SCHEDULE 1

Regulation 3(1)

DISAPPLICATIONS TO THESE REGULATIONS

1. These Regulations shall not apply to—

(a) gas cylinders used as a component part of breathing appliances;

(b) UN 2857 REFRIGERATING MACHINES containing non-flammable, non-toxic, liquefied gas or ammonia solutions (UN 2672) or UN 3358 REFRIGERATING MACHINES containing flammable, non-toxic, liquefied gas, provided those machines—

(i) contain less than 12 kg of gas, and

(ii) are protected and stowed so as to prevent damage to the refrigeration system;

(c) UN 1044 FIRE EXTINGUISHERS with compressed or liquefied gas, provided—

(i) those extinguishers are packaged in strong outer packagings, and

(ii) have protection against inadvertent discharge; or

(d) UN 3164 ARTICLES, PRESSURIZED, PNEUMATIC OR HYDRAULIC (containing non-flammable gas), designed and manufactured to withstand stresses greater than the internal gas pressure by virtue of transmission of force, intrinsic strength or construction provided those articles—

(i) are packaged in strong outer packagings, and

(ii) in the case of articles intended to function as shock absorbers, comply with Special Provision 283 of Appendix 1 to the Approved Carriage List.

2. These Regulations shall not apply to any transportable pressure vessel which is used exclusively for the transport of a gas, UN 1051 STABILISED HYDROGEN CYANIDE, UN 1052 ANHYDROUS HYDROGEN FLUORIDE or UN 1790 HYDROFLUORIC ACID, solution, with more than 85% hydrofluoric acid, between the European Community and third-countries provided that—

(a) the goods are being carried in connection with the transport of those goods by sea and the goods are classified, packaged and labelled in accordance with the appropriate provisions of the International Maritime Dangerous Goods Code issued by the International Maritime Organization(**1**), as revised or re-issued from time to time;

(b) the goods are being carried in connection with the transport of those goods by air and the goods are classified, packaged and labelled in accordance with the appropriate provisions of the Technical Instructions for the Safe Transport of Dangerous Goods by Air issued by the International Civil Aviation Organization(**2**), as revised or re-issued from time to time;

(c) the transport forms part of an international transport operation within the meaning of article 1(c) of ADR and conforms with the provisions of that agreement; or

(d) the transport forms part of an international transport operation within the meaning of COTIF and conforms with the provisions of RID.

3. These Regulations shall not apply to transportable pressure vessels—

(a) where the maximum quantity per vessel (or, in the case of a gas, the maximum vessel volume) does not exceed that stated in column 3 of Schedule 3 to the CDGCPL Regulations for the appropriate classification of the goods it contains and provided that the total gross mass of any package containing such vessels does not exceed 30 kg;

(**1**) Current edition: Volumes I to IV ISBN 92 801 5090 1; Supplement ISBN 92 801 5093 6.
(**2**) Current edition and supplement (2001-2002): Doc 9284-AN/905.

(b) containing non-flammable, non-toxic gases the pressure of which in the vessel, referred to a temperature of 15°C, does not exceed 200 kPa (2 bar) and which are completely in the gaseous state during transport;

(c) containing gases of UN 1013 CARBON DIOXIDE or UN 1070 NITROUS OXIDE, in the gaseous state containing not more than 0.5% air, in metal capsules with not more than 25g of the gas and not more than 0.75g/cm3 of capacity of both gases;

(d) containing goods which are intended for use solely in connection with the operation of the vehicle in which those goods are being carried;

(e) containing—

(i) UN 1913 NEON, REFRIGERATED LIQUID,

(ii) UN 1951 ARGON, REFRIGERATED LIQUID,

(iii) UN 1963 HELIUM, REFRIGERATED LIQUID,

(iv) UN 1970 KRYPTON, REFRIGERATED LIQUID,

(v) UN 1977 NITROGEN, REFRIGERATED LIQUID,

(vi) UN 2187 CARBON DIOXIDE, REFRIGERATED LIQUID,

(vii) UN 2591 XENON, REFRIGERATED LIQUID,

(viii) UN 3136 TRIFLUOROMETHANE, REFRIGERATED LIQUID, or

(ix) UN 3158 GAS, REFRIGERATED LIQUID N.O.S.,

used for the cooling of medical or biological specimens provided they are contained in double-walled, vacuum-jacketed glass vessels surrounded by an absorbent insulating material, protected by iron wire baskets and placed in metal cases;

