Official Gazette of the Republic of Macedonia No. 17 of 14 February 2007

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 TRANSPORTABLE PRESSURE EQUIPMENT

I. GENERAL PROVISIONS

Article 1

This rulebook prescribes the conformity assessment procedures for new transportable pressure equipment, conformity re-assessment procedures of the current transportable pressure equipment, procedures for periodic inspection of transportable pressure equipment, and the conditions which need to be met by the authorized and approved bodies involved in the conformity assessment procedures.

Article 2

The purpose of this Rulebook shall be to enhance safety with regard to transportable pressure equipment approved for inland transport of dangerous goods by road and by rail and to ensure the free movement of such equipment within the Republic of Macedonia, including the placing on the market and repeated putting into service and repeated use aspects.

Article 3

The provisions of this Rulebook shall apply for:

(a) placing on the market of new transportable pressure equipment as defined in Article 4 of this Rulebook;

(b) for reassessment of conformity of existing transportable pressure equipment as defined in Article 4 of this Rulebook, which meets the technical requirements laid down in the regulations for transport of dangerous goods by road or by rail;

(c) for repeated use and periodic inspections:
- to the transportable pressure equipment referred to in (a) and (b) of this paragraph;
- to existing gas cylinders bearing the conformity marking laid down in the appropriate technical regulations which refer to gas cylinders manufactured from unalloyed and alloyed aluminium and aluminium alloys.

Transportable pressure equipment used exclusively for transport of dangerous goods is regulated in the Law on transportation of dangerous products, covering directives 94/55/EC, 96/49/EC and 99/36/EC.

Article 4

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

1. “transportable pressure equipment” are all:

- all receptacles (cylinders, tubes, pressure drums, cryogenic receptacles, bundles of cylinders as defined in technical regulations on inland transport of dangerous goods),
- all tanks, including demountable tanks, tank containers (mobile tanks), tanks of tank wagons, tanks or receptacles of battery vehicles or battery wagons, tanks of tank vehicles,

used for the transport of Class 2 gases in accordance with the regulations for inland transport of dangerous goods by road or by rail and for the transport of certain dangerous substances of other classes indicated in the List of dangerous goods, other than those of Class 2 subject to Article 4 of this Rulebook (Appendix 1) enclosed to this Rulebook, including their valves and other accessories used for transport.

This definition from point 1 of this Article excludes equipment subject to the general exemption principles applicable to small quantities and to the special cases provided for in other regulations regarding transport of dangerous goods as well as aerosol dispensers (UN number 1950) and gas cylinders for breathing appliances;

2. “mark” means the symbol referred to in Chapter VII of this Rulebook;

3. "conformity assessment procedures" means those procedures set out in provisions of Chapter IV of this Rulebook;

4. "reassessment of conformity" means the procedure for subsequent assessment, at the request of the owner or his authorised representative established in the Republic of Macedonia or of the holder, of the conformity of transportable pressure equipment already manufactured and put into service prior to entrance into force of this Rulebook;

5. "notified body" means an inspection body designated by the regulations on product safety and meet the criteria of this Rulebook;

6. "approved body" means an inspection body designated by the regulations on product safety and meet the criteria of this Rulebook.

II. CONFORMITY ASSESSMENT

1. Conformity assessment or placing on the Community market of new transportable pressure equipment

Article 5

New receptacles and new tanks shall meet the relevant provisions on the appropriate regulations on inland transport of dangerous goods by road and by rail. The compliance of such transportable pressure equipment with the provisions on the appropriate regulations on inland transport of dangerous goods by road and by rail shall be established by a notified body exclusively in accordance with the conformity assessment procedures set out in Chapter IV of this Rulebook, and specified in Modules which need to be taken into account when assessing the conformity (Appendix 2) enclosed to this Rulebook.

New valves and other accessories used for transport shall meet the relevant provisions of appropriate regulations on inland transport of dangerous goods by road and by rail.

Valves and other accessories having a direct safety function in transportable pressure equipment, in particular safety valves, valves for filling and emptying and cylinder valves, shall be subject to a conformity assessment procedure at least a stringent as that undergone by the receptacle or tank to which they are fitted.

Valves and other accessories used for transport may be subject to a different conformity assessment procedure separate from that used for the receptacle or tank.

Should provisions of appropriate regulations on inland transport of dangerous goods by road and by rail do not contain any detailed technical provisions for the valves and accessories referred to in paragraphs 3 and 4 of this Article, such valves and accessories should meet the requirements contained in the technical regulation for pressure equipment and shall be subject to a category II, III or IV conformity assessment procedure as laid down in the technical regulation for pressure equipment according to whether the receptacle or tank belongs to category 1, 2 or 3 as laid down in Appendix 2.

Transportable pressure equipment referred to in Article 3, paragraph 1(a) of this Rulebook which bears the relevant mark provided for in Articles 150 and 151 of this Rulebook, shall be regarded as compliant with the provisions of this Rulebook.

2. Conformity assessment for the placing on the market in the Republic of Macedonia of new transportable pressure equipment

Article 6

By way of derogation from Article 5 of this Rulebook, the placing on the market, transport and putting into service by users, of the receptacles - including their valves and other accessories used for transport - covered by Article 3, paragraph 1(a) of this Rulebook, the conformity of which has been assessed by an approved body, may be authorised.

Transportable pressure equipment the conformity of which has been assessed by an approved body may not bear the marking described in Article 150 of this Rulebook.

The approved body shall work exclusively for the group of which it is a member.

