

**COUNCIL DIRECTIVE 1999/36/EC**  
**of 29 April 1999**  
**on transportable pressure equipment**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 75(1)(c) thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 189c of the Treaty<sup>(3)</sup>,

- (1) Whereas within the framework of the common transport policy further measures must be adopted to ensure transport safety;
- (2) Whereas each Member State currently requires all transportable equipment to be used on its territory to undergo certification and inspection, including periodic inspections, by its designated bodies; whereas this practice, requiring multiple approvals if equipment is to be used in more than one State in the course of a transport operation, constitutes an obstacle to the provision of transport services within the Community; whereas action by the Community to harmonise approval procedures is justified in order to facilitate the use of transportable pressure equipment on the territory of another Member State in the context of a transport operation;
- (3) Whereas measures should be adopted for the progressive establishment of a single market in transport and, in particular, for free movement of transportable pressure equipment;

- (4) Whereas action at Community level is the only possible way of achieving such harmonisation, since Member States acting independently or through international agreements cannot establish the same degree of harmonisation in the approvals for such equipment; whereas, currently, recognition of approvals given in different Member States is not satisfactory because of the element of discretion;
- (5) Whereas a Council Directive is the appropriate legal instrument to enhance the safety of this equipment, as it provides a framework for uniform and compulsory application of the approval procedures by Member States;
- (6) Whereas Council Directives 94/55/EC<sup>(4)</sup> and 96/49/EC<sup>(5)</sup> have extended the application of the provisions of the ADR<sup>(6)</sup> and RID<sup>(7)</sup> to cover national traffic in order to harmonise across the Community the conditions under which dangerous goods are transported by road and by rail;
- (7) Whereas Directives 94/55/EC and 96/49/EC provide for the option of applying conformity assessment procedures based on modules in accordance with Decision 93/465/EEC<sup>(8)</sup> to certain new transportable pressure equipment; whereas this option should be replaced by an obligation extended to cover all new transportable pressure equipment used for the

<sup>(1)</sup> OJ C 95, 24.3.1997, p. 2, and OJ C 186, 16.6.1998, p. 11.

<sup>(2)</sup> OJ C 296, 29.9.1997, p. 6.

<sup>(3)</sup> Opinion of the European Parliament of 19 February 1998 (OJ C 80, 16.3.1998, p. 217), Council Common Position of 30 November 1998 (OJ C 18, 22.1.1999, p. 1) and Decision of the European Parliament of 10 March 1999 (not yet published in the Official Journal).

<sup>(4)</sup> Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (OJ L 319, 12.12.1994, p. 7).

<sup>(5)</sup> Council Directive 94/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail (OJ L 235, 17.9.1996, p. 25).

<sup>(6)</sup> ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

<sup>(7)</sup> RID: Regulations concerning the International Carriage of Dangerous Goods by Rail as set out in Annex I to Appendix B of the amended version of the Convention concerning the international carriage of goods by rail (COTIF).

<sup>(8)</sup> Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directive (OJ L 220, 30.8.1993, p. 23).

