

L.N. 331 of 2002

**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)**

Transportable Pressure Equipment Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

1.1. The title of these regulations is the Transportable Pressure Equipment Regulations, 2002. Citation and commencement.

1.2. These regulations shall become operative on the 1st January 2003:

Provided that the requirements to provide information to the European Commission referred to in regulation 14.3 of these regulations shall come into force on such date as the Minister responsible for Consumer Affairs, after consultation with the Malta Standards Authority, may prescribe.

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

2.2. These regulations shall apply:

2.2.1. for the purpose of placing on the market: to new transportable pressure equipment as defined in regulation 3 of these regulations;

2.2.2. for the purpose of reassessment of conformity: to existing transportable pressure equipment as defined in regulation 3 of these regulations which meets the technical requirements laid down in Directives 94/55/EC¹ and 96/49/EC²;

2.2.3. for repeated use and periodic inspections:

¹ OJ No. L 319, 12.12.94, p. 07.

² OJ No. L 235, 17.09.96, p. 25.

2.2.3.1. - to the transportable pressure equipment referred to in regulations 2.2.1 and 2.2.2 of these regulations,

2.2.3.2. - to existing gas cylinders bearing the conformity marking laid down in Directives 84/525/EEC³, 84/526/EEC⁴ and 84/527/EEC⁵, (Schedules V, VI and VII of L.N. 146 of 2002: Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002.)

2.3. The following shall be excluded from the scope of these regulations:

2.3.1. Transportable pressure equipment which was placed on the market before 1 July 2001 or, in the case of Article 18 of the Directive, within two years of that date and which has not been reassessed as to its conformity with the requirements of Directives 94/55/EC and 96/49/EC, shall be outside the scope of these regulations.

2.3.2. Transportable pressure equipment used exclusively for the transport of dangerous goods between Community territory and third-country territory, carried out in accordance with Article 6(1) and Article 7 of Directive 94/55/EC or Article 6(1) and Article 7(1) and (2) of Directive 96/49/EC.

Definitions.

3.1. For the purposes of these regulations, the following definitions shall apply:

3.1.1. "The Directive" means Council Directive 1999/36/EC⁶ on the approximation of the laws of the Member States relating to transportable pressure equipment.

3.1.2. "Transportable pressure equipment" means:

- all receptacles (cylinders, tubes, pressure drums, cryogenic receptacles, bundles of cylinders as defined in Annex A to Directive 94/55/EC),

- 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 Annexes to Directives 94/55/EC and 96/49/EC and for the transport of certain dangerous substances of other

³ OJ No. L 300, 19.11.84, p. 01-19.

⁴ OJ No. L 300, 19.11.84, p. 20-47.

⁵ OJ No. L 300, 19.11.84, p. 48-71.

⁶ OJ No. L 138, 01.06.99, p. 20.

classes indicated in Annex VI to this Directive, which is set out in Schedule VI hereto, including their valves and other accessories used for transport.

3.1.2.1. This definition excludes equipment subject to the general exemption principles applicable to small quantities and to the special cases provided for in the Annex to Directive 94/55/EC and the Annex to Directive 96/49/EC as well as aerosol dispensers (UN number 1950) and gas cylinders for breathing appliances;

3.2. “Mark” means the symbol referred to in regulation 12 of these regulations;

3.3. “Conformity assessment procedures” means those procedures set out in Annex IV, Part I of the Directive, which is set out in Schedule IV hereto;

3.4. “Reassessment of conformity” means the procedure for subsequent assessment, at the request of the owner or his authorised representative or of the holder, of the conformity of transportable pressure equipment already manufactured and put into service before 1 July 2001 or, in the case of Article 18 of the Directive, within two years of that date;

3.5. “Notified body” means an inspection body designated by the national competent authority of a Member State in accordance with Article 8 of the Directive and meeting the criteria of Annexes I and II of the Directive, which are set out in Schedules I and II hereto;

3.6. “Approved body” means an inspection body designated by the national competent authority of a Member State in accordance with regulation 12 of these regulations and meeting the criteria of Annexes I and III of the Directive, which are set out in Schedules I and III hereto.

3.1.3. “OJ” means the Official Journal of the European Communities.

3.1.4. “Manufacturer” means the person:

3.1.4.1. who is primarily responsible for the design and construction of the transportable pressure equipment so that it complies with the requirements of these regulations;

3.1.4.2. who is responsible for “re-building” or modifying an existing transportable pressure equipment, and who in so doing is creating an “as-new” transportable pressure equipment;

3.1.4.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used transportable pressure equipment.

3.1.5. "Authorised representative" means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.6. "Importer" means any person who places transportable pressure equipment from a foreign country on to the Community or Maltese market so that he supplies such transportable pressure equipment on the first occasion that they are supplied in the Community or Malta;

3.1.7. "Person who supplies transportable pressure equipment" means wholesalers, distributors, retailers etc.