The procedures applicable to conformity assessment by approved bodies shall be modules A1, C1, F and G, as described in Chapter IV of this Rulebook.

3. Reassessment of conformity for existing transportable pressure equipment

Article 7

The compliance of transportable pressure equipment as described in Article 3, paragraph 1(b) of this Rulebook with the provisions on the appropriate regulations on inland transport of dangerous goods by road and by rail shall be established by a notified body in accordance with the reassessment of conformity procedures set out in Chapter V of this Rulebook.

Where equipment mentioned in paragraph 1 of this Article was manufactured in a batch, including their valves and other accessories used for transport, the conformity reassessment in regards to receptacles may be carried out by an approved body provided that conformity of the type is reassessed by a notified body.

4. Periodic inspections and repeated use

Article 8

Periodic inspections of the receptacles, including their valves and accessories used for transport, covered with Article 3, paragraph 1(c) of this Rulebook, shall be arranged by a notified or approved body in accordance with the procedure set out in Chapter VI of this Rulebook.

Periodic inspections of tanks, including their valves and other accessories used for transport, shall be arranged by a notified body in accordance with the procedure laid down in Chapter VI, subchapter 1 of this Rulebook.

By way of derogation, periodic inspections of tanks may be performed by the approved bodies which have been recognised for carrying out periodic inspections of tanks and which act under the supervision of a body notified under the procedure provided for in Chapter VI, subchapter 2 of this Rulebook concerning periodic inspection through quality assurance.

The transportable pressure equipment referred to in Article 3, paragraph 1 of this Article may be subjected to periodic inspections.

5. National standards

Article 9

Connection with other equipment and colour codes applicable to transportable pressure equipment shall be compliant with the provisions contained in the national standards developed on the basis of European harmonised standards (hereinafter: national standards).

In cases where the ambient temperature is regularly lower than -20°C, more stringent standards may be imposed as regards to the operating temperature of the material intended for use in the national transport of dangerous goods.

6. Notified bodies

Article 10

The notified body shall meet the criteria for performing the assessment of conformity, listed in Chapter III of this Rulebook, and 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 IV, subchapter 1 of this Rulebook,
- internal manufacturing checks with monitoring of the final assessment (Module “A1”), in accordance with the provisions from Chapter IV, subchapter 2 of this Rulebook,
- type-examination (Module “B”), in accordance with the provisions from Chapter IV, subchapter 3 of this Rulebook,
- design-examination (Module “B1”), in accordance with the provisions from Chapter IV, subchapter 4 of this Rulebook,
- conformity to type (Module “C1”), in accordance with the provisions from Chapter IV, subchapter 5 of this Rulebook,
- production quality assurance (Module “D”), in accordance with the provisions from Chapter IV, subchapter 6 of this Rulebook,
- production quality assurance (Module “D1”), in accordance with the provisions from Chapter IV, subchapter 7 of this Rulebook,

- product quality assurance (Module “E”), in accordance with the provisions from Chapter IV, subchapter 8 of this Rulebook,
- product quality assurance (Module “E1”), in accordance with the provisions from Chapter IV, subchapter 9 of this Rulebook,
- product verification (Module “F”), in accordance with the provisions from Chapter IV, subchapter 10 of this Rulebook,
- unit verification (Module “G”), in accordance with the provisions from Chapter IV, subchapter 11 of this Rulebook,
- full quality assurance (Module “H”), in accordance with the provisions from Chapter IV, 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 IV, subchapter 13 of this Rulebook.

The notified body from paragraph 1 of this Article may be authorized to carry out reassessment of conformity for the existing types or equipment with the requirements listed in the appropriate regulations on inland transport of dangerous goods by road or by rail, in accordance with the provisions from Chapter V of this Regulation, and/or carry out periodic inspections in accordance with the provisions of Chapter VI, subchapter 1 of this Rulebook, and/or carry out monitoring in accordance with the provisions of Chapter VI, subchapter 2 of this Rulebook.

The notified body which performs the assessment of conformity of transportable pressure equipment shall be assigned with an unique identification number of the body.

Article 11

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

7. Approved bodies

Article 12

Approved body which satisfy the criteria in Chapter III of this Rulebook to perform conformity assessment may be authorised to carry out periodic inspections of receptacles - including their valves and other accessories used for transport - referred to in Article 4, point 1, first indent of this Rulebook; or conformity reassessment of existing receptacles - including their valves and other accessories used for transport - which conform to a type reassessed by a notified body, to ensure continued compliance with the relevant provisions of the regulations on inland transport of dangerous goods by road or by rail, in accordance with the procedure laid down in Articles 136, 137 and 138 of this Rulebook.

The approved body mentioned in paragraph 1 of this Article may be authorised to carry out periodic inspections of tanks in accordance with the Article 8, paragraph 3 of this Rulebook.

The approved body which performs the assessment of conformity of transportable pressure equipment should be assigned with an unique identification number of the body.

III. CRITERIA TO BE MET BY NOTIFIED OR APPROVED BODIES ENGAGED IN THE CONFORMITY ASSESSMENT PROCEDURES

1. Notified bodies and approved bodies

Article 13

A notified body or an approved body that is part of an organisation involved in inspection and in functions other than inspection should be identifiable within that organisation.

Article 14

The notified body, approved body and their staff should not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities.

The staff of the inspection body should be free from any commercial, financial and other pressures which might affect their judgment, particularly from persons or organisations external to the inspection body with an interest in the results of inspections carried out, and the impartiality of the inspection staff of the body should be guaranteed.