- transport of dangerous goods and falling within the scope of Directives 94/55/EC and 96/49/EC;
- (8) Whereas Directive 97/23/EC<sup>(1)</sup> lays down the general requirements for the free movement and safety of pressure equipment;
- (9) Whereas aerosol dispensers and gas cylinders for breathing appliances should be excluded from the scope of this Directive as their free movement and safety are already covered by Directive 75/324/EEC<sup>(2)</sup> and Directive 97/23/EC;
- (10) Whereas recognition of the approval certificates issued by the inspection bodies designated by the Member States' competent authorities, of the conformity assessment or reassessment procedures and of the periodic inspection procedures contributes towards removing obstacles to freedom to provide transport services; whereas such an objective cannot be achieved satisfactorily at another level by the Member States; whereas, to eliminate the element of discretion, it is necessary to establish clearly which procedures should be followed;
- (11) Whereas it is necessary to lay down common rules for establishing recognition of designation inspection bodies which ensure compliance with Directives 94/55/EC and 96/49/EC; whereas these common rules will have the effect of eliminating unnecessary costs and administrative procedures related to the approval of the equipment and of eliminating technical barriers to trade;
- (12) Whereas, in order not to hinder transport operations between a Member State and a third country, this Directive should not be applied to transportable pressure equipment exclusively used for transport operations of dangerous goods between the territory of the Community and that of third countries;
- (13) Whereas Member States have to designate inspection bodies entitled to perform the conformity assessment or reassessment procedures and periodic inspections; whereas they must also ensure that such bodies are sufficiently independent, efficient and professionally able to carry out their appointed tasks;
- (14) Whereas specific procedures should be introduced for evaluating the conformity of new valves and other accessories used for transport;
- (15) Whereas provisions should be introduced regarding the reassessment of existing equipment, as defined in Annex IV, Part II; so as to enable this Directive to be applied to such equipment;
- (16) Whereas compliance with the technical provisions of the Annexes to Directives 94/55/EC and 96/49/EC for new equipment must be shown by means of the conformity assessment procedures set out in Annex IV, Part I; whereas periodic inspections of existing equipment will be carried out according to the procedures set out in Annex IV, Part III;
- (17) Whereas equipment referred to in this Directive should bear a mark to indicate its compliance with the requirements of Directive 94/55/EC or 96/49/EC and this Directive in order to be placed on the market, filled, used and refilled in accordance with its intended purpose;
- (18) Whereas Member States must allow transportable pressure equipment bearing the mark referred to in Annex VII to move freely on their territory, to be placed on the market, to be used in the course of any transport operation or to be used in accordance with its intended purpose, without undergoing further assessment or having to comply with further technical requirements;
- (19) Whereas it is appropriate that a Member State, provided it informs the Commission, should be able to take measures to limit or prohibit the placing on the market and use of equipment in cases where it presents a particular risk to safety;
- (20) Whereas a committee procedure should be followed for amendment of the Annexes to this Directive and for postponing the date the Directive is brought into effect for certain transportable pressure equipment;

(1) Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181, 9.7.1997, p. 1).

(2) Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40). Directive as amended by Directive 94/1/EC (OJ L 23, 28.1.1994, p. 28).

- (21) Whereas provision should be made for transitional arrangements to enable pressure equipment, manufactured in accordance with the national rules in force before this Directive is brought into effect, to be placed on the market and put into service;
- (22) Whereas Directives 84/525/EEC<sup>(1)</sup> 84/526/EEC<sup>(2)</sup> and 84/527/EEC<sup>(3)</sup> on gas cylinders provide for a conformity procedure different from that provided for by this Directive; whereas a single procedure should be established for all transportable pressure equipment;
- (23) Whereas a periodic inspection procedure should be established for existing gas cylinders which are in accordance with Directives 84/525/EEC, 84/526/EEC and 84/527/EEC,
- (c) for repeated use and periodic inspections:
- to the transportable pressure equipment referred to in (a) and (b),
  - to existing gas cylinders bearing the conformity marking laid down in Directives 84/525/EEC, 84/526/EEC and 84/527/EEC.
3. Transportable pressure equipment which was placed on the market before 1 July 2001 or, in the case of Article 18, 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 this Directive.
4. 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, shall be outside the scope of this Directive.

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

##### Scope

1. The purpose of this Directive shall be to enhance safety 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 within the Community, including the placing on the market and repeated putting into service and repeated use aspects.

2. This Directive shall apply:

- (a) for the purpose of placing on the market: to new transportable pressure equipment as defined in Article 2;
- (b) for the purpose of reassessment of conformity: to existing transportable pressure equipment as defined in Article 2 which meets the technical requirements laid down in Directives 94/55/EC and 96/49/EC;

<sup>(1)</sup> Council Directive 84/525/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, steel gas cylinders (OJ L 300, 19.11.1984, p. 1).

<sup>(2)</sup> Council Directive 84/526/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders (OJ L 300, 19.11.1984, p. 20).

<sup>(3)</sup> Council Directive 84/527/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to welded unalloyed steel gas cylinders (OJ L 300, 19.11.1984, p. 48).

#### Article 2

##### Definitions

For the purposes of this Directive:

1. '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 classes indicated in Annex VI to this Directive, including their valves and other accessories used for transport.

