COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 08.01.1997
COM(96) 674 final

97/ 0011 (SYN)

Proposal for a

COUNCIL DIRECTIVE

on transportable pressure equipment

(presented by the Commission)

EXPLANATORY MEMORANDUM

A. General introduction

1. This proposal has as its primary objective safety in the transport of transportable pressure equipment. Although the Council has already ensured, by adoption of Directives 94/55/EC[1] and 96/49/EC[2], a sufficiently high level of safety in the transport of dangerous goods - including transportable pressure equipment - the aspect of free provision of transport services involving such equipment, including use and refilling, is not guaranteed. That is to say, there are additional national requirements which impede the free provision of transport services for such equipment, as well as its use. These restrictions are mainly due to the absence of a harmonised system for approvals for such equipment at the time of periodic inspections in use, and consequently to a lack of recognition of approvals and marks issued by inspecting bodies. Thus, the approval attesting the periodic inspection of the equipment as carried out by a designated inspection body in one Member State should be recognised throughout all Member States. This contrasts to the current situation where, for example, gas cylinders transported from country *x* to country *y* and used may not be refilled in country *y* and transported back again to country *x* without being retested, inspected and approved in country *y*.

Therefore, although by Council Directives 94/55/EC and 96/49/EC great progress has been made in harmonising technical provisions for the safe transport of transportable pressure equipment, particularly with regard to construction and use, certain measures still remain to be taken. Although a limited number of Member States already operate a voluntary form of mutual recognition of approvals for transportable pressure equipment for both periodic inspections and placing on the market, without requiring further testing, there is no mandatory requirement obliging Member States to do so, so that unfortunately obstacles to freedom to provide transport services still exist where other Member States require additional inspection of approved equipment for use on their territory in the course of a transport operation.

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1 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 319/7, 12.12.94

2 Council Directive 96/49/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 235/25, 17.9.1996

2. A secondary objective is to ensure free circulation of such equipment on the Community market. Although the Council recently adopted Directive 96/../EC[3], covering the aspect of placing on the market of pressure equipment, this Directive excludes *transportable* pressure equipment from its scope, given that most technical aspects are already covered under the scope of Council Directives 94/55/EC and 96/49/EC. In its original proposal to the Council for this Directive on pressure equipment (COM(93)319), the Commission already announced that Community measures would be taken to ensure free circulation and use of transportable pressure equipment where these aspects were not addressed through Council Directive 94/55/EC (see III, pg 1b of COM(93)319). Thus, this proposal will likewise seek to overcome the additional national requirements which impede the placing on the market of transportable pressure equipment, through the establishment of uniform requirements for construction and use, taken from Directives 94/55/EC and 96/49/EC, recognition of certification issued by approved bodies and the inclusion of a mark of conformity.

3. In order to fullfil the above objectives, this proposal provides for a guarantee of transport safety by introducing new procedures for periodic inspection of all existing transportable pressure equipment in Annex V, part II, as well as conformity assessment procedures following the modular approach in Annex V, part I, for all new equipment other than that manufactured in accordance with Council Directives 84/525/EEC[4], 84/526/EEC[5] and 84/527/EEC[6].

Freedom to provide transport services will be fully attained if, as a result of the harmonisation provided by this proposal, new transportable pressure equipment as well as all existing equipment which complies with Council Directives 94/55/EC and 96/49/EC, including cylinders manufactured in conformity with Council Directives 84/525/EEC, 84/526/EEC and 84/527/EEC, used in the context of a transport operation will be recognised in other Member States.

4. Existing equipment, manufactured to national standards, that does not comply with Council Directives 94/55/EC and 96/49/EC, does not fall within the scope of this proposal.

5. There are large numbers of testing and certification houses currently existing in the 15 Member States, which under this proposal would take on the status of designated inspection bodies on condition that they meet the relevant criteria. This proposal provides that the inspection bodies have to fulfill common quality criteria to be designated by the national administrations. The basis of these criteria is taken from the newly developed and adopted CEN standard in the EN 45000 series, namely EN 45004 adopted in 1995 laying down "General criteria for the operation of various types of bodies performing inspection".

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[3] Council Directive 96/../EC on the approximation of the laws of the Member States concerning pressure equipment, OJ L ..., ...

[4] OJ L 300/1, 19.11.1984

[5] OJ L 300/20, 19.11.1984

[6] OJ L 300/48, 19.11.1984

6. A positive effect of this proposal is the granting of access to a larger market for products falling within its scope with the twofold benefit of economies of scale and reduced administrative costs related to approval of transportable pressure equipment. Such equipment should be easily identifiable to facilitate further its circulation. The most effective way to do so is to affix a distinguishing mark to it (see Annex VII). Each Member State shall recognise all equipment bearing such a mark, since it is a guarantee of compliance of the equipment with the requirements of this proposal, that is, a guarantee of a high level of safety of the equipment.