Article 15

The notified body and the approved body should have at its disposal the necessary staff and possess the necessary facilities to enable it to perform the technical and administrative tasks connected with the inspection and verification operations properly, as well as have access to the equipment required to perform special verifications.

Article 16

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

Approved body shall have at least three expert full time employees, as follows:

- a mechanical engineer with a continuous experience of minimum five years in performing operations defined in Article 12 of this Rulebook,
- a mechanical engineer with a continuous experience of minimum three years in performing operations defined in Article 12 of this Rulebook,
- a high school degree mechanical technician with a continuous experience of minimum three years in performing operations defined in Article 12 of this Rulebook.

The full time employees in the notified body and in the approved body referred to in paragraphs 1 and 2 of this Article should have appropriate qualifications in accordance with the national standards.

Article 17

The staff of the notified and approved body responsible for inspection should have appropriate qualifications, sound technical and vocational training in accordance with the

national standards and a satisfactory knowledge of the requirements of the inspections to be carried out and adequate experience of such operations.

In order to guarantee a high level of safety the notified and the approved body should be in a position to provide expertise in the field of safety of transportable pressure equipment.

The staff of the notified and the approved body should have the ability to make professional judgments as to conformity with general requirements using examination results.

The staff of the notified and the approved body should also have the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

Article 18

The staff of the notified and the approved body should also have relevant knowledge of the technology used for the manufacturing of the transportable pressure equipment, including accessories, which they inspect, of the way in which the equipment submitted to their inspections is used or is intended to be used, and of the defects which may occur during use or in service.

Article 19

The notified and the approved body and their staff should carry out the assessments and verifications with the highest degree of professional integrity and technical competence.

The notified and the approved body and their staff should ensure the confidentiality of information obtained in the course of its inspection activities. Proprietary rights should be protected.

Article 20

The remuneration of persons engaged in inspection activities should not directly depend on the number of inspections carried out, nor on the results of such inspections.

The notified and the approved body should have adequate liability insurance unless its liability is assumed by organisation of which they form a part.

Article 21

The notified and the approved body should themselves normally perform the inspections which it contracts to undertake.

When a notified or the approved body sub-contracts any part of the inspection, they should ensure and be able to demonstrate that its sub-contractor is competent to perform the service in question and should take full responsibility for that sub-contracting.

2. Supplementary criteria to be met by the notified bodies

Article 22

The notified body should be independent of the parties involved and therefore provide "third party" inspection services.

The notified body and its staff responsible for carrying out the inspection should not be the designer, manufacturer, supplier, purchaser, owner, holder, user or maintainer of the

transportable pressure equipment, including accessories, which that body inspects, nor the authorised representative of any of these parties.

The notified body and its staff should not be directly involved in the design, manufacture, marketing or maintenance of the transportable pressure equipment, including accessories, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of transportable pressure equipment and the inspection body.

Article 23

All interested parties should have access to the services of the inspection body. There should be no undue financial or other conditions.

The procedures under which the body operates should be administered in a non-discriminatory manner.

3. Supplementary criteria to be met by the approved bodies

Article 24

The approved body should form a separate and independent part of an organisation involved in the design, manufacture, supply, use or maintenance of the items it inspects.

Article 25

The approved body may not become directly involved in the design, manufacture, supply or use of the transportable pressure equipment, including accessories inspected, or similar competitive items.

Article 26

There should be a clear separation of the responsibilities of the inspection staff from those of the staff employed in the other functions, which should be established by organisational identification and the reporting methods of the inspection body within the parent organisation.

IV. CONFORMITY ASSESSMENT PROCEDURES

1. Internal production control (Module "A")

Article 27

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 28 of this Rulebook, shall ensure and declare that the transportable pressure equipment satisfies the relevant requirements set out in the provisions of this Rulebook.

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

Article 28

The manufacturer should draw up the technical documentation described in Article 29 of this Rulebook and either the manufacturer or his authorized representative established within the Republic of Macedonia shall keep it at the disposal of the relevant national authorities for inspection purposes for a period of 10 years after the last of the transportable 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 of legal person who places the transportable pressure equipment on the market.

Article 29

The technical documentation should enable an assessment to be made of the conformity of the transportable 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 transportable 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 description of the solutions adopted to meet the requirements as set out in this Rulebook,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 30

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 31

The manufacturer shall take all necessary measures to ensure that the manufacturing process guarantees that the manufactured transportable pressure equipment is in compliance with the technical documentation referred to in Article 28 of this Rulebook and with the relevant requirements laid down in the provisions of this Rulebook that apply to that equipment.

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

Article 31-a

Internal production control (Module "A") covers also the request of internal manufacturing checks with monitoring of the final assessment (Module "A1") of Article 32 of this Rulebook on transportable pressure equipment.

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Article 32

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:

- ensure that the manufacturer actually performs final assessment,
- take samples of the transportable 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 transportable 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 transportable pressure equipment.

3. Type-examination (Module "B")

Article 33

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 envisaged meets the provisions of the Rulebook which apply to it.

Article 34

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 35 of this Rulebook.

The applicant should place at the disposal of the notified body a representative example of the production envisaged, (hereinafter: called '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 35

The technical documentation should enable an assessment to be made of the conformity of the transportable 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 transportable 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 description of the solutions adopted to meet the essential requirements as set out in the provisions of this Rulebook,
- 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.

Article 36

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 this Rulebook.