3.1.8. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly:

Provided that "supply" does not include exhibition at trade fairs and exhibitions of transportable pressure equipment, in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the transportable pressure equipment in question to the effect:-

3.1.8.1. that it does not satisfy those provisions; and

3.1.8.2. that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.9. "Responsible person" in relation to transportable pressure equipment means:

3.1.9.1. the manufacturer thereof;

3.1.9.2. the manufacturer's authorised representative;
or

3.1.9.3. where the manufacturer is not established in the Community or Malta and he has not appointed an authorised representative, the person who places the transportable pressure equipment on the Community or Maltese market.

3.1.10. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

3.1.11. In these regulations, unless the context otherwise requires, a reference to-

3.1.11.1. a numbered regulation or Schedule is a reference to the regulation or Schedule in these regulations so numbered;

3.1.11.2. a numbered paragraph is a reference to the paragraph so numbered in the regulation or Schedule in which that reference appears; and

3.1.11.3. a lettered sub-paragraph is a reference to the sub-paragraph so lettered in the paragraph in which that reference appears.

4.1. The provisions of these regulations are applicable to all imported transportable pressure equipment as well as to those manufactured for the local market. Applicability.

4.1.1. No person may construct, import, place on the market or put into service any transportable pressure equipment which do not comply with the provisions of these regulations.

5.1. New receptacles and new tanks shall meet the relevant provisions of Directive 94/55/EC and 96/49/EC. The compliance of such transportable pressure equipment with these provisions shall be established by a notified body exclusively in accordance with the conformity assessment procedures set out in Annex IV, Part I, and specified in Annex V of the Directive, which are set out in Schedules IV and V hereto. Conformity assessment for the placing on the Community market of new transportable pressure equipment

5.2. New valves and other accessories used for transport shall meet the relevant provisions of the Annexes to Directives 94/55/EC and 96/49/EC.

5.3. 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 as stringent as that undergone by the receptacle or tank to which they are fitted.

5.3.1. Such 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.

5.4. Should Directive 94/55/EC and 96/49/EC not contain any detailed technical provisions for the valves and accessories referred to in regulation 5.3, such valves and accessories must meet the requirements of Directive 97/23/EC⁷ (L.N. 248 of 2002: Pressure Equipment Regulations, 2002) and, pursuant to that Directive, be subject to a category II, III or IV conformity assessment procedure as laid down in Article 10 of Directive 97/23/EC according to whether the receptacle or tank belongs to category 1, 2 or 3 as laid down in Annex V to this Directive, which is set out in Schedule V hereto.

Conformity assessment for the placing on the national market of new transportable pressure equipment.

6.1. By way of derogation from regulation 5 of these regulations, 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 regulation 2.2.1 of these regulations, the conformity of which has been assessed by an approved body, may be authorised.

6.2. Transportable pressure equipment the conformity of which has been assessed by an approved body may not bear the marking described in regulations 13.1, 13.2, 13.3 and 13.4 of these regulations.

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

6.4. The procedures applicable to conformity assessment by approved bodies shall be modules A1, C1, F and G, as described in Annex IV, Part I of the Directive, which is set out in Schedule I hereto.

Reassessment of conformity for existing transportable pressure equipment.

7.1. The conformity of the transportable pressure equipment referred to in regulation 2.2.2 of these regulations with the relevant provisions of the Annexes to Directives 94/55/EC and 96/49/EC shall be established by a notified body in accordance with the conformity reassessment procedure set out in Annex IV, Part II, to this Directive, which is set out in Schedule IV hereto.

7.1.1. Where such equipment was manufactured in series, the reassessment of conformity with regard to receptacles, including their valves and other accessories used for transport, to be carried out by an approved body provided that conformity of the type is reassessed by a notified body may be authorized.

⁷ OJ No. L 181, 09.07.97, p. 01-55.

8.1. The placing on the market or putting into service of transportable pressure equipment referred to in regulation 2.2.1 of these regulations which complies with these regulations and bears the relevant mark provided for in regulations 13.1, 13.2, 13.3, 13.4 and 13.5, shall not be prohibited, restricted or impeded. Free movement

8.2. The placing on the market or putting into service of transportable pressure equipment referred to in regulation 2.2.2 which complies with these regulations and bears the relevant mark provided for in regulations 13.1, 13.2, 13.3 and 13.4, shall not be prohibited, restricted or impeded.

9.1. Periodic inspections of the receptacles, including their valves and accessories used for transport, referred to in regulation 2.2.3 of these regulations shall be arranged by a notified or approved body in accordance with the procedure set out in Annex IV, Part III of the Directive, which is set out in Schedule IV hereto. 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 Annex IV, Part III, module 1 of the Directive, which is set out in Schedule IV hereto. Periodic inspection and repeated use.

9.1.1. However, periodic inspections of tanks also to be performed by the approved bodies which have been recognized for carrying out periodic inspections of tanks and which act under the supervision of a body notified under the procedure provided for in Annex IV, Part III, Module 2 of the Directive, which is set out in Schedule IV hereto, concerning periodic inspection through quality assurance, may be permitted.

9.2. The transportable pressure equipment referred to in regulation 2.2 of these regulations may be subjected to periodic inspection.