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;

2. 'mark' means the symbol referred to in Article 10;
3. 'conformity assessment procedures' means those procedures set out in Annex IV, Part I;
4. 'reassessment of conformity' means the procedure for subsequent assessment, at the request of the owner or his authorised representative established in the Community 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, within two years of that date;
5. 'notified body' means an inspection body designated by the national competent authority of a Member State in accordance with Article 8 and meeting the criteria of Annexes I and II;
6. 'approved body' means an inspection body designated by the national competent authority of a Member State in accordance with Article 9 and meeting the criteria of Annexes I and III.

#### *Article 3*

##### **Conformity assessment or the placing on the Community market of new transportable pressure equipment**

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.
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.
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.

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.

4. Should Directive 94/55/EC and 96/49/EC not contain any detailed technical provisions for the valves and accessories referred to in paragraph 3, such valves and accessories must meet the requirements of Directive 97/23/EC 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.

5. No Member State shall prohibit, restrict or impede the placing on the market or putting into service on its territory of transportable pressure equipment referred to in Article 1(2)(a) which complies with this Directive and bears the relevant mark provided for in Article 10(1) and (2).

#### *Article 4*

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

1. By way of derogation from Article 3, Member States may authorise on their territory the placing on the market, transport and putting into service by users, of the receptacles — including their valves and other accessories used for transport — covered by Article 1(2)(a), the conformity of which has been assessed by an approved body.
2. Transportable pressure equipment the conformity of which has been assessed by an approved body may not bear the marking described in Article 10(1).
3. The approved body shall work exclusively for the group of which it is a member.
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.
5. The effects of this Article shall be monitored by the Commission and evaluated as from 1 July 2004. To this end, Member States shall forward to the Commission any useful information on the

implementation of this Article. If necessary the evaluation shall be accompanied by a proposal for amendment of this Directive.

#### Article 5

##### Reassessment of conformity for existing transportable pressure equipment

1. The conformity of the transportable pressure equipment referred to in Article 1(2)(b) 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.

Where such equipment was manufactured in series, Member States may authorise 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.

2. No Member States shall prohibit, restrict or impede the placing on the market or putting into service on its territory of transportable pressure equipment referred to in Article 1(2)(b) which complies with this Directive and bears the relevant mark provided for in Article 10(1).

#### Article 6

##### Periodic inspection and repeated use

1. Periodic inspections of the receptacles, including their valves and accessories used for transport, referred to in Article 1(2)(c) shall be arranged by a notified or approved body in accordance with the procedure set out in Annex IV, Part III. 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.

However, Member States may permit periodic inspections of tanks carried out on their territory also to be performed by the approved bodies which have been recognised for carrying out periodic inspections of tanks and which act under the supervision of a body notified under the procedure provided for in

Annex IV, Part III, Module 2 concerning periodic inspection through quality assurance.

2. The transportable pressure equipment referred to in Article 1(2) may be subjected to periodic inspection in any Member State.

3. No Member State may, on grounds concerning transportable pressure equipment as such, prohibit, restrict or impede the use (including filling, storing, emptying and refilling) on its territory of the following transportable pressure equipment:

- the equipment referred to in Article 1(2)(a) and (b) and the first indent of Article 1(2)(c), which satisfies the provisions of this Directive 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 and the mark and identification number referred to in Article 10(3) of this Directive indicating that it has undergone periodic inspection.

4. Member States may establish national requirements for the storage or use of transportable pressure equipment, but not for transportable pressure equipment itself or for the accessories needed during transport. Member States may, however, pursuant to Article 7, retain national requirements for connecting devices, colour codes and reference temperatures.

#### Article 7

##### National provisions

1. A Member State may retain its national provisions concerning devices intended for connection with other equipment and colour codes applicable to transportable pressure equipment until such time as European standards for use are added to the Annexes to Directives 94/55/EC and 96/49/EC.

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, in order to enable Member States to retain their national provisions even after the European standards have been added to the Annexes to Directives 94/55/EC and 96/49/EC.

2. A Member State in which the ambient temperature is regularly lower than  $-20^{\circ}\text{C}$  may impose more stringent standards as regards the operating temperature of material intended for use in the national transport of dangerous goods within its territory 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.