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 provisions of this Rulebook and check the certificate issued by the materials manufacturer;
- approve the procedures for the permanent joining of parts of the pressure equipment or check that they have been previously approved;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved.

2.perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the requirements of this Rulebook;

3.perform or have performed the appropriate examinations and necessary tests to establish whether the relevant provisions of this Rulebook have been applied;

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

Article 37

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 ten 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 a 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 38

The applicant should inform the notified body that holds the technical documentation concerning the type-examination certificate of all modifications to the approved transportable pressure equipment which may be subject to additional approval where they may affect conformity with the essential requirements of this Rulebook 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 type-examination certificate.

Article 39

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 40

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 41

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 10 years after the last of the transportable 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 of legal person who places the transportable pressure equipment on the market.

4. Design-examination (Module “B1”)

Article 42

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 transportable pressure equipment meets the provisions of this Rulebook which apply to it.

Article 43

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.

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 44 of this Rulebook.

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

Article 44

The technical documentation should enable an assessment to be made of the conformity of the transportable 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 transportable 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 description of the solutions adopted to meet the requirements set out in the provisions of this Rulebook,
- the necessary supporting evidence for the adequacy of the design solution; 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.

Article 45

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 this Rulebook.

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

- assess the materials used where these are not in conformity with the relevant provisions of the Rulebook,
- approve the procedures for the permanent joining of the pressure equipment parts or check that they have been previously approved;
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved;

2.perform the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the requirements of this Rulebook;

3.perform the necessary examinations to establish whether the relevant provisions of this Rulebook have actually been applied.

Article 46

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 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 47

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 may be subject to additional approval where they 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 48

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 49

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 50

The manufacturer, or his authorized representative established within the Republic of Macedonia, should keep with the technical documentation referred to in Article 44 of this Rulebook, and copies of design-examination certificates and their additions for a period of 10 years after the last of the transportable 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 of legal person who places the transportable pressure equipment on the market.

5. Conformity to type (Module "C1")

Article 51

For the purposes of this Rulebook, conformity to type (Module "C1") is a part of the procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia, shall ensure and declare that the transportable 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 his authorized representative established within the Republic of Macedonia, should affix the П-marking to all transportable pressure equipment and draw up a declaration of conformity.

Article 52

The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees 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 53

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 transportable 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 of legal person who places the transportable pressure equipment on the market.

Article 54

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:

- ensure that the manufacturer actually performs the final assessment,

– take samples of the transportable 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 equipment samples.

Should one or more of the items of transportable 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 transportable pressure equipment.

6. Production quality assurance (Module "D")

Article 55

For the purposes of this Rulebook, production quality assurance (Module "D") is a procedure whereby the manufacturer who satisfies the obligations of Article 56 of this Rulebook ensures and declares that the transportable 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 his authorized representative established within the Republic of Macedonia, should affix the П-marking to all transportable pressure equipment and draw up a declaration of conformity.

The П-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 61 to 64 of this Rulebook.

Article 56

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 57 to 60 of this Rulebook and be subject to surveillance as specified in Articles 61 to 64 of this Rulebook.

6. 1. Quality system

Article 57

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 transportable 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 58

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 transportable pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used,
- 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 of the personnel concerned, etc.,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

Article 59

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 58 of this Rulebook.

The auditing team should have at least one member with experience of assessing the transportable 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 60

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 58 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 61

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

Article 62

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 63

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 64

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 65

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

- the documentation referred to in the paragraph 2 of Article 57 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 60 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 59 and paragraph 4 of Article 60 and in Articles 63 and 64 of this Rulebook.

Article 66

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 67

For the purposes of this Rulebook (Module "D1") is a procedure whereby the manufacturer satisfies the obligations from Article 69 of this Rulebook and ensures and declares that the items of transportable pressure equipment concerned satisfy the requirements of this Rulebook which apply to them.

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

The П-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 74 to 77 of this Rulebook.

Article 68

The manufacturer should draw up the technical documentation in order to enable an assessment to be made of the conformity of the transportable 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 transportable 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 description of the solutions adopted to meet the requirements as set out in the provisions of this Rulebook,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 69

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 70 to 73 of this Rulebook and be subject to surveillance as specified in Articles 74 to 77 of this Rulebook.

7.1. Quality system

Article 70

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 transportable pressure equipment concerned,
- the documentation concerning the quality system.

Article 71

The quality system should ensure compliance of the transportable 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 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 transportable pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures used,
- 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 or approvals concerning the qualifications of the personnel concerned, etc.,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

Article 72

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 71 of this Rulebook.

The auditing team should have at least one member with experience of assessing the transportable 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 73

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 71 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 74

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

Article 75

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 76

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 77

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 78

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

- the technical documentation described in Article 68 of this Rulebook.
- the documentation referred to in the paragraph 2 of Article 70 of this Rulebook,
- the adjustments referred to in the second paragraph of Article 73 of this Rulebook,
- the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 72 and paragraph 4 of Article 73 and in Articles 76 and 77 of this Rulebook.

Article 79

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. Product quality assurance (Module "E")

Article 80

For the purposes of this Rulebook, product quality assurance (Module "E") is a procedure whereby the manufacturer who satisfies the obligations of Article 81 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 such equipment.

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

The П-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 86 to 89 of this Rulebook.

Article 81

The manufacturer should operate an approved quality system for production, final inspection and testing as specified in Articles 82 to 85 of this Rulebook and be subject to surveillance as specified in Articles 86 to 89 of this Rulebook.