7. As regards economic advantages of this Directive over the current situation, today the situation of type approval for transportable pressure equipment is such that manufacturers have to submit their equipment for type approval to the national administration of all Member States where they intend to place their product on the market. Once this Directive enters into force, they will not be obliged to obtain approval from all Member States individually; approval and marking in one Member State will be enough to place the equipment on the market or use it in any part of the Community.

8. Equipment transported into the Community from third countries can be approved for periodic inspection by a designated inspection body established within the Community provided that this equipment satisfies the provisions of this Directive. Also, new equipment manufactured in third countries and placed on the Community market for the first time must comply with the provisions of this Directive.

9. In developing its proposal the Commission consulted Member States' governments, as well as European trade federations such as AEGPL, EIGA, CEFIC, ECM, EPTA, UIP, the representative bodies of inspecting agencies, CEOC and ECUI, and the standardisation body CEN, who in principle all agree on the need for regulation at Community level in this sector in order to enhance safety and speed up the procedures for type approval of equipment.

B. Justification for action at Community level

Subsidiarity

(a) What are the objectives of the proposed action in relation to the Community's obligations?

The main objective of the action envisaged is to facilitate the freedom to provide transport services and to enhance safety in the transport of transportable pressure equipment within the Community. In addition, the proposal regulates the placing on the market of new equipment. All this can be achieved through a recognition of approvals issued by Competent Authorities' testing bodies (designated inspection bodies), whether independent or in-house, and by affixing a recognised mark for approved equipment.

(b) Does competence for the planned activity lie solely with the Community or is it shared with the Member States?

It is a competence shared between the Community and the Member States.

(c) What is the Community dimension of the problem (for example, how many Member States are involved and what solution has been used up to now)?

All Member States are already bound by Council Directives 94/55/EC and 96/49/EC which establish the technical requirements for the transport of dangerous goods including transportable pressure equipment. Further to these obligations Member States will need to transpose the provisions of this Directive in order to adequately cover the aspects of placing on the market and periodic inspections of these goods within the Community.

(d) What is the most effective solution taking into account the means available to the Community and those of the Member States?

Action at Community level is the only possible way to solve these problems. A mutual recognition clause in the Council Directives 94/55/EC and 96/49/EC would be insufficient given that, for the purposes of transport, a cylinder, for example, can already be approved in one Member States then filled and transported to another Member State. The obstacle arises in the course of a transport operation when the cylinder needs to be refilled and moved again. At this stage Member States require their own Competent Authority approval of the testing of transportable pressure equipment.

Therefore the completion of the Internal Market for transportable pressurised equipment, as foreseen in Article 8A of the EEC Treaty, calls for measures that can only be taken satisfactorily at Community level in order to achieve this objective.

(e) What real added value will the activity proposed by the Community provide and what would be the cost of inaction?

A positive effect of the principle of recognition of approvals of the equipment established in the Directive will be the free provision of transport services of such equipment throughout the Community, as well as the elimination of the unnecessary costs and administrative procedures related to the equipment approvals.

As regards economic advantages of this Directive over the current situation, today the situation of type approval for transportable pressure equipment is such that manufacturers have to submit their equipment for type approval to the national administration of all Member States where they intend to place their product on the market. These manufacturers already have to bear the costs related to conformity assessment. Once this Directive enters into force, they will not be obliged to obtain approval from all Member States individually; approval and marking in one Member State will be enough to place the equipment on the market or use it in any part of the Community. The consequent savings may be reflected in the price of the equipment.

Moreover, the approval attesting the periodic inspection of the equipment as carried out by a designated inspection body in one Member State should be recognised throughout all Member States. This contrasts to the current situation where, for example, gas cylinders transported from country *x* to country *y* and used may not be refilled in country *y* and transported back again to country *x* without being retested, inspected and approved in country *y*.

Embracing certain tanks for the transport of dangerous goods within the scope of this proposal, thereby assuring them free circulation, has important economic advantages considering the high value of such equipment.

A further advantage of recognition of approvals is that it will allow better use of existing equipment. For example, where a company has premises in more than one country, transportable pressure equipment in excess in country *x* can be transferred to country *y* for use without incurring additional costs for inspection by the designated inspection body of country *y*.

(f) What forms of action are available to the Community (recommendation, financial support, regulation, mutual recognition, etc...)?

Action at international level is insufficient in the absence of efficient enforcement possibilities.

It is considered that a Directive is the best means available of achieving the goal of free circulation of this transportable pressure equipment. A Directive would allow the flexibility of amending existing national rules rather than abandoning these for a Regulation. A recommendation is considered insufficient given the sensitive safety aspects involved in this transport. Financial support would clearly be inadequate.

(g) Is it necessary to have a uniform Regulation or is a Directive setting out the general objectives sufficient, leaving implementation at the level of the Member States?