#### Article 8

##### Notified bodies

1. Member States shall communicate to the Commission and the other Member States the list of notified bodies established within the Community which they have designated to carry out the new transportable pressure equipment conformity assessment procedures pursuant to Annex IV, Part I, to reassess the conformity of existing types or equipment with the requirements of the Annexes to Directives 94/55/EC and 96/49/EC pursuant to Annex IV, Part II, and/or to perform the task of periodic inspections pursuant to Annex IV, Part III, module 1 and/or to perform the task of surveillance pursuant to Annex IV, Part III, module 2. They shall also communicate the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies, with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

2. Member States shall apply the criteria set out in Annexes I and II for the designation of notified bodies. Each body shall submit to the Member State which intends to designate it complete information concerning, and evidence of, compliance with the criteria in Annexes I and II.

3. A Member State which has notified a body shall withdraw such notification if it finds that the body no longer meets the criteria referred to in paragraph 2.

It shall forthwith inform the Commission and the other Member States of any such withdrawal of notification.

#### Article 9

##### Approved bodies

1. Member States shall communicate to the Commission and the other Member States the list of approved bodies established in the Community, which

they have recognised in accordance with the criteria of paragraph 2, for the purpose of carrying out periodic inspections of receptacles — including their valves and other accessories used for transport — referred to in Article 2(1), first indent, or conformity reassessment of existing receptacles — including their valves and other accessories used for transport — which conform to a type reassessed by a notified body, to ensure continued compliance with the relevant provisions of Directives 94/55/EC and 96/49/EC in accordance with the procedures laid down in Annex IV, Part III, module 1. They shall also communicate the identification numbers assigned to them beforehand by the Commission.

Member States using the option provided for in Article 6(1), second subparagraph, shall also communicate to the Commission and the other Member States the list of approved bodies established in the Community, which they have recognised for the purpose of carrying out periodic inspections of tanks.

The Commission shall publish in the *Official Journal of the European Communities* a list of the approved bodies recognised, with their identification numbers and the tasks for which they have been recognised. The Commission shall ensure that this list is kept up to date.

2. Member States shall apply the criteria set out in Annexes I and III for the recognition of approved bodies. Each body shall submit to the Member State which intends to recognise it complete information concerning, and evidence of, compliance with the criteria in those Annexes.

3. A Member State which has recognised a body shall withdraw the approval if it finds that the body no longer meets the criteria referred to in paragraph 2.

It shall forthwith inform the Commission and the other Member States of any such withdrawal of approval.

#### Article 10

##### Marking

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 Article 3(1) and Article 5(1) shall have a mark affixed to them in accordance with Annex IV, Part I. The form of the mark to be used is set out in Annex VII. 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. In the event of reassessment, this mark shall be accompanied by the identification number of the notified or approved body.

For transportable pressure equipment complying with Article 7(2), the identification number of the notified or approved body shall be followed by '-40 °C'.

2. New valves and other accessories having a direct safety function shall bear either the mark provided for in Annex VII hereto or that provided for in Annex VI to Directive 97/23/EC. 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.

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

3. 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 Article 6(1) shall bear the identification number of the body which performed the periodic inspection of the equipment to indicate that it may continue to be used.

With regard to gas cylinders covered by Directives 84/525/EEC, 84/526/EEC and 84/527/EEC, when the first periodic inspection is carried out in accordance with this Directive, the aforementioned identification number shall be preceded by the mark described in Annex VII.

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

5. 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 this Directive shall be prohibited. Any other marking may be affixed to equipment provided that the visibility and legibility of the marking in Annex VII is not thereby reduced.

## Article 11

### Safeguard clause

1. Where a Member State finds 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, it 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. It shall forthwith inform the Commission of any such measure, indicating the reasons for its decision.

2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States.

Where the Commission considers, after this consultation, that the measure is unjustified, it shall immediately so inform the Member State which took the initiative and the owner or his authorised representative established in the Community or the holder, or the manufacturer or his authorised representative established within the Community.