9.3. On grounds concerning transportable pressure equipment, the use (including filling, storing, emptying and refilling) of the following transportable pressure equipment may not be prohibited, restricted or impeded:

- the equipment referred to in regulation 2.2.1 and 2.2.2 and the first indent of regulation 2.2.3 of these regulations, which satisfies the provisions of these regulations and bears the corresponding mark,

- existing gas cylinders bearing the conformity mark provided for in Directives 84/525/EEC, 84/526/EEC and 84/527/

EEC (Schedules V, VI and VII of L.N. 146 of 2002: Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002) and the mark and identification number referred to in regulation 13.6 of these regulations indicating that it has undergone periodic inspection.

9.4. National requirements may be established for the storage or use of transportable pressure equipment, but not for transportable pressure equipment itself or for the accessories needed during transport. However, pursuant to regulation 10 of these regulations, national requirements for connecting devices, colour codes and reference temperatures may be retained.

National provisions.

10.1. National provisions concerning devices intended for connection with other equipment and colour codes applicable to transportable pressure equipment may be retained until such time as European standards for use are added to the Annexes to Directives 94/55/EC and 96/49/EC.

10.1.1. However, where safety problems arise with the transport or use of certain types of gas, a short transitional period may be allowed, in accordance with the procedure laid down in Article 15 of the Directive, in order to enable the national provisions to be retained even after the European standards have been added to the Annexes to Directives 94/55/EC and 96/49/EC.

10.2. Where the ambient temperature is regularly lower than -20°C more stringent standards as regards the operating temperature of material intended for use in the national transport of dangerous goods may be imposed until provisions on the appropriate reference temperatures for given climatic zones are incorporated in the Annexes to Directives 94/55/EC and 96/49/EC.

Notified bodies.

11.1. The criteria set out in Annexes I and II of the Directive, which are set out in Schedules I and II hereto, for the designation of notified bodies shall be applied. Each body shall submit to the Consumer and Industrial Goods Directorate⁸ of the Malta Standards Authority complete information concerning, and evidence of, compliance with the criteria in those Schedules.

11.2. The notification shall be withdrawn if it is found that the body no longer meets the criteria referred to in regulation 11.1 of these regulations.

Approved bodies

12.1. The criteria set out in Annexes I and III of the Directive, which are set out in Schedules I and III hereto, for the recognition of

⁸ L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

approved bodies shall be applied. Each body shall submit to the Consumer and Industrial Goods Directorate of the Malta Standards Authority complete information concerning, and evidence of, compliance with the criteria in those Schedules.

12.2. The approval shall be withdrawn if it is found that the body no longer meets the criteria referred to in regulations 12.1 of these regulations.

13.1. Without prejudice to the requirements for the marking of receptacles and tanks laid down in Directives 94/55/EC and 96/49/EC, receptacles and tanks satisfying the provisions of regulations 5.1 and 7.1 of these regulations shall have a mark affixed to them in accordance with Annex IV, Part I of the Directive, which is set out in Schedule IV hereto. Marking

13.2. The form of the mark to be used is set out in Annex VII of the Directive, which is set out in Schedule VII hereto.

13.3. This mark shall 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.

13.3.1. In the event of reassessment, this mark shall be accompanied by the identification number of the notified or approved body.

13.4. For transportable pressure equipment complying with regulation 10.2 of these regulations, the identification number of the notified or approved body shall be followed by “- 40°C”.

13.5. New valves and other accessories having a direct safety function shall bear either the mark provided for in Annex VII of the Directive, which is set out in Schedule VII hereto or that provided for in Annex VI to Directive 97/23/EC (L.N. 248 of 2002: Pressure Equipment Regulations, 2002). Such marks 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.

13.5.1. The other valves and accessories shall not be subject to any special marking requirements.

13.6. Without prejudice to the requirements for the marking of receptacles and tanks laid down in Directives 94/55/EC and 96/49/EC, for the purposes of periodic inspections, all transportable pressure equipment referred to in regulation 9.1 of these regulations 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.

13.6.1. With regard to gas cylinders covered by Directives 84/525/EEC, 84/526/EEC and 84/527/EEC (Schedules V, VI and VII of L.N. 146 of 2002: Common Provisions for Pressure Vessels and Inspection Methods Regulations, 2002), when the first periodic inspection is carried out in accordance with these regulations, the aforementioned identification number shall be preceded by the mark described in Annex VII of the Directive, which is set out in Schedule VII hereto.

13.7. 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, or by the owner or his authorised representative, or by the holder.

13.8. The affixing of markings on transportable pressure equipment which are likely to mislead third parties with regard to the meaning or the graphics of the mark referred to in these regulations shall be prohibited. Any other marking may be affixed to equipment provided that the visibility and legibility of the marking in Annex VII of the Directive, which is set out in Schedule VII hereto, is not thereby reduced.

13.9. Without prejudice to regulation 14 of these regulations, where it is established that the marking described in Annex VII of the Directive, which is set out in Schedule VII hereto, has been affixed unduly, the owner or his authorized representative or the holder, or the manufacturer or his authorized representative, shall be obliged to make the transportable pressure equipment conform as regards the provisions concerning the marking and to end the infringement under the conditions imposed by the Director of Consumer Affairs.