The adoption of a Council Directive is the appropriate procedure for laying down a legal framework to enhance safety performances of the equipment through a uniform and compulsory application of the technical provisions for the equipment as set out in the Annexes to Directives 94/55/EC and 96/49/EC, while leaving to the Member States the means of enforcement and the implementation of this Directive.

Coherence with other Community policies

This proposal for a Directive will fill the legislative gap currently existing with regard to harmonised conditions for a Single Market in transportable pressure equipment, as it complements not only existing Community legislation with regard to the transport of dangerous goods but also that which establishes a Single Market for pressure equipment in general.

C. Scope of the proposal

This proposal requires that all transportable pressure equipment used for the transport of dangerous goods meets the provisions relating to such equipment in the Annexes to Council Directives 94/55/EC and/or 96/49/EC. (For the purposes of manufacture and type approval, cylinders covered under Directives 84/525/EEC, 84/526/EEC and 84/527/EEC already satisfy these requirements.)

In addition, new equipment equipment has to be subjected to the conformity assessment procedures set out in Annex V, part I, approved by a recognised inspection body, in order to bear the mark set out in Annex VII.

Existing equipment meeting the provisions set out in the Annexes to Council Directives 94/55/EC and 96/49/EC with regard to periodic inspection may bear the mark set out in Annex VII if the testing and inspection is carried out by a recognised inspection body and the tests are carried out in accordance with Part II of Annex V.

It covers existing equipment, including receptacles and tanks of Class 2, used for the transport of gases of Class 2 as well as stabilized hydrogen cyanide of Class 6.1 and hydrogen fluoride, anhydrous and hydrofluoric acid solution of Class 8 transported in receptacles of Class 2.

Under Council Directives 94/55/EC and 96/49/EC already today most "packagings", including tanks, containing dangerous goods bear a "UN" mark. But this is not the case for packagings for gases (Class 2), e.g. cylinders, tubes, which have no widely recognised/uniform mark.

A new mark is being proposed here for all new transportable pressure equipment for the purposes of placing on the market as well as for all existing equipment for the purposes of periodic inspection.

Currently all gas cylinders complying with Council Directives 84/525/EEC, 84/526/EEC and 84/527/EEC are engraved with an ϵ mark. However, a different mark is being proposed for such equipment here, because this Directive includes the aspect of conformity assessment, together with the recognition of approvals issued by recognised inspection bodies for initial and periodic inspections. So, the new mark will provide proof of periodic inspection by an approved inspection body for all transportable pressure equipment covered by this proposal.

New transportable pressure equipment complying with the provisions of Council Directives 94/55/EC and 96/49/EC and stamped with the authorized mark prescribed by this Directive would have free circulation including placing on the market, transport and use in all 15 Member States.

Moreover, existing transportable pressure equipment complying with the provisions of Council Directives 94/55/EC and 96/49/EC and stamped with the authorized mark prescribed by this Directive after periodic inspection would be able to be refilled and subsequently transported in all 15 Member States.

Existing transportable pressure equipment manufactured according to national requirements which do not satisfy the provisions of Directives 94/55/EC and 96/49/EC is excluded from the scope of this proposal.

D. Contents of the proposal

Article 1 outlines the purpose of this proposal and determines its scope.

Article 2 defines the main terms used in the proposal, including the three types of inspection body taken from EN 45004.

Article 3 introduces the requirement for conformity assessment procedures for the equipment and requires Member States to permit free movement of new equipment approved and inspected in other Member States where this equipment satisfies the requirements of this Directive.

Article 4 introduces a requirement for periodic inspection in accordance with the procedures set out in part II of Annex V. It also requires Member States to permit free movement of existing equipment approved and inspected in other Member States where this equipment satisfies the requirements of this Directive and bears the mark of Annex VII.

Article 5 establishes the responsibilities of Member States in designating notified bodies (Type A inspection bodies) and withdrawing approval where the criteria of Annexes I and II are no longer met.

Article 6 sets out the requirements to be met by Type B inspection bodies.

Article 7 sets out the requirements to be met by Type C inspection bodies.

Article 8 introduces a requirement for marking equipment conforming to the requirements of the Directive.

Article 9 has been designed as a safeguard clause to cover the case where equipment is found by a Member State to be liable to cause damage to health or endanger safety. Such cases will be handled through the Committee procedure set out in Article 12.

Article 10 covers the case where marking according to Article 8 has been unduly affixed.

Article 11 provides for adaptation of the Annexes to the Directive by the Commission. The procedure laid down in Article 12 will apply.

Article 12 describes the procedure to be followed in the Committee to be used by this Directive.

Article 13 establishes the measures with which each Member State has to comply in order to enforce the Directive.

Articles 14 and 15 : No comment.

Annex I :Minimum criteria to be met when designating inspection bodies.