3. Where transportable pressure equipment which does not comply bears the marking provided for in Article 10, the competent Member State shall take appropriate action against the person(s) who affixed the marking and shall so inform the Commission and the other Member States.

4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

## Article 12

### Undue marking

Without prejudice to Article 11, where a Member State establishes that the marking described in Annex VII has been affixed unduly, the owner or his authorised representative established in the Community or the holder, or the manufacturer or his authorised representative established within the Community, 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 Member State.

Should non-conformity persist, the Member State shall immediately inform the Commission thereof and 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 Article 11.

#### *Article 13*

##### **Decisions leading to refusal or restriction**

Any decision taken pursuant to this Directive which has the effect of restricting the placing on the market, transport or use or requires the withdrawal from the market or from circulation of transportable pressure equipment shall state the exact grounds on which it is based. Such Decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in the Member State concerned and of the time limits to which such remedies are subject.

#### *Article 14*

##### **Committee**

The amendments necessary for adapting the Annexes to this Directive shall be adopted in accordance with the procedure laid down in Article 15.

#### *Article 15*

1. Where reference is made to the procedure provided for in this Article, the Commission shall be assisted by the Committee on the transport of dangerous goods set up under Article 9 of Directive 94/55/EC, hereinafter referred to as 'the Committee', composed of representatives of the Member States and chaired by a representative of the Commission.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If within three months of the date of referral to the Council the Council has not acted, the proposed measures shall be adopted by the Commission.

#### *Article 16*

##### **Adoption and publication**

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 December 2000. They shall forthwith inform the Commission thereof.

When Member States adopt those measures they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

#### *Article 17*

##### **Implementation**

1. Member States shall adopt no later than 1 July 2001 the provisions which they have adopted to comply with this Directive to transportable pressure equipment.

2. The date referred to in paragraph 1 shall be deferred for certain transportable pressure equipment for which there are no detailed technical specifications or for which adequate reference to the relevant European standards has not been added to the Annexes to Directives 94/55/EC and 96/49/EC.

The equipment concerned by any such deferral and the date on which this Directive becomes applicable to it shall be determined in accordance with the procedure laid down in Article 15.

*Article 18***Transitional arrangements**

Member States shall authorise the placing on the market and putting into service of transportable pressure equipment which complies with the regulations in force within their territory before 1 July 2001 until 24 months from that date and shall authorise the subsequent putting into service of such equipment placed on the market prior to that date.

*Article 19***Penalties**

Member States shall lay down a system of penalties for breaches of the national provisions adopted pursuant to this Directive and shall take all the measures necessary to ensure that those penalties are applied. The penalties thus provided for shall be effective, proportionate and dissuasive.

Member States shall notify the relevant provisions to the Commission not later than 1 December 2000 and shall inform it of any subsequent changes as soon as possible.

*Article 20***Applicability of provisions of other Directives**

As from 1 July 2001 or, in the case of Article 18, within two years of the date, the only provisions of Directives 84/525/EEC, 84/526/EEC and 84/527/EEC

to remain applicable shall be those of Article 1 and those of Annex I, Parts 1 to 3, of each of those Directives.

The provisions of Directive 76/767/EEC<sup>(1)</sup> shall no longer apply from 1 July 2001 or, in the case of Article 18, within two years of that date, for transportable pressure equipment falling within the scope of this Directive.

However, EEC pattern approval certificates for cylinders, issued pursuant to Directives 84/525/EEC, 84/526/EEC and 84/527/EEC shall be recognised as equivalent to the EC type-examination certificates provided for in this Directive.

*Article 21*

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

*Article 22*

This Directive is addressed to the Member States.

Done at Luxembourg, 29 April 1999.

*For the Council*

*The President*

W. MÜLLER

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<sup>(1)</sup> Council Framework Directive 76/767/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods of inspecting them (OJ L 262, 27.9.1976, p. 153). Directive as last amended by the 1994 Act of Accession.