13.9.1. Should non-conformity persist, the Director of Consumer Affairs shall take all appropriate measures to restrict or prohibit the placing on the market, transport or use of the equipment in question or to ensure that it is withdrawn from the market or from circulation in accordance with the procedure laid down in regulation 14 of these regulations.

14.1. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations.

14.2. Where it is found that transportable pressure equipment, when correctly maintained, and used for its intended purpose, is liable to endanger the health and/or safety of persons and, where appropriate, domestic animals or property, during transport and/or use, notwithstanding the fact that it bears a mark, the Director of Consumer Affairs may restrict or prohibit the placing on the market, transport or use of the equipment in question or have it withdrawn from the market or from circulation.

14.2.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

14.2.2. The Director of Consumer Affairs shall immediately inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority, stating the grounds for its decision.

14.3. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission and the other Member States of any measures taken in pursuance of regulation 14.2.2 of these regulations.

Schedule I

Based on Annex I of the Directive

MINIMUM CRITERIA TO BE MET BY NOTIFIED OR APPROVED BODIES, AS REFERRED TO IN REGULATIONS 11 AND 12

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

2. The inspection body and its staff must not engage in any activities that may conflict with their independence of judgment and integrity in relation to their inspection activities. In particular the staff of the inspection body must 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. The impartiality of the inspection staff of the body must be guaranteed.

3. The inspection body must 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. It must also have access to the equipment required to perform special verifications.

4. The staff of the inspection body who are responsible for inspection must have appropriate qualifications, sound technical and vocational training 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 inspection body must be in a position to provide expertise in the field of safety of transportable pressure equipment. The staff must have the ability to make professional judgments as to conformity with general requirements using examination results and to report thereon. They must also have the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. They must 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..

6. The inspection body and its staff must carry out the assessments and verifications with the highest degree of professional integrity and technical competence. The inspection body must ensure the confidentiality of information obtained in the course of its inspection activities. Proprietary rights must be protected.

7. The remuneration of persons engaged in inspection activities must not directly depend on the number of inspections carried out and in no case on the results of such inspections.

8. The inspection body must have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organisation of which it forms a part.

9. The inspection body must itself normally perform the inspections which it contracts to undertake. When an inspection body sub-contracts any part of the inspection, it must ensure and be able to demonstrate that its sub-contractor is competent to perform the service in question and must take full responsibility for that sub-contracting.

Schedule II

Based on Annex II of the Directive

SUPPLEMENTARY CRITERIA TO BE MET BY THE NOTIFIED BODIES REFERRED TO IN REGULATION 11

1. A notified body must 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 must 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. They must 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.

2. All interested parties must have access to the services of the inspection body. There must be no undue financial or other conditions. The procedures under which the body operates must be administered in a non-discriminatory manner.

Schedule III

Based on Annex III of the Directive

**SUPPLEMENTARY CRITERIA TO BE MET BY THE APPROVED BODIES
REFERRED TO IN REGULATION 12**

1. The approved body must form a separate and identifiable part of an organization involved in the design, manufacture, supply, use or maintenance of the items it inspects.
2. The approved body must not become directly involved in the design, manufacture, supply or use of the transportable pressure equipment, including accessories inspected, or similar competitive items.
3. There must be a clear separation of the responsibilities of the inspection staff from those of the staff employed in the other functions, which must be established by organisational identification and the reporting methods of the inspection body within the parent organisation.

Schedule IV

Based on Annex IV of the Directive

PART I

CONFORMITY ASSESSMENT PROCEDURES

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer, or his authorised representative who carries out the obligations laid down in section 2 of this module, ensures and declares that transportable pressure equipment satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the $\square$ marking to all transportable pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must draw up the technical documentation described in section 3 of this module and either the manufacturer or his authorised representative must 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 authorised representative is established in the Community or Malta, The obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the market.

3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a general description of the transportable 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 transportable pressure equipment,
- a description of the solutions adopted to meet the requirements of the regulations,
- results of the design calculations, examinations carried out, etc.,
- test reports.

4. The manufacturer, or his authorised representative, must keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured transportable pressure equipment to comply with the technical documentation referred to in section 2 of this module and with the requirements of the regulations which apply to it.

Module A1 (internal manufacturing checks with monitoring of the final assessment)

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

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

During such visits, the notified body must:

- ensure that the manufacturer actually performs final assessment,
- take samples of 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 must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix that body's identification number to each item of transportable pressure equipment.

Module B (EC type-examination)

1. This module describes 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 regulations which apply to it.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative with a single notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

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- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in section 3 of this module.

The applicant must 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 transportable pressure equipment provided that the differences between the versions do not affect the level of safety.

3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- 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 transportable pressure equipment,
- a description of the solutions adopted to meet the essential requirements of the regulations,
- results of the design calculations made, examinations carried out, etc.,
- test reports,
- information concerning the tests provided for in manufacture,
- information concerning the qualifications or approvals.