Annex II:Supplementary criteria to be met when designating notified bodies (inspection bodies of Type A).

Annex III: Supplementary criteria to be met when designating inspection bodies of Type B.

Annex IV :Supplementary criteria to be met when designating inspection bodies of Type C.

Annex V: Conformity assessment procedures and Procedures for periodic inspection

Annex VI : Modules to be followed for conformity assessment

Annex VII : Mark of conformity

Proposal for a Council Directive
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[1],

Acting in accordance with the procedure referred to in Article 189c of the Treaty and in cooperation with the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas within the framework of the common transport policy further measures must be adopted to ensure transport safety;

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[1] OJ C ...

[2] OJ C ...

[3] OJ C ...

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 appointed 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 for a harmonisation of 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;

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;

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;

Whereas a Council Directive is the appropriate legal instrument to enhance safety in this equipment as it provides a framework for uniform and compulsory application of the approval procedures by Member States; whereas, in order to eliminate discretionary elements, it is necessary to establish clearly in Annexes V and VI which approval procedures for initial and periodic inspection of the transportable pressure equipment should be followed by Member States;

Whereas Council Directives 94/55/EC[4] and 96/49/EC[5] have extended the application of the provisions of the ADR and RID to cover national traffic in order to harmonise across the Community the conditions under which dangerous goods are transported by road and by rail; whereas the provisions relating to transport equipment are laid down in order to facilitate the provision of transport services and that such Directives apply to the transport of dangerous goods;

Whereas Council Directives 84/525/EEC[6], 84/526/EEC[7] and 84/527/EEC[8] on gas cylinders do not provide for the aspect of periodic inspection; whereas therefore this Directive imposes such a requirement also to the equipment covered by those Directives;

Whereas in view of the nature of the risks involved in the use of transportable pressure equipment Directives 94/55/EC and 96/49/EC establish a requirement for certain such equipment to follow procedures for the assessment of conformity; whereas this requirement should be extended to cover all new transportable pressure equipment used for the transport of dangerous goods and falling within the scope of Directives 94/55/EC and 96/49/EC;

Whereas recognition of certification of inspection bodies designated by the Competent Authority of a Member State as well as of the conformity assessment procedures is the principal means of removing these obstacles to freedom to provide transport services; whereas this objective cannot be achieved satisfactorily at another level by the individual Member States;

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4 Council Directive 94/55/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road of 21 November 1994, OJ L 319/7, 12.12.94

5 Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail of 23 July 1996, OJ L 235/25, 17.9.1996

6 OJ L 300/1, 19.11.1984

7 OJ L 300/20, 19.11.1984

8 OJ L 300/48, 19.11.1984

Whereas it is necessary to lay down common rules to establish recognition of designated inspection bodies which ensure compliance with the provisions of Directive 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;

Whereas Member States have to designate inspection bodies entitled to perform the conformity assessment procedures and periodic inspections and they also have to ensure that such bodies are independent, efficient and professionally capable to carry out their appointed tasks;

Whereas compliance with the technical provisions of the Annexes to Council Directives 94/55/EC and 96/49/EC for new equipment shall be proven by conformity assessment procedures set out in Annex V, part I; whereas periodic inspections of existing equipment shall be carried out according to the procedures set out in Annex V, part II;

Whereas equipment referred to in this Directive should bear a mark to indicate its compliance with the requirements of Directives 94/55/EC or 96/49/EC and this Directive and be placed on the market, filled, transported, used, refilled and transported in accordance with its intended purpose;

Whereas Member States shall allow transportable pressure equipment bearing the mark in Annex VII to move freely on their territory, to be placed on the market, to be used in the course of a transport operation or to be used in accordance with its intended purpose, without further evaluation or technical requirements;

Whereas it is appropriate that the Commission takes measures to limit or prohibit the placing on the market and use of equipment in cases where it presents a particular risk to safety, in accordance with the procedure established in Article 12,2;

Whereas a simplified procedure involving a consultative committee must be followed for the purposes of administering the safeguard procedure of Article 9 as well as for amendment of the Annexes to this Directive;

HAS ADOPTED THIS DIRECTIVE :

Article 1

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 and to ensure the free movement, including the aspects of placing on the market, repeated putting into service and use of such equipment within the Community.

2. This Directive shall apply:

   (a) to new transportable pressure equipment as defined in Article 2, with the exception of gas cylinders bearing an ϵ mark in accordance with Council Directives 84/525/EEC, 84/526/EEC and 84/527/EEC,

   (b) only for the purposes of periodic inspections to:

   new transportable pressure equipment as defined in Article 2 bearing a mark in accordance with Annex VII of this Directive;

   new and existing gas cylinders bearing an ϵ mark in accordance with Council Directives 84/525/EEC, 84/526/EEC and 84/527/EEC; and

   existing transportable pressure equipment as defined in Article 2 and meeting the requirements of Council Directives 94/55/EC and 96/49/EC in force at 1 January 1999.