8.1. Quality system

Article 82

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 transportable 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 83

Under the quality system, each item of transportable pressure equipment should be examined and appropriate tests should be carried out in order to ensure its conformity 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 transportable pressure equipment,
- 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 or approvals concerning the qualifications of the personnel concerned, etc.,

Article 84

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 83 of this Rulebook.

The auditing team should have at least one member with experience of assessing the transportable 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 85

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 83 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 86

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

Article 87

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 88

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 89

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 90

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

- the documentation referred to in the paragraph 2 of Article 82 of this Rulebook,
- the adjustments referred to in the second paragraph of Article 85 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 84 and paragraph 4 of Article 85 and in Articles 88 and 89 of this Rulebook.

Article 91

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 92

For the purposes of this Rulebook, product quality assurance (Module "E1") is a procedure whereby the manufacturer who satisfies the obligations of Article 94 of this Rulebook, ensures and declares that the transportable pressure equipment satisfies the requirements of the provisions form this Rulebook which apply to it.

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

The П-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 99 to 102 of this Rulebook.

Article 93

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

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

- general description of the equipment in question,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the drawings and diagrams and the operation of the equipment,
- a description of the solutions adopted to meet the requirements as set out in provisions of this Rulebook,
- results of design calculations made, examinations carried out, etc.,
- test reports.

Article 94

The manufacturer should operate an approved quality system for the final transportable pressure equipment inspection and testing as specified in Articles 95 to 98 of this Rulebook and be subject to surveillance as specified in Articles 99 to 102 of this Rulebook.

9.1. Quality system

Article 95

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 transportable pressure equipment concerned,
- the documentation concerning the quality system.

Article 96

Under the quality system, each item of transportable pressure equipment should be examined and appropriate tests should be carried out in order to ensure its conformity 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 transportable pressure equipment,
- the procedures used for the permanent joining of parts,
- 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 or approvals concerning the qualifications of the personnel concerned, etc.,

Article 97

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 96 of this Rulebook.

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

The results 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 98

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 96 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 99

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

Article 100

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

Article 101

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 102

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 103

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 Article 93 of this Rulebook,
- the documentation referred to in the second indent, paragraph 2 of Article 95 of this Rulebook,
- the adjustments referred to in the second paragraph of Article 98 of this Rulebook;

– the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 97 and paragraph 4 of Article 98 and in Articles 101 and 102 of this Rulebook.

Article 104

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 105

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 transportable pressure equipment subject to the procedure set out in the Article 107 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 106

The manufacturer should take all measures necessary to ensure that the manufacturing process requires the transportable 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 Republic of Macedonia, should affix the П-marking to all transportable pressure equipment and draw up a declaration of conformity.

Article 107

The notified body should perform the appropriate examinations and tests in order to check the conformity of the transportable pressure equipment with the relevant requirements of this Rulebook by examining and testing every product in accordance with the provisions of Articles 108 to 110 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 transportable pressure equipment has been manufactured.

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

Article 108

Each item of the transportable pressure equipment shall be individually examined and shall undergo appropriate 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 pressure equipment parts and the non-destructive tests are qualified or approved,
- check the certificate issued by the materials manufacturer,
- carry out the final inspection and proof test or have them carried out and, where appropriate, examine the safety devices.

Article 109

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 110

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 111

For the purposes of this Rulebook, unit verification (Module "G") shall describe the procedure whereby the manufacturer ensures and declares that transportable pressure equipment which has been issued with the certificate referred to in Article 115 of this Rulebook satisfies the requirements set out in the provisions of this Rulebook which apply to it.

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

Article 112

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 113

The technical documentation should enable the conformity of the transportable 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 technical documentation referred to in paragraph 1 of this Article should include:

- general description of the pressure equipment in question,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the drawings and diagrams and the operation of the equipment,
- results of design calculations made, examinations carried out, etc.,
- test reports,
- appropriate particulars related to the approvals for production and test procedures and the qualifications and approvals of the staff concerned, etc.

Article 114

The notified body should examine the design and construction of each item of transportable pressure equipment and appropriate tests should be carried out during the manufacturing process in order to ensure its conformity with the requirements 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 provisions of this Rulebook and check the certificate issued by the materials manufacturer,
- approve the procedures for permanent joining of the pressure equipment parts,
- verify the necessary qualifications or approvals,
- carry out the final inspection and proof test or have them carried out and, where appropriate, examine the safety devices.

Article 115

The notified body should affix its identification number or have it affixed to the transportable 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 116

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 117

For the purposes of this Rulebook, full quality assurance (Module "H") describes the procedure whereby the manufacturer who satisfies the obligations of Article 118 of this Rulebook ensures and declares that the transportable 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 П-marking to each item of pressure equipment and draw up a written declaration of conformity.

The П-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 123 to 126 of this Rulebook.

Article 118

The manufacturer should implement an approved quality system for design, manufacture, final inspection and testing as specified in Articles 119 to 122 of this Rulebook and be subject to surveillance as specified Articles 123 to 126 of this Rulebook.

12.1. Quality system

Article 119

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 transportable pressure equipment concerned,
- the documentation concerning the quality system.

Article 120

The quality system should ensure compliance of the transportable 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 standards, that will be applied,
- the design control and design verification techniques, processes and systematic measures that will be used when designing the transportable pressure equipment,
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures used,
- 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 or approvals concerning the qualifications of the personnel concerned, etc.,
- the means of monitoring the achievement of the required pressure equipment design and quality and the efficiency of the quality system.