4. The notified body must:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the regulations.

In particular, the notified body must:

- 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 the regulations and check the certificate issued by the materials manufacturer,

- approve the procedures for the permanent joining of pressure equipment parts or check that they have been previously approved,

- verify that the staff undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved,

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

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

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

5. Where the type satisfies the provisions of the regulations which apply to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate, which should be valid for 10 years and be renewable, must contain the name and address of the manufacturer, 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 must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his authorised representative, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved transportable pressure equipment; these are subject to additional approval where they may affect conformity with the requirements of the regulations or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the Member States the relevant information concerning EC type-examination certificates which it has withdrawn, and, on request, those it has issued. Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.

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

9. The manufacturer, or his authorised representative, must keep with the technical documentation copies of EC 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 authorised representative is, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module B1 (EC design examination)

1. This module describes the part of the procedure whereby a notified body ascertains and attests that the design of an item of transportable pressure equipment meets the provisions of the regulations which apply to it.

2. The manufacturer, or his authorised representative, must lodge an application for EC design examination with a single notified body.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation described in section 3 of this module.

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

3. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a 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 said drawings and diagrams and the operation of the equipment,
- a description of the solutions adopted to meet the requirements of the regulations,
- the necessary supporting evidence for the adequacy of the design solution; this supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,
- results of the design calculations made, examinations carried out, etc.,
- information regarding qualifications or approvals.

4. The notified body must:

4.1. examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the regulations.

In particular, the notified body must:

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

4.2. perform the necessary examinations to establish whether the solutions adopted by the manufacturer meet the requirements of the regulations;

4.3. perform the necessary examinations to establish whether the relevant provisions of the regulations have actually been applied.

5. Where the design meets the provisions of the regulations which apply to it, the notified body must issue an EC design-examination certificate to the applicant. The certificate must contain the name and address of the applicant, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC design-examination certificate to the manufacturer or to his authorised representative, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC design-examination certificate of all modifications to the approved design; these are subject to additional approval where they may affect conformity with the requirements of the regulations or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC design-examination certificate.

7. Each notified body must communicate to the Member States the relevant information concerning EC design-examination certificates which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the EC design-examination certificates it has withdrawn or refused.

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

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

9. The manufacturer, or his authorised representative, must keep with the technical documentation referred to in section 3 of this module copies of EC 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 authorised representative is, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative, ensures and declares that transportable pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the [] marking to all transportable pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured transportable pressure equipment

to comply with the type as described in the EC type-examination certificate and with the requirements of the regulations which apply to it.

3. The manufacturer, or his authorised representative, must 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 authorised representative is established in the Community or Malta, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the market.

4. Final assessment must be subject to monitoring in the form of unexpected visits by a notified body chosen by the manufacturer.

During such visits, the notified body must:

- ensure that the manufacturer actually performs final assessment,
- take samples of 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 must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix that body's identification number to each item of transportable pressure equipment.

Module D (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the transportable pressure equipment concerned is in conformity with the type described in the EC type-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the Π marking to all transportable pressure equipment and draw up a written declaration of conformity. The Π marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in section 4 of this module.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 3 of this module and be subject to surveillance as specified in section 4 of this module.

3. *Quality system*

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

The application must 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 EC type-examination certificate.

3.2. The quality system must ensure compliance of the transportable pressure equipment with the type described in the EC type-examination certificate and with the requirements of the regulations which apply to it.

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

It must contain in particular an adequate description of:

- the quality objectives and the organisational 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 or approvals of the personnel concerned,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

3.4. The manufacturer must 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 authorised representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

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

4.2. The manufacturer must 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:

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

4.3. The notified body must 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 must be such that a full reassessment is carried out every three years.

4.4. 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 must be considered in the visit control system:

- the category of the equipment,

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

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

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

- the documentation referred to in the second indent of point 3.1 of this module,
- the adjustments referred to in the second paragraph of point 3.4 of this module,
- the decisions and reports from the notified body which are referred to in the last paragraph of point 3.3, in the last paragraph of point 3.4, and in points 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module D1 (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 of this module ensures and declares that the items of transportable pressure equipment concerned satisfy the requirements of the regulations which apply to them. The manufacturer, or his authorised representative, must affix the $\square$ marking to all transportable pressure equipment and draw up a written declaration of conformity. The $\square$ marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in section 5 of this module.

2. The manufacturer must draw up the technical documentation described below. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a 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 said drawings and diagrams and the operation of the equipment,
- a description of the solutions adopted to meet the requirements of the regulations,
- results of the design calculations made, examinations carried out, etc.;
- test reports.

3. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 4 of this module and be subject to surveillance as specified in section 5 of this module.

4. *Quality system*

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

The application must include:

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

4.2. The quality system must ensure compliance of the transportable pressure equipment with requirements of the regulations which apply to it.

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

It must contain in particular an adequate description of:

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- the quality objectives and the organisational 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,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned,
- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 4.2 of this module.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

4.4. The manufacturer must 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 authorised representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in point 4.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. *Surveillance under the responsibility of the notified body*

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

5.2. The manufacturer must 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:

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

5.3. The notified body must 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 must be such that a full reassessment is carried out every three years.