3. Transportable pressure equipment placed on the market before 1 January 1999 which does not meet the requirements of Council Directives 94/55/EC and 96/49/EC does not fall within the scope of this Directive.

Article 2

For the purposes of this Directive:

'transportable pressure equipment' shall mean refillable equipment, including valves and other accessories of Class 2 of the Annexes to Council Directives 94/55/EC and 96/49/EC, approved for the transport of gases of Class 2, as well as for the transport of stabilized hydrogen cyanide of Class 6.1 and hydrogen fluoride, anhydrous and hydrofluoric acid solution of Class 8; it shall include receptacles, demountable tanks, tank containers (portable tanks), and tanks of tank wagons, tanks or receptacles of battery vehicles and tanks of tank vehicles as defined in marginals 2211 and 10 014, 211 and Appendices X and XI, paragraph 1.1.3 respectively of the Annexes to those Directives;

'mark' shall mean the symbol referred to in Article 8;

'conformity assessment procedures' shall mean those procedures set out in Annex V, part I;

'notified body or Type A inspection body' shall mean a body designated by the national Competent Authority of a Member State in conformity with Article 5 and meeting the criteria of Annexes I and II;

'Type B inspection body' shall mean a body designated by the national Competent Authority of a Member State in conformity with Article 6 and meeting the criteria of Annexes I and III;

'Type C inspection body' shall mean a body designated by the national Competent Authority of a Member State in conformity with Article 7 and meeting the criteria of Annexes I and IV;

Article 3

1. New transportable pressure equipment, with the exception of gas cylinders bearing an ϵ mark in accordance with Council Directives 84/525/EEC, 84/526/EEC and 84/527/EEC, placed on the market or put into service on or after 1 January 1999 shall meet the provisions applicable to equipment of Class 2 of the Annexes to Council Directive 94/55/EC and 96/49/EC. Compliance of such transportable pressure equipment with these provisions shall be proven exclusively in accordance with the conformity assessment procedures set out in Annex V, part I and specified in Annex VI.

2. Member States shall not prohibit, restrict or impede the placing on the market or putting into service on their territory of transportable pressure equipment referred to in Article 1,2(a) which complies with this Directive and bears the marking in accordance with Article 8,1.

Article 4

1. For transportable pressure equipment mentioned in Article 1,2(b) compliance of such equipment with the provisions of the Annexes to Council Directives 94/55/EC and 96/49/EC shall be proven exclusively in accordance with the procedures for periodic inspection in Annex V, part II.

2. Member States shall not prohibit, restrict or impede the use (including filling, emptying and refilling) on their territory of transportable pressure equipment referred to in Article 1,2(b) which complies with this Directive and bears the marking in accordance with Article 8,2 indicating that it has undergone periodic inspection.

Article 5

1. Member States shall inform the Commission and the other Member States of the notified bodies (Type A inspection bodies) which they have appointed to carry out the conformity assessment procedures according to Annex V, part I, and/or to perform the task of periodic inspections according to Annex V, part II, modules 1 or 2, including the specific tasks which those bodies carry out on behalf of the competent authority and 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 designated notified bodies (Type A inspection bodies), with their identification numbers and the tasks for which they have been designated. 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 (Type A inspection bodies). Each inspection 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 designated a notified body (inspection body of Type A) shall withdraw such designation if it finds that the body no longer meets the criteria referred to in 2. It shall immediately inform the Commission and the other Member States of any such withdrawal of a designation.

Article 6

1. Member States shall likewise inform the Commission and the other Member States of the Type B inspection bodies which they have appointed, in accordance with the criteria of paragraph 2, to carry out periodic inspections of transportable pressure equipment defined in Article 2, to ensure continued compliance with the relevant provisions of Council Directives 94/55/EC and 96/49/EC in accordance with the procedures laid down in Annex V, part II, modules 1 or 2, including the specific tasks which these bodies carry out on behalf of the competent authority and 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 designated Type B inspection bodies, with their identification numbers and the tasks for which they have been designated. 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 designation of Type B inspection bodies. Each inspection 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 III.

3. A Member State which has designated an inspection body of Type B shall withdraw such a designation if it finds that the body no longer meets the criteria referred to in paragraph 2 above. It shall immediately inform the Commission and the other Member States of any such withdrawal of a designation.

Article 7

1. Member States shall likewise inform the Commission and the other Member States of the Type C inspection bodies which they have appointed, in accordance with the criteria of paragraph 2, to carry out periodic inspections transportable pressure equipment defined in Article 2, to ensure continued compliance with the relevant provisions of Council Directives 94/55/EC and 96/49/EC in accordance with the procedures laid down in Annex V, part II, modules 1 or 2, including the specific tasks which these bodies carry out on behalf of the competent authority and 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 designated Type C inspection bodies, with their identification numbers and the tasks for which they have been designated. 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 IV for the designation of Type C inspection bodies. Each inspection 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 IV.