Article 121

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 120 of this Rulebook.

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

The results 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 122

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 120 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 123

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

Article 124

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 125

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 126

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 127

The manufacturer should, for a period of 10 years after the last of the transportable 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 119 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 122 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 121 and paragraph 4 of Article 122 and in Articles 125 and 126 of this Rulebook.

Article 128

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 test (Module “H1”)

Article 129

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 transportable 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 should include:

- the technical design specifications, including standards, which have been applied,
- the necessary supporting evidence for their adequacy which shall 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 the Rulebook which apply to it issue an 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 130

Final assessment 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 transportable pressure equipment.

V. CONFORMITY REASSESSMENT PROCEDURES

Article 131

For the purposes of this Rulebook, conformity reassessment procedure shall mean a method for ensuring that transportable pressure equipment placed on the market as defined in Article 3, paragraph 1, point (b) of this Rulebook complies with the relevant requirements of set out in the regulations on inland transport of dangerous goods by road and by rail.

Article 132

The user should make available to a notified body information regarding transportable pressure equipment placed on the market which enables that body to identify the equipment precisely (origin, design rules and, for acetylene cylinders, also details of the porous mass).

The user should, where appropriate, notify any prescribed restrictions on use, and forward any notes on possible damage or repairs which have been carried out.

The notified body should also check that valves and other accessories having a direct safety function ensure a level of safety in line with that defined pursuant to Article 5 of this Rulebook.

Article 133

The notified body should check whether transportable pressure equipment which has been placed on the market affords at least the same degree of safety as the transportable pressure equipment referred to in the appropriate regulations on inland transport of dangerous goods by road and by rail.

The check referred to in paragraph 1 of this Article should be carried out on the basis of documents produced in accordance with Article 132 and, where appropriate, of further inspections.

Article 134

If the results of the checks referred to in Articles 132 and 133 of this Rulebook are satisfactory, the transportable pressure equipment should be subject to the periodic inspections provided for in Chapter VI of this Rulebook.

Article 135

For receptacles manufactured in series, including their valves and other accessories used for transport, the relevant conformity reassessment operations relating to individual inspections of equipment, as indicated in Articles 132 and 133 above, may be carried out by an approved body provided that a notified body has previously carried out the relevant conformity reassessment operations indicated in Article 133 of this Rulebook.

VI. PROCEDURES FOR PERIODIC INSPECTION

1. Periodic inspection of products (Module 1)

Article 136

For the purposes of this Rulebook, periodic inspection of the product (Module 1) is a procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia or the owner, shall ensure that the transportable pressure equipment, subject to conformity assessment in accordance with Article 138 of this Rulebook continues to satisfy the relevant requirements set out in the provisions of this Rulebook.

Article 137

To meet the requirements referred to in Article 1 of this Rulebook the owner or his authorised representative established in the Republic of Macedonia or the holder should take all measures necessary to ensure that the conditions of use and of maintenance ensure the continued conformity of the transportable pressure equipment to the requirements of this Rulebook, in particular so that:

- the transportable pressure equipment is used as intended,
- it is filled in appropriate filling centres,
- any maintenance work or repairs are carried out,
- the periodic inspections necessary are carried out.

The measures carried out referred to in paragraph 1 of this Article should be recorded in documents and held at the disposal of the national authorities by the owner or his authorised representative established in the Republic of Macedonia or the holder.

Article 138

The inspection body should perform the appropriate examinations and tests in order to check the conformity of the transportable pressure equipment with the relevant requirements of this Rulebook by examining and testing every product.

All transportable pressure equipment should be examined individually and appropriate tests, as set out in the relevant regulations on inland transport of dangerous goods by road or by rail, should be carried out in order to check that it meets the requirements of those regulations.

The inspection body should affix its identification number or have it affixed to each product being periodically inspected immediately after the date of periodic inspection and draw up a written periodic-inspection certificate. That certificate may cover a number of items of equipment (group certificate).

The owner or his authorised representative established in the Republic of Macedonia or the holder should keep the periodic-inspection certificate required under paragraph 3 of this Article, and the documents required under Article 137 of this Rulebook at least until the next periodic inspection.

2. Periodic inspection through quality assurance (Module 2)

Article 139

For the purposes of this Rulebook, periodic inspection through quality assurance (Module 2) shall mean the following procedures:

- procedure whereby the manufacturer or his authorized representative established in the Republic of Macedonia or the owner who carries out the obligations laid down in Article 140 of this Rulebook, shall ensure and declare that the transportable pressure equipment satisfies the relevant requirements set out in the provisions of this Rulebook. The manufacturer, or his authorized representative established within the Republic of Macedonia, or the owner should affix the date of the periodic inspection on all transportable pressure equipment and draw up a written declaration of conformity. The date of the periodic inspection should be accompanied by the identification number of the notified body responsible for surveillance as specified in Articles 145 to 148 of this Rulebook.

- the procedure whereby, in the case of periodic inspection of tanks performed by the approved body in accordance with the Article 8, paragraph 3 of this Rulebook, the approved body which satisfies the obligations of the forth paragraph of Article 140 of this Rulebook, certifies that the transportable pressure equipment continues to meet the requirements of this Rulebook. The approved body should affix the date of periodic inspection to all transportable pressure equipment and draw up a periodic inspection certificate. The date of periodic inspection should be accompanied by the identification number of the approved body.