5.4. 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 must 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,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

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

- the documentation referred to in section 2 of this module,
- the documentation referred to in the second indent of point 4.1 of this module,
- the adjustments referred to in the second paragraph of point 4.4 of this module,

- the decisions and reports from the notified body which are referred to in the last paragraph of point 4.3, in the last paragraph of point 4.4, and in points 5.3 and 5.4 of this module.

7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the item of transportable pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the $\square$ marking to each product and draw up a written declaration of conformity. The $\square$ marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in section 4 of this module.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 3 of this module and be subject to surveillance as specified in section 4 of this module.

3. Quality system

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

The application must 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 EC type-examination certificate.

3.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements of the regulations which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and

instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational 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 concerning the qualifications or approvals of the personnel concerned.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

3.4. The manufacturer must 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 authorised representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

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

4.2. The manufacturer must 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:

- the 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.

4.3. The notified body must 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 must be such that a full reassessment is carried out every three years.

4.4. 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 must 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,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

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

- the documentation referred to in the second indent of point 3.1 of this module,
- the adjustments referred to in the second paragraph of point 3.4 of this module,

- the decisions and reports from the notified body which are referred to in the last paragraph of point 3.3, in the last paragraph of point 3.4, and in points 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E1 (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 of this module ensures and declares that the transportable pressure equipment satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the $\square$ marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The $\square$ marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 5 of this module.

2. The manufacturer must draw up the technical documentation described below. The technical documentation must enable an assessment to be made of the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure equipment and contain:

- a 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 said drawings and diagrams and the operation of the equipment,
- a description of the solutions adopted to meet the requirements of the regulations,
- results of the design calculations made, examinations carried out, etc.;
- test reports.

3. The manufacturer must operate an approved quality system for the final transportable pressure equipment inspection and testing as specified in section 4 of

this module and be subject to surveillance as specified in section 5 of this module.

4. *Quality system*

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

The application must include:

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

4.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements of the regulations which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment,
- the procedures used for the 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 concerning the qualifications or approvals of the staff concerned.

4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 4.2 of this module.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

4.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorised representative, must inform the notified body which has approved the quality system of any intended adjustment to the quality system. The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 4.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. *Surveillance under the responsibility of the notified body*

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

5.2. The manufacturer must 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:

- the 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.

5.3. The notified body must 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 must be such that a full reassessment is carried out every three years.

5.4. 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 must 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,
- where applicable, special conditions linked to the approval of the system,

- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

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

- the documentation referred to in section 2 of this module,
- the documentation referred to in the third indent of point 4.1 of this module,
- the adjustments referred to in the second paragraph of point 4.4 of this module,
- the decisions and reports from the notified body which are referred to in the last paragraph of point 4.3, in the last paragraph of point 4.4, and in points 5.3 and 5.4 of this module.

7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module F (product verification)

1. This module describes the procedure whereby a manufacturer, or his authorized representative, ensures and declares that the transportable pressure equipment subject to the provisions of section 3 of this module is in conformity with the type described:

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

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

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

The manufacturer, or his authorised representative, must affix the (marking to all transportable pressure equipment and draw up a declaration of conformity.

3. The notified body must perform the appropriate examinations and tests in order to check the conformity of the transportable pressure equipment with the relevant requirements of the regulations by examining and testing every product in accordance with section 4 of this module.

The manufacturer, or his authorised representative, must 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.

4. *Verification by examination and testing of each item of transportable pressure equipment*

4.1. Each item of transportable pressure equipment must be individually examined and must undergo appropriate examinations and tests in order to verify that it conforms to the type and the requirements of the regulations which apply to it.

In particular, the notified body must:

- verify that the personnel undertaking the permanent joining of 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.

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

4.3. The manufacturer, or his authorised representative, must ensure that the certificates of conformity issued by the notified body can be made available on request.

Module G (EC unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that transportable pressure equipment which has been issued with the certificate referred to in point 4.1 of this module satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the Π marking to the equipment and draw up a declaration of conformity.

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

The application must contain:

- the name and address of the manufacturer and the location of the transportable pressure equipment,
- a written declaration to the effect that a similar application has not been lodged with another notified body,
- technical documentation.

3. The technical documentation must enable the conformity of the transportable pressure equipment with the requirements of the regulations which apply to it to be assessed and the design, manufacture and operation of the transportable pressure equipment to be understood.

The technical documentation must contain:

- a 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 said drawings and diagrams and the operation of the equipment,
- results of design calculations made, examinations carried out, etc.,
- test reports,
- appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the staff concerned.

4. The notified body must examine the design and construction of each item of transportable pressure equipment and during manufacture perform appropriate tests to ensure its conformity with the requirements of the regulations which apply to it.

4.1. The notified body must 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. This certificate must be kept for a period of 10 years.

4.2. The manufacturer, or his authorised representative, must ensure that the declaration of conformity and certificate of conformity issued by the notified body can be made available on request.

In particular, the notified body must:

- 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 the regulations and check the certificate issued by the materials manufacturer,
- approve the procedures for the permanent joining of pressure equipment parts,
- verify the qualifications or approvals required,
- perform the final inspection, perform the proof test or have it performed and examine the safety devices if applicable.