3. A Member State which has designated an inspection body of Type C shall withdraw such a designation if it finds that the body no longer meets the criteria referred to in paragraph 2 above. It shall immediately inform the Commission and the other Member States of any such withdrawal of a designation.

Article 8

1. Equipment satisfying the provisions of Article 3,1 shall have a mark affixed to it by the manufacturer or his authorized representative established within the Community. The form of the mark to be used is set out in Annex VII. This mark shall be immovably affixed and shall be accompanied by the identification number of the notified body (Type A inspection body) which has performed the conformity assessment procedure on the equipment, as appropriate, as well as by the further requirements for marking the equipment as set out in Directives 94/55/EC and 96/49/EC.

2. For the purposes of periodic inspections, all transportable pressure equipment referred to in Article 4 shall have the mark set out in Annex VII immovably affixed to it by a designated Type A (notified body), B or C inspection body. The mark shall be accompanied by the identification number of the body which has performed the periodic inspection of the equipment, followed by a letter U of the same dimensions as the number, to indicate in-use or in-service, as well as by the further requirements for marking the equipment as set out in Directives 94/55/EC and 96/49/EC.

3. For both conformity assessment and periodic inspections, the identification number of the inspection body shall be immovably affixed under its responsibility either by the body itself or by the manufacturer or his authorized representative established within the Community.

4. 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 pressure equipment provided that the visibility and legibility of the marking in Annex VII is not thereby reduced.

Article 9

Where a Member State establishes that 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 shall immediately inform the Commission and appropriate measures shall be taken in accordance with the procedure laid down in Article 12,2.

Article 10

Without prejudice to Article 9, where a Member State establishes that the marking as defined in Article 8 has been unduly affixed, the manufacturer, or his authorized representative established within the Community, shall be obliged to make the 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 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 shall be taken in accordance with the procedures laid down in Article 12,2.

Article 11

The Annexes to this Directive may be amended in accordance with the procedure laid down in Article 12,2.

Article 12

1. The Commission shall be assisted by the Committee on the transport of dangerous goods set up by Article 9 of Directive 94/55/EC[9], hereinafter referred to as 'the Committee'.

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, if necessary by taking a vote.

   The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

   The Commission shall take the utmost account of the opinion delevered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 13

1. The Member States shall adopt and publish the laws, regulations and administrative provisions necessary for them to comply with this Directive before 30 June 1998. They shall forthwith inform the Commission thereof.

   When the Member States adopt those measures they shall include references to this Directive or shall accompany them with such references on their official publication. The Member States shall lay down the manner in which such references shall be made.

   Member States shall apply these provisions from 1 January 1999.

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9 OJ L 319/7, 12.12.1994

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

3. Member States shall lay down the system of penalties for breaching 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 30 June 1998 and shall notify any subsequent changes as soon as possible.

Article 14

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

Article 15

This Directive is addressed to the Member States.

ANNEX I

MINIMUM CRITERIA TO BE MET BY DESIGNATED INSPECTION BODIES OF TYPES A (NOTIFIED BODIES), B OR C REFERRED TO IN ARTICLES 5, 6 & 7

1. A notified body/inspection body that is part of an organization involved in functions other than inspection shall be identifiable within that organization.

2. The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular the personnel of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgement, particularly from persons or organizations external to the inspection body with an interest in the results of inspections carried out. The impartiality of the inspection personnel of the body must be guaranteed.

3. The inspection body shall have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and verification operations. It must also have access to the equipment required to perform special verifications.

4. The staff responsible for inspection shall 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 shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report thereon. They shall also have the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. They shall 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 personnel shall carry out the assessments and verifications with the highest degree of professional integrity and te nical competence. The inspection body shall ensure confidentiality of information obta..ed in the course of its inspection activities. Proprietary rights shall be protected.

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

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

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

ANNEX II

CRITERIA SUPPLEMENTARY TO ANNEX I TO BE MET BY NOTIFIED BODIES (DESIGNATED INSPECTION BODIES OF TYPE A) REFERRED TO IN ARTICLE 5

1. A notified body (Type A inspection body) shall be independent of the parties involved and shall therefore provide "third party" inspection services.

   The notified body/inspection body, and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, purchaser, owner, 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, construction, 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 shall have access to the services of the inspection body. There shall not be undue financial or other conditions. The procedures under which the body operates shall be administered in a non-discriminatory manner.

ANNEX III

CRITERIA SUPPLEMENTARY TO ANNEX I TO BE MET BY DESIGNATED INSPECTION BODIES OF TYPE B REFERRED TO IN ARTICLE 6

1. The body shall form a separate and identifiable part of an organisation involved in the design, manufacture, supply, use or maintenance of the items it inspects and shall have been established to supply inspection services to its parent organisation.