Article 140

The owner or his authorised representative established in the Republic of Macedonia or the holder should take all measures necessary to ensure that the conditions of use and of maintenance ensure the continued conformity of the transportable pressure equipment to the requirements of this Rulebook, in particular so that:

- the transportable pressure equipment is used as intended;
- it is filled in appropriate filling centres;
- any maintenance work or repairs are carried out;
- the periodic inspections necessary are carried out.

The measures carried out, referred to in paragraph 1 of this Article, should be recorded in documents and held at the disposal of the national authorities by the owner or his authorised representative established in the Republic of Macedonia or the holder.

The owner or his authorised representative established within the Republic of Macedonia or the holder should ensure that the qualified staff and necessary facilities within the meaning of Articles 15, 17, 18 and 19 of this Rulebook, are available for the purpose of the periodic inspections.

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should operate an approved quality system for the periodic inspection and tests of the equipment as specified in Articles 141 to 144 of this Rulebook, and be subject to surveillance as specified in Articles 145 to 148 of this Rulebook.

2.1. Quality system

Article 141

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should lodge an application for assessment of his quality system for the transportable 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 transportable pressure equipment being submitted for periodic inspection,
- the documentation regarding the quality system.

Article 142

Under the quality system, each item of transportable pressure equipment should be examined and appropriate tests should be carried out in order to ensure its conformity with the requirements set out in the relevant regulations on inland transport of dangerous goods by road or by rail.

All the elements, requirements and acts 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 transportable pressure equipment;
- the examinations and tests to be carried out for the periodic inspection;

- the means of monitoring the effective operation of the quality system;
- the quality records, such as inspection reports and test data, calibration data, reports or approvals concerning the qualifications of the personnel concerned.

Article 143

The notified body should assess the quality system to determine whether it satisfies the requirements referred to in Article 142 of this Rulebook.

The auditing team should have at least one member with experience of assessing the transportable pressure equipment technology concerned. The assessment procedure should include an inspection visit to the premises of the owner or of his authorised representative established in the Republic of Macedonia or of the holder or of the approved body.

It should notify its decision to the owner or his authorised representative established in the Republic of Macedonia or to the holder or the approved body. The notification should contain the conclusions of the examination and the reasoned assessment decision.

Article 144

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should inform the notified body which 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 142 of this Rulebook or whether a reassessment is required.

The notified body should notify its decision to the owner or his authorised representative established in the Republic of Macedonia or to the holder or the approved body. The notification should contain the conclusions of the examination and the reasoned assessment decision.

2.2. Surveillance under the responsibility of the notified body

Article 145

The purpose of surveillance is to make sure that the owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body duly fulfils the obligations arising out of the approved quality system.

Article 146

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should allow the notified body access for inspection purposes to the locations of inspection, testing and storage and provide it with all necessary information, in particular:

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

Article 147

The notified body should carry out periodic audits to make sure that the owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body maintains and applies the quality system and provide the owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body with an audit report.

Article 148

In addition, the notified body may pay unannounced visits to the owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body.

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 owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body with a visit report and, if a test has taken place, with a test report.

2.3. Keeping the documentation and communication of information

Article 149

The owner or his authorised representative established in the Republic of Macedonia or the holder or the approved body should, for a period of 10 years from the date of the last periodic inspection of the transportable pressure equipment, hold at the disposal of the national authorities:

- the documentation referred to in the second indent, paragraph 2 of Article 141 of this Rulebook;
- the adjustments referred to in the second paragraph of Article 144 of this Rulebook;
- the decisions and reports from the notified body which are referred to in the paragraph 3 of Article 143 and paragraph 4 of Article 144 and in Articles 147 and 148 of this Rulebook.

VII. MARKING

Article 150

Without prejudice to the requirements for the marking of receptacles and tanks laid down in the regulations on inland transport of dangerous goods by road or by rail, receptacles and tanks satisfying the provisions of Article 5, paragraphs 1 and 7 of this Rulebook shall have a mark affixed to them in accordance with the provisions of Chapter IV of this Rulebook.

П-marking should contain the initials “П”. П-conformity marking consist of the abbreviation П taking the form given in Appendix 3 enclosed to this Rulebook.

Should the П-marking be reduced or enlarged, the proportions given in the Appendix 3 of this Rulebook should be complied with.

The various components of the П-marking, in essence, should have the same vertical dimensions, which may not be less than 5 mm.

П-marking should be visibly and immovably affixed and shall be accompanied by the identification number of the notified body which has performed the conformity assessment procedure on the receptacles and tanks.

In case of reassessment, П-marking should be accompanied by an identification number of the notified or approved body.

For transportable pressure equipment complying with Article 9, paragraph 2 of this Rulebook, the identification number of the notified or approved body shall be followed by "-40°C".

Article 151

New valves and other accessories having a direct safety function should bear either the marking provided for in Appendix 3 of this Rulebook or that given in the technical regulation on pressure equipment.

The markings referred to in paragraph 1 of this Article need not be accompanied by the identification number of the notified body which carried out the conformity assessment on the valves and other accessories used for transport.

Other valves should not be subject to any special marking requirements.

Article 152

Without prejudice to the requirements for the marking of receptacles and tanks laid down in the regulations on inland transport of dangerous goods by road or by rail, for the purposes of periodic inspections, all transportable pressure equipment referred to in Article 8 of this Rulebook shall bear the identification number of the body which performed the periodic inspection of the equipment to indicate that it may continue to be used.