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the transportable pressure equipment in question satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorised representative, must affix the [] marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The [] marking must be accompanied by the identification number of the notified body responsible for the surveillance referred to in section 4 of this module.

2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in section 3 of this module and be subject to surveillance as specified in section 4 of this module.

3. *Quality system*

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

The application must include:

- all relevant information concerning the transportable pressure equipment in question,
- the documentation concerning the quality system.

3.2. The quality system must ensure compliance of the transportable pressure equipment with the requirements of the regulations which apply to it.

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

It must contain in particular an adequate description of:

- the quality objectives and the organisational 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 corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be 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 concerning the qualifications or approvals of the personnel concerned,
- the means of monitoring the achievement of the required transportable pressure equipment design and quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

3.4. The manufacturer must 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 authorised representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

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

4.2. The manufacturer must 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:

- the 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 staff concerned, etc.

4.3. The notified body must 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 must be such that a full reassessment is carried out every three years.

4.4. 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 must 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,
- where applicable, special conditions linked to the approval of the system,
- significant changes in manufacturing organisation, policy or techniques.

During such visits the notified body may, if necessary, carry out tests, or have them carried out, to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure equipment has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second paragraph of point 3.1 of this module,
- the adjustments referred to in the second paragraph of point 3.4 of this module,
- the decisions and reports from the notified body which are referred to in the last paragraph of point 3.3, in the last paragraph of point 3.4, and in points 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module H1 (full quality assurance with design examination and special surveillance of the final test)

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

(a) the manufacturer must lodge an application for examination of the design with the notified body;

(b) the application must enable the design, manufacture and operation of the transportable pressure equipment to be understood, and enable conformity with the relevant requirements of the regulations to be assessed.

It must include:

- the technical design specifications, including standards, which have been applied,
- the necessary supporting evidence for their adequacy. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;

(c) the notified body must examine the application and where the design meets the provisions of the regulations which apply to it issue an EC design-examination certificate to the applicant. The certificate must 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 transportable pressure equipment;

(d) the applicant must inform the notified body that has issued the EC design-examination certificate of all modifications to the approved design.

Modifications to the approved design must receive additional approval from the notified body that issued the EC design-examination certificate where they may affect conformity with the requirements of the regulations or the prescribed conditions for use of the transportable pressure equipment.

This additional approval must be given in the form of an addition to the original EC design-examination certificate;

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

2. 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 must conduct examinations on the transportable pressure equipment.

PART II

CONFORMITY REASSESSMENT PROCEDURE

1. This procedure describes the method for ensuring that transportable pressure equipment placed on the market as defined in regulation 2.2.2 of these regulations complies with the relevant requirements of Directive 94/55/EC and 96/49/EC.

2. The user must 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 must, 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 must also check that valves and other accessories having a direct safety function ensure a level of safety in line with that defined pursuant to regulation 5 of these regulations.

3. The notified body must 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 Directive 94/55/EC and 96/49/EC. The check must be carried out on the basis of documents produced in accordance with section 2 of Part II of this Schedule and, where appropriate, of further inspections.

4. If the results of the above checks are satisfactory, the transportable pressure equipment must be subject to the periodic inspection provided for in Annex IV, Part III of the Directive, which is set out in Schedule III hereto.

5. 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 sections 3 and 4 of Part II of this Schedule, may be carried out by an approved body provided that a notified body has previously carried out the relevant conformity reassessment operations indicated in section 3 of Part II of this Schedule.

PART III

PROCEDURES FOR PERIODIC INSPECTION**Module 1** (periodic inspection of products)

1. This module describes the procedure whereby an owner or his authorized representative or the holder ensures that the transportable pressure equipment subject to section 3 of this module continues to meet the requirements of these regulations.

2. To meet the requirements referred to in section 1 of this module the owner or his authorized representative or the holder must 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 these regulations, 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 must be recorded in documents and held at the disposal of the national authorities by the owner or his authorised representative or the holder.

3. The inspection body must perform the appropriate examinations and tests in order

3.1. All transportable pressure equipment must be examined individually and appropriate tests, as set out in the Annexes to Directives 94/55/EC and 96/49/EC, must be carried out in order to check that it meets the requirements of those Directives.

3.2. The inspection body must 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).

3.3. The owner or his authorised representative or the holder must keep the periodic-inspection certificate required under point 3.2 of this module, and the documents required under section 2 of this module at least until the next periodic inspection.

Module 2 (periodic inspection through quality assurance)

1. This module describes the following procedures:

- the procedure whereby the owner or his authorised representative or the holder, who satisfies the obligations of section 2 of this module, ensures and declares that the transportable pressure equipment continues to meet the requirements of the regulations. The owner or his authorised representative or the holder must affix the date of periodic inspection to all transportable pressure equipment and draw up a written declaration of conformity. The date of periodic inspection must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4 of this module,

- the procedure whereby, in the case of periodic inspection of tanks performed by the approved body in accordance with the second paragraph of regulation 9.1 of these regulations, the approved body which satisfies the obligations of the last paragraph of section 2 of this module, certifies that the transportable pressure equipment continues to meet the requirements of these regulations. The approved body must affix the date of periodic inspection to all transportable pressure equipment and draw up a periodic inspection certificate.