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

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

4. Inspection services shall only be supplied to the organisation of which the inspection body forms a part and the clients to whom they supply gas.

ANNEX IV

CRITERIA SUPPLEMENTARY TO ANNEX I TO BE MET BY DESIGNATED INSPECTION BODIES OF TYPE C REFERRED TO IN ARTICLE 7

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

ANNEX V

PART I
CONFORMITY ASSESSMENT PROCEDURES

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community who carries out the obligations laid down in section 2 ensures and declares that transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the Π marking to all transportable pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must draw up the technical documentation described in section 3 and either the manufacturer or his authorized representative established within the Community must keep it at the disposal of the relevant national authorities for inspection purposes for a period of ten years after the last of the transportable pressure equipment has been manufactured.

   Where neither the manufacturer nor his authorized 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 authorized 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 section 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 (type A inspection 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 transportable pressure 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 the former's identification number on 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 (type A inspection 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 authorized 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 authorized representative, his name and address as well;

- a written declaration that the same application has not been lodged with any other notified body;

- the technical documentation described in section 3.

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 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;

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 ten 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 authorized 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 transportable pressure 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 authorized representative established within the Community, must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of ten years after the last of the transportable pressure equipment has been manufactured.

   Where neither the manufacturer nor his authorized 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 (type A inspection 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 authorized 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 authorized representative, his name and address as well;

   - a written declaration that the same application has not been lodged with any other notified body;

   - the technical documentation described in section 3.

   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 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;

- 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 design calculations made, examinations carried out, etc.

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 where these are not in conformity with the relevant provisions of the Directive;

- approve the procedures for joining the pressure equipment parts;

- verify that the personnel undertaking the 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 been applied.

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

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

If the notified body refuses to issue an EC design-examination certificate to the manufacturer or to his authorized 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 design-examination certificate of all modifications to the approved design; these are subject to additional approval where such changes may affect the conformity of the transportable pressure equipment 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 design-examination certificate.

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

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

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

   - the EC design-examination certificates and additions granted;

   - the EC design-examination certificates and additions withdrawn.

9. The manufacturer, or his authorized representative established within the Community, must keep with the technical documentation referred to in section 3 copies of EC design-examination certificates and their additions for a period of ten years after the last of the transportable pressure equipment has been manufactured.

   Where neither the manufacturer nor his authorized 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 authorized 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 authorized representative established within the Community, must affix the Π 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 authorized representative established within the Community, must keep a copy of the declaration of conformity for a period of ten years after the last of the transportable pressure equipment has been manufactured.

   Where neither the manufacturer nor his authorized 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 (type A inspection 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 must assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the transportable pressure 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 the former's identification number on each item of transportable pressure equipment.

Module D (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 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 authorized 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 (type A inspection body) responsible for Community surveillance as specified in section 4.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 3 and be subject to surveillance as specified in section 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 organizational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment;
- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications 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 authorized 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;

- special conditions linked to the approval of the system, where applicable;

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may carry out or have carried out tests to verify if necessary 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 ten 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, 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 section 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 authorized representative established within the Community, must affix the Π marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The Π marking must be accompanied by the identification number of the notified body (type A inspection body) responsible for Community surveillance as specified in section 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 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 design calculations made, examinations carried out, etc.;

- test reports.

3. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 4 and be subject to surveillance as specified in section 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 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 organizational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment;

- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used;

- 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 authorized 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;
- special conditions linked to the approval of the system, where applicable;
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may carry out or have carried out tests to verify if necessary 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 ten years after the last of the transportable pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the technical documentation referred to in section 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, 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 also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the 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 authorized 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 (type A inspection body) responsible for surveillance as specified in section 4.

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

3. Quality system

3.1. The manufacturer 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 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. 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 organizational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure equipment;

- the examinations and tests to be carried out after manufacture;

- the means of monitoring the effective operation of the quality system;

- the quality records, such as inspection reports and test data, calibration data, reports 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 asscssing 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.

3.4. 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 authorized 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 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 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;
- special conditions linked to the approval of the system, where applicable;
- significant changes in manufacturing organization, policy or techniques.

During such visits, the notified body may carry out or have carried out tests to verify if necessary 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 ten 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, 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 (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 ensures and declares that the transportable pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorized representative established within the Community, must affix the Π marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The Π marking must be accompanied by the identification number of the notified body (type A inspection body) responsible for surveillance as specified in section 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 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 traznsportable pressure equipment;

   - a description of the solutions adopted to meet the requirements of the Directive;

   - results of design calculations made, examinations carried out, etc.;

   - test reports.