## ANNEX I

**MINIMUM CRITERIA TO BE MET BY NOTIFIED OR APPROVED BODIES, AS REFERRED TO IN ARTICLES 8 AND 9**

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 a 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.
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*ANNEX II***SUPPLEMENTARY CRITERIA TO BE MET BY THE NOTIFIED BODIES REFERRED TO IN  
ARTICLE 8**

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.
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*ANNEX III***SUPPLEMENTARY CRITERIA TO BE MET BY THE APPROVED BODIES REFERRED TO IN  
ARTICLE 9**

1. The approved body must form a separate and identifiable part of an organisation 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.
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## ANNEX IV

## PART I

## CONFORMITY ASSESSMENT PROCEDURES

**Module A** (internal production control)

1. This module describes the procedure whereby the manufacturer, or his authorised representative established within the Community who carries out the obligations laid down in point 2, ensures and declares that transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II 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 point 3 and either the manufacturer or his authorised representative established within the Community 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 within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the Community 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 Directive 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 Directive,
  - results of the design calculations, examinations carried out, etc.,
  - test reports.
4. The manufacturer, or his authorised representative established within the Community, 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 point 2 and with the requirements of the Directive 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 Directive which apply to it.
2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community 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 established within the Community, 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 point 3.

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 Directive 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 Directive,
  - 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 Directive.

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 Directive 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 Directive;
  - 4.3. perform or have performed the appropriate examinations and necessary tests to establish whether the relevant provisions of the Directive 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 Directive 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 established within the Community, 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 Directive 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 established within the Community, 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 established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community 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 Directive which apply to it.
2. The manufacturer, or his authorised representative established within the Community, 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 established within the Community, 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 point 3.

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 Directive 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 Directive,
  - 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 Directive.

In particular, the notified body must:

- assess the materials used where these are not in conformity with the relevant provisions of the Directive,
  - 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 Directive;
  - 4.3. perform the necessary examinations to establish whether the relevant provisions of the Directive have actually been applied.

5. Where the design meets the provisions of the Directive which apply to it, the notified body must issue an EC type-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 type-examination certificate to the manufacturer or to his authorised representative established within the Community, 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 design; these are subject to additional approval where they may affect conformity with the requirements of the Directive 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 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 type-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 established within the Community, must keep with the technical documentation referred to in point 3 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 established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the community market.

#### Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative established within the Community, 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 Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II 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 Directive which apply to it.
3. The manufacturer, or his authorised representative established within the Community, 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 within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure equipment on the Community 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 point 2 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 Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in point 3 and be subject to surveillance as specified in point 4.
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 Directive 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 3.2.

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 established within the Community, 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 3.2 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,
- 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 3.1,
  - the adjustments referred to in the second paragraph of 3.4,
  - the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.
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 point 3 ensures and declares that the items of transportable pressure equipment concerned satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorised representative established within the Community, must affix the II marking to all transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 5.
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 Directive 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 Directive,
  - 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 point 4 and be subject to surveillance as specified in point 5.
  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 Directive 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,
- 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 4.2.

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 established within the Community, 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 4.2 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 point 2,
- the documentation referred to in the second indent of 4.1,
- the adjustments referred to in the second paragraph of 4.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, in the last paragraph of 4.4, and in 5.3 and 5.4.

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 point 2 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 Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each product and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for Community surveillance as specified in point 4.

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

#### 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 Directive 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 3.2.

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 established within the Community, 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 3.2 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 3.1,
- the adjustments referred to in the second paragraph of 3.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.

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 point 3 ensures and declares that the transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in point 5.

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 Directive 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 Directive,
- 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 point 4 and be subject to surveillance as specified in point 5.

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 Directive 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 4.2.

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 established within the Community, 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 4.2 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,
  - the documentation referred to in the third indent of 4.1,
  - the adjustments referred to in the second paragraph of 4.4,
  - the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, in the last paragraph of 4.4, and in 5.3 and 5.4.
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 authorised representative established within the Community, ensures and declares that the transportable pressure equipment subject to the provisions of point 3 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 Directive 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 Directive which apply to it.

The manufacturer, or his authorised representative established within the Community, must affix the II 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 Directive by examining and testing every product in accordance with point 4.

The manufacturer, or his authorised representative established within the Community, 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 Directive 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 established within the Community, 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 satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II 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 Directive 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 Directive 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 established within the Community, 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 Directive 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 point 2 ensures and declares that the transportable pressure equipment in question satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the II marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The II marking must be accompanied by the identification number of the notified body responsible for the surveillance referred to in point 4.
2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in point 3 and be subject to surveillance as specified in point 4.
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 Directive 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 3.2.