The date of periodic inspection must be accompanied by the identification number of the approved body.

2. The owner or his authorised representative or the holder must take all steps necessary to ensure that the conditions of use and of maintenance are such as to enable the transportable pressure equipment to comply permanently with the requirements of these regulations and in particular 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 must be recorded in documents and held by the owner or his authorised representative or the holder at the disposal of the national authorities.

The owner or his authorised representative or the holder must ensure that the qualified staff and necessary facilities within the meaning of Annex I, points 3 to 6 of the Directive, which is set out in Schedule I hereto, are available for the purpose of the periodic inspections.

The owner or his authorised representative or the holder or the approved body must operate an approved quality system for the periodic inspection and tests of the equipment as specified in section 3 of this module, and be subject to surveillance as specified in section 4 of this module.

3. *Quality system*

3.1. The owner or his authorised representative or the holder or the approved body must lodge an application for assessment of his quality system for the transportable pressure equipment with a notified body of his choice.

The application must include:

- all relevant information on the transportable pressure equipment being submitted for periodic inspection,
- the documentation regarding the quality system.

3.2. Under the quality system, each item of transportable pressure equipment must be examined and appropriate tests must be carried out in order to ensure its conformity with the requirements set out in the Annexes to Directives 94/55/EC and 96/49/EC. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational 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 concerning the qualifications or approvals of the staff concerned.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module.

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

The decision must be notified to the owner or his authorized representative or to the holder or the approved body. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The owner or his authorised representative or the holder or the approved body must 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 or the holder or the approved body must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the owner or his authorised representative or to the holder or the approved body.

The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

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

4.2. The owner or his authorised representative or the holder or the approved body must 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:

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

4.3. The notified body must carry out periodic audits to make sure that the owner or his authorised representative or the holder or the approved body maintains and applies the quality system and provide the owner or his authorised representative or the holder or the approved body with an audit report.

4.4. In addition, the notified body may pay unannounced visits to the owner or his authorised representative or the holder or the approved body. During such visits, the notified body may if necessary perform tests or have tests performed to verify if necessary that the quality system is functioning correctly. The notified body must provide the owner or his authorised representative or the holder or the approved body with a visit report and, if a test has taken place, with a test report.

5. The owner or his authorised representative or the holder or the approved body must, 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 of the second paragraph of point 3.1 of this module,
- the adjustments referred to in the second paragraph of point 3.4 of this module,
- the decisions and reports from the notified body which are referred to in the last paragraph of point 3.3, in the last paragraph of point 3.4 and in points 4.3 and 4.4 of this module.

Schedule V

Based on Annex V of the Directive

MODULES TO BE FOLLOWED FOR CONFORMITY ASSESSMENT

The following table indicates which conformity assessment modules as described in Annex IV, Part I of the Directive, which is set out in Schedule I hereto, are to be followed for the transportable pressure equipment defined in regulation 3.1.2 of these regulations.

Categories of transportable pressure equipment	Modules
1. Receptacles in respect of which the product of the test pressure and the capacity is not more than 30 Mpa x litre (300 bar x litre),	A1, or D1 or E1
2. Receptacles in respect of which the product of the test pressure and the capacity is more than 30 and not more than 150 Mpa x litre (300 and 1 500 bar 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 in respect of which the product of the test pressure and the capacity is more than 150 Mpa x litre (1 500 bar x litre), and likewise for the tanks.	G, or H1, or B in combination with D, or B in combination with F

Notice 1.

Transportable pressure equipment must 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.

Notice 2.

As part of the quality assurance procedures, the notified body must, 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, to verify compliance with the requirements of these regulations. For this purpose the manufacturer must inform the notified body of the production programme planned. The notified body shall carry out at least two visits during the first year of manufacturing. The frequency of subsequent visits will be determined by the notified body on the basis of the criteria set out in point 4.4 of the relevant modules in Annex IV, Part I of the Directive, which is set out in Schedule IV hereto.

Schedule VI**Based on Annex VI of the Directive****LIST OF DANGEROUS SUBSTANCES OTHER THAN THOSE IN CLASS 2
REFERRED TO IN REGULATION 3**

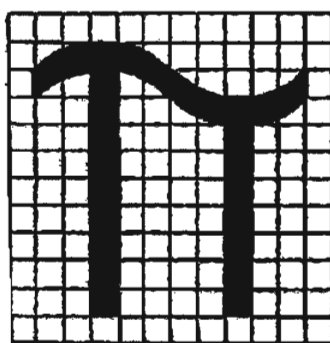
UN number	Class	ADR/RID figures	Dangerous substances
1 051	6.1	1	Stabilised hydrogen cyanide
1 052	8	6	Anhydrous hydrogen fluoride
1 790	8	6	Hydrofluoric acid

Schedule VII

Based on Annex VII of the Directive

MARK OF CONFORMITY

The conformity mark shall take the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the conformity mark.

If the mark is reduced or enlarged, the proportions of the above drawing must be respected.

The various components of the mark must have substantially the same vertical dimensions, which may not be less than 5 mm.

This minimum dimension may be waived for small devices.