3. The manufacturer must operate an approved quality system for the final transportable pressure equipment inspection and testing as specified in section 4 and be subject to surveillance as specified in section 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 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. 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 organizational 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 personnel 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 authorized 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 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;
- special conditions linked to the approval of the system, where applicable;
- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may carry out or have carried out tests to verify if necessary 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 ten years after the last of the transportable pressure equipment has been manufactured, keep at the disposal of the national authorities:

- the technical 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, 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 also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module F (product verification)

1. This module describes the procedure whereby a manufacturer, or his authorized representative established within the Community, ensures and declares that the transportable pressure equipment subject to the provisions of section 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 authorized representative established within the Community, must affix the Π marking to all transportable pressure equipment and draw up a declaration of conformity.

3. The notified body (type A 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 in accordance with section 4.

The manufacturer, or his authorized representative established within the Community, must keep a copy of the declaration of conformity for a period of ten 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.

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 authorized 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 section 4.1 satisfies the requirements of the Directive which apply to it. The manufacturer must affix the Π marking to the transportable pressure equipment and draw up a declaration of conformity.

2. The manufacturer must apply to a notified body (type A inspection 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 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;

- results of design calculations made, examinations carried out, etc.;

- test reports.

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 ten years.

4.2. The manufacturer, or his authorized 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.

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 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 authorized representative established within the Community, must affix the Π marking to each item of transportable pressure equipment and draw up a written declaration of conformity. The Π marking must be accompanied by the identification number of the notified body (type A inspection body) responsible for the surveillance referred to in section 4.

2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in section 3 and be subject to surveillance as specified in section 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. This 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 organizational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality;

- the technical design specifications, including standards, that will be applied;

- the design control and design verification techniques, processes and systematic measures that will be used when designing the transportable pressure equipment;

- the 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 a 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 authorized 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 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;

- special conditions linked to the approval of the system, where applicable;

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may carry out or have carried out tests to verify if necessary 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 ten 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 subparagraph of 3.1;

   - the adjustments referred to in the second subparagraph of 3.4;

   - the decisions and reports from the notified body which are referred to in the last subparagraph of 3.3, the last subparagraph 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 (type A inspection 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.

ANNEX V

PART II

PROCEDURES FOR PERIODIC INSPECTION

Module 1 (periodic inspection of product)

1. This module describes the procedure whereby an owner ensures and declares that the transportable pressure equipment subject to the provisions of section 3 continues to meet the requirements of this Directive.

2. The owner must take all measures necessary to ensure that the conditions of use and of maintenance, in particular during filling, assure the continued conformity of the transportable pressure equipment with the requirements of this Directive. The owner, or his authorised representative established within the Community, must affix the date of his periodic inspection alongside the Π marking to all transportable pressure equipment and draw up a declaration of conformity.

3. The inspection body (type A, B or C) 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 verify their conformity with the requirements of those Directives.

3.2. The inspection body (type A, B or C) 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 certificate of conformity.

3.3. The owner must keep a copy of the declaration of conformity required under section 2, as well as the certificate of conformity required under section 3.2. until at least the next periodic inspection.

Module 2 (periodic inpection through quality assurance)

1. This module describes the procedure whereby the owner or his authorised representative who satisfies the obligations of section 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 must affix the date of periodic inspection alongside the II marking to all transportable pressure equipment and draw up a declaration of conformity. The date of periodic inspection must be accompanied by the identification number of the notified body (type A inspection body) responsible for surveillance as specified in point 4.

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

3. Quality system

3.1. The owner or his authorised representative 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 particilar 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 personnel concerned.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in section 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 owner or his authorised representative. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4 The owner or his authorised representative 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 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 section 3.2 or whether a reassessment is required.

It must notify its decision to the owner or his authorised representative. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsiblity of the notified body

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

4.2 The owner or his authorised representative 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 maintains and applies the quality system and provide the owner or his authorised representative with an audit report.

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

5. The owner must, for a period of ten 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 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 3.4, and in 4.3 and 4.4.

ANNEX VI

MODULES TO BE FOLLOWED FOR CONFORMITY ASSESSMENT

The following table indicates which modules of conformity assessment in accordance with Annex V, part I shall be followed for transportable pressure equipment provided for under Article 2.

Type of transportable pressure equipment	*Modules*
Receptacles of Class 2 (not more than 100 MPa.litre)	A1, or B in combination with C1
Receptacles of Class 2 (100 - 300 MPa.litre)	H, or B in combination with E, or B in combination with C1
Receptacles of Class 2 (more than 300 MPa.litre), including demountable tanks, tank containers portable tanks), tanks of tank wagons, tanks of battery vehicles, tanks of tank vehicles	G, or H1, or B in combination with D, or B in combination with F

ANNEX VII

MARK OF CONFORMITY

The conformity mark shall take the following form :

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

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

This minimum dimension may be waived for small-scale devices.

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