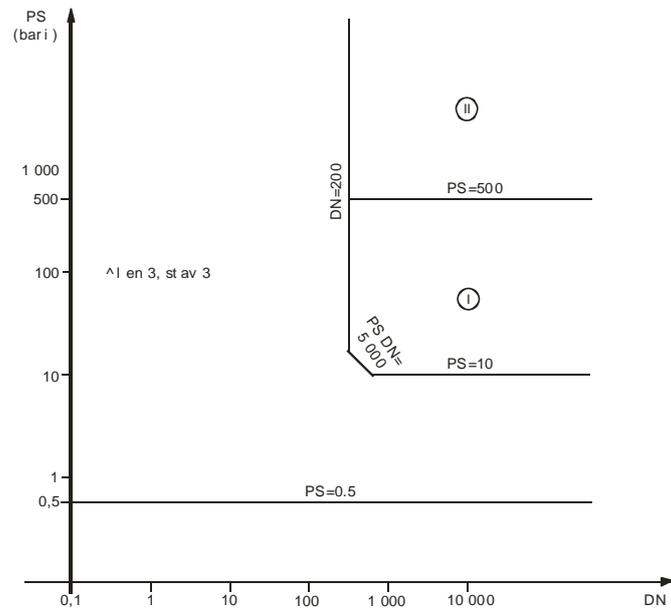
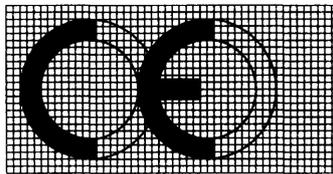


Table 9. Piping referred to in Article 7, point 3, subpoint (b), second indent of this Rulebook

Appendix II

‘CE’ MARKING

The CE marking consists of the initials ‘CE’ taking the following form:



ОБРАЗЕЦ Бр. 1**Поимник на термини и изрази**

За секој CELEX-број на правниот акт на ЕУ се пополнува овој Образец бр.1 - Поимник на термини и изрази. Пополнетиот Образец бр.1 прикачете го на крајот на преводот, така што преводот и Образецот бр.1 ќе претставуваат ЕДЕН документ.

CELEX-број	/					
Наслов на документот (АНГ)	RULEBOOK CONCERNING PRESSURE EQUIPMENT					
Наслов на документот (МАК)	ПРАВИЛНИК ЗА ОПРЕМА ПОД ПРИТИСОК					
Област на примена						
Агенција за преведување	Еуролингва		Преведувач			
Тел.	070/305760	е-пошта	eurolingua@eurolingua.com.mk		Датум	26.03.2007

Место на зборот во текстот (член, став, точка, прилог ...)	Изворен збор (АНГ)	Превод (МАК)	Забелешка / Коментар	Извор на преводот¹ (користен речник / МАКТЕРМ)
	headraces	доводни канали		
	penstocks	доводни цевководи за хидроцентрали		
	EC (CE) marking	ЕС (СЕ) ознака		МАКТЕРМ
	EC (CE) type approval	ЕС (СЕ) одобрение на тип		МАКТЕРМ
	EC certificate of conformity	ЕС потврда за сообразност		МАКТЕРМ
	EC declaration	ЕС декларација		МАКТЕРМ
	EC declaration of conformity to type	ЕС декларација за усогласеност со тип		МАКТЕРМ
	EC declaration of production conformity	ЕС декларација за сообразност на производството		МАКТЕРМ
	EC design examination certificate	сертификат за ЕС-испиување на дизајн		МАКТЕРМ

¹ КОРИСТЕН РЕЧНИК/ МАКТЕРМ – Ве молиме, запишете го името на речникот што е користен при преводот. Доколку терминот се наоѓа во МАКТЕРМ - базата на термини на веб-страницата на СЕП, Ве молиме нотирајте. Слободен пристап до базата на термини имаат сите корисници во процесот.