With regard to gas cylinders covered by the relevant technical regulations on gas cylinders manufactured from unalloyed and alloyed steels and aluminium and aluminium alloys, when the first periodic inspection is carried out in accordance with this Rulebook, the aforementioned identification number shall be preceded by the marking described in Appendix III of this Rulebook.

Article 153

For both conformity assessment and reassessment and for periodic inspections, the identification number of the notified or approved body shall be visibly and immovably affixed under its responsibility either by the body itself or by the manufacturer, or his authorised representative established in the Republic of Macedonia, or by the owner or his authorised representative established in the Republic of Macedonia, or by the holder.

Article 154

The affixing of markings on transportable pressure equipment which are likely to mislead the natural and legal persons with regard to the meaning or the graphics of the marking referred to in the Appendix III of this Rulebook shall be prohibited.

Any other marking may be affixed to the transportable pressure equipment provided that the visibility and legibility of the marking in Appendix III of this Rulebook is not thereby reduced.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 155

The provisions of this Rulebook shall not apply to transportable pressure equipment placed on the market prior to the entrance into force of this Rulebook and which is not being reassessed with regards to its conformity with the regulations on inland transport of dangerous goods by road and by rail.

Article 156

The provisions from this Rulebook, which refer to 'П'-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 and notified body of Republic of Macedonia in the European Commission.

Article 157

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 transportable pressure equipment which bear the conformity marking complying with the essential requirements as laid down in the provisions of this Rulebook, without placing the "П"-marking.

In case of paragraph 1 of this Article, the manufacturer of transportable pressure equipment or his authorized representative established in the Republic of Macedonia shall provide for certificate of conformity for the transportable pressure equipment from the notified body registered to certify such equipment, 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 the certificate of conformity issued in accordance with the paragraph 2 of this Article for a period of 10 years after the last of the transportable pressure equipment has been manufactured. Documentation for each product verified by the manufacturer shall be accompanied by a copy of the certificate.

Article 158

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 Community or before entrance into force of an appropriate bilateral agreement for mutual document recognition, any transportable pressure equipment imported and placed on the market within the Republic of Macedonia shall possess a conformity certificate issued by an notified body established in the Republic of Macedonia.

The certificate of conformity referred to in paragraph 1 of this Article shall be issued based upon an EC-declaration of conformity from the manufacturer, EC-certificate for conformity for transportable pressure equipment 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 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 transportable pressure equipment and it should be accompanied by documentation for each individual item of transportable pressure equipment.

Where non-conformity of the transportable pressure equipment 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 159

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 will apply:

- "authorized representative established in the European Union or in the Republic of Macedonia" instead of "authorized representative established in the Republic of Macedonia",
- "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”,
- "П-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 160

The rulebook on technical norms for transportable closed pressure vessels, liquid and dissolved gasses under pressure (Official Gazette of SFRY No. 25/80 and 9/86) shall cease to be valid with entrance into force of this Rulebook.

Article 161

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 1

List of dangerous substances other than those in Class 2 referred to in Article 4 of this Rulebook

UN-number	Class	ADR/RID- figure	Dangerous substances
1051	6.1	1	Stabilized hydrogen cyanide
1052	8	6	Anhydrous hydrogen fluoride
1790	8	6	Hydrofluoric acid

Appendix 2

Modules to be followed for conformity assessment

The following table indicates which conformity assessment modules as described in Chapter IV of this Rulebook, are to be followed for the transportable pressure equipment defined in Article 4, point 1 of this Rulebook.

The category of the transportable pressure equipment	Modules
1. Receptacles for which the product of the test pressure and the capacity is no more than 100 MPa x litre (300 bar x litre)	A1 or D1 or E1
2. Receptacles for which the product of the test pressure and the capacity is no more than 30 and no more than 150 MPa x litre (300 bar and 1500 x litre respectively)	H, or B in combination with E, or B in combination with C1 or B1 in combination with F, or B1 in combination with D
3. Receptacles for which the product of the test pressure and the capacity exceeds 150 MPa x litre ×1500 bar x litre), and tanks	G, or H1, or B in combination with D or B in combination with F

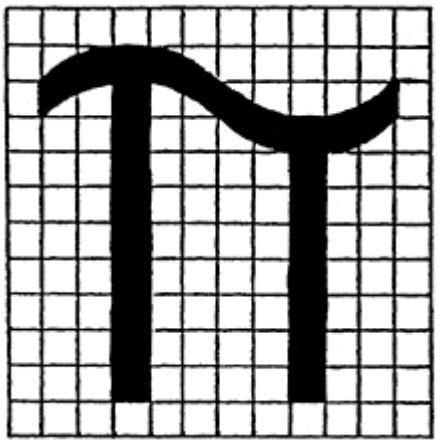
1. Transportable pressure equipment should be subject, at the choice of the manufacturer, to one of the conformity assessment procedures laid down for the category in which it is classified. In the case of receptacles or their valves or other accessories used for transport, the manufacturer may also choose to apply one of the set procedures for the higher categories.

2. As part of the quality assurance procedures, the notified body should, when making unannounced visits, take a sample of the equipment at the manufacturing or storage premises for the purpose of carrying out a check, or having a check carried out, in conformity to the requirements of this Rulebook. For this purpose the manufacturer should inform the notified body of the production programme planned. The notified body should make at least two visits during the first year of manufacture. The frequency of subsequent visits will be determined by the notified body on the basis of the criteria set out in control visit system of the relevant modules in Chapter IV of this Rulebook.

Appendix 3

Conformity marking

The conformity mark shall take the following form:



This minimum dimension may be waived for small devices.