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 established within the Community, 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 3.2 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 3.1,
  - the adjustments referred to in the second paragraph of 3.4,
  - the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4, and in 4.3 and 4.4.
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 Directive 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 Directive 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 Directive 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 Article 1(2)(b) 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 Article 3 of this Directive.

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 point 2 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.
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 points 3 and 4 above, may be carried out by an approved body provided that a notified body has previously carried out the relevant conformity reassessment operations indicated in point 3.

## PART III

## PROCEDURES FOR PERIODIC INSPECTION

**Module 1** (periodic inspection of products)

1. This module describes the procedure whereby an owner or his authorised representative established within the Community or the holder ensures that the transportable pressure equipment subject to point 3 continues to meet the requirements of this Directive.
2. To meet the requirements referred to in point 1 the owner or his authorised representative established in the Community 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 this Directive, 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 established in the Community or the holder.

3. The inspection 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 Directive by examining and testing every product.
  - 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 established in the Community or the holder must keep the periodic-inspection certificate required under section 3.2, and the documents required under point 2 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 established in the Community or the holder, who satisfies the obligations of point 2, ensures and declares that the transportable pressure equipment continues to meet the requirements of the Directive. The owner or his authorised representative established in the Community 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 point 4,
  - the procedure whereby, in the case of periodic inspection of tanks performed by the approved body in accordance with the second paragraph of Article 6(1), the approved body which satisfies the obligations of the last paragraph of point 2, certifies that the transportable pressure equipment continues to meet the requirements of this Directive. 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 established in the Community 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 this Directive 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 established in the Community or the holder at the disposal of the national authorities.

The owner or his authorised representative established within the Community or the holder must ensure that the qualified staff and necessary facilities within the meaning of Annex I, points 3 to 6, are available for the purpose of the periodic inspections.

The owner or his authorised representative established in the Community 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 point 3, and be subject to surveillance as specified in point 4.

### 3. *Quality system*

- 3.1. The owner or his authorised representative established in the Community 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 3.2.

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 established in the Community or of the holder or of the approved body.

The decision must be notified to the owner or this authorised representative established in the Community 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 established in the Community 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 established in the Community 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 3.2 or whether a reassessment is required.

It must notify its decision to the owner or his authorised representative established in the Community 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 established in the Community 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 established in the Community 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 established in the Community or the holder or the approved body maintains and applies the quality system and provide the owner or his authorised representative established in the Community 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 established in the Community 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 established in the Community 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 established in the Community 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 3.1,
- the adjustments referred to in the second paragraph of 3.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, in the last paragraph of 3.4 and in 4.3 and 4.4.

## ANNEX V

## MODULES TO BE FOLLOWED FOR CONFORMITY ASSESSMENT

The following table indicates which conformity assessment modules as described in Annex IV, Part I, are to be followed for the transportable pressure equipment defined in Article 2(1).

Category of transportable pressure equipment	Modules
1. Receptacles for which the product of the test pressure and the capacity is no more than 100 MPa × litre (1 000 bar × litre)	A1, or B in combination with C1
2. Receptacles for which the product of the test pressure and the capacity is more than 100 and no more than 300 MPa × litre (1 000 and 3 000 bar × litre respectively)	H, or B in combination with E, or B in combination with C1
3. Receptacles for which the product of the test pressure and the capacity exceeds 300 MPa × litre (3 000 bar × litre), and tanks	G, or H1, or B in combination with D, or B in combination with F

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.
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, in conformity to the requirements of this Directive. For this purpose the manufacturer must inform the notified body of the production programme planned. The notified body must make at least two visits during the first year of manufacture. The frequency of subsequent visits will be determined by the notified body on the basis of the criteria set out in point 4.4 of the relevant modules in Annex IV, Part I.

## ANNEX VI

LIST OF DANGEROUS SUBSTANCES OTHER THAN THOSE IN CLASS 2 REFERRED TO IN  
ARTICLE 2

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