(f) transporting gases which are contained in foodstuffs or beverages;

(g) which are being carried by a vehicle not being used for, or in connection with, work;

(h) which are not named individually in the Approved Carriage List and which contain goods in their internal or operational equipment;

(i) which are being transported in an emergency with the intention of saving human life or protecting the environment, provided that all measures are taken to ensure that such transport is carried out safely;

(j) where those vessels or the vehicle transporting them have been damaged as a result of an accident, or where that vehicle has broken down, and the vessels are taken to a safe place for repair, cleaning or purging;

(k) transported in a vehicle which is being used to transfer those vessels—

(i) between private premises and another vehicle situated in the immediate vicinity of those premises, or

(ii) between one part of private premises and another part of those premises situated in the immediate vicinity of that first part where both parts are occupied by the same person, notwithstanding that those parts may be separated by a road;

(l) transported in a road construction vehicle engaged in the repair or construction of a road; and in this sub-paragraph—

(i) "road construction vehicle" means a vehicle constructed or adapted for the transport of built-in road construction machinery and not constructed or adapted for the transport of any other load, except articles and materials used for the purposes of that machinery,

(ii) "built-in road construction machinery" means road construction machinery built in as part of a road construction vehicle or permanently attached to it, and

(iii) "road construction machinery" means a machine or contrivance suitable for the repair and construction of roads.

SCHEDULE 2

Regulations 4 to 6

STANDARDS

The standards referred to in regulations 4 to 6 are—

1. In respect of materials—

(a) EN ISO 11114-1:1997, entitled "Transportable gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 1: Metallic materials";

(b) EN ISO 11114-2:2000, entitled "Transportable gas cylinders—Compatibility of cylinder and valve materials with gas contents—Part 2: Non-metallic materials";

(c) EN 1797-1:1998, entitled "Cryogenic vessels—Gas/material compatibility—Part 1: Oxygen compatibility";

(d) EN 1252-1:1998, entitled "Cryogenic vessels—Materials—Part 1: Toughness requirements for temperatures below −80°C".

2. In respect of cylinders—

(a) Annex I, Parts 1 to 3 to Council Directive 84/525/EEC of 17 September 1984(**3**) on the approximation of the laws of the member States relating to seamless steel gas cylinders;

(b) Annex I, Parts 1 to 3 to Council Directive 84/526/EEC of 17 September 1984(**4**) on the approximation of the laws of the member States relating to welded unalloyed steel gas cylinders;

(c) Annex I, Parts 1 to 3 to Council Directive 84/527/EEC of 17 September 1984(**5**) on the approximation of the laws of the member States relating to seamless, unalloyed aluminium and aluminium alloy gas cylinders;

(d) EN 1442:1998, entitled "Transportable refillable welded steel cylinders for liquefied petroleum gas (LPG)—Design and construction";

(e) EN 1800:1998/AC:1999, entitled "Transportable gas cylinders—Acetylene cylinders—Basic requirements and definitions";

(f) EN 1964-1:1999, entitled "Transportable gas cylinders—Specifications for the design and construction of refillable transportable seamless steel gas cylinders of capacity from 0.5 litres up to 150 litres—Part 1: Cylinders made of seamless steel with a Rm value of less than 1100 MPa";

(g) EN 1975:1999 (except Annex G), entitled "Transportable gas cylinders—Specifications for the design and construction of refillable transportable seamless aluminium and aluminium alloy gas cylinders of capacity from 0.5 litres up to 150 litres";

(h) EN ISO 11120:1999, entitled "Gas cylinders—Refillable seamless steel tubes for compressed gas transport of water capacity between 150 litres and 3000 litres—Design, construction and testing";

(**3**) OJ No. L300, 19.11.1984, p.1.
(**4**) OJ No. L300, 19.11.1984, p.20.
(**5**) OJ No. L300, 19.11.1984, p.48.

(i) EN 1964-3:2000, entitled "Transportable gas cylinders—Specifications for the design and construction of refillable transportable seamless steel gas cylinders of capacity from 0.5 litres up to 150 litres—Part 3: Cylinders made of stainless steel";

(j) EN 12862:2000, entitled "Transportable gas cylinders—Specifications for the design and construction of refillable transportable welded aluminium alloy gas cylinders";

(k) EN 1251-1:2000, entitled "Cryogenic vessels—Transportable, vacuum insulated, of not more than 1000 litres volume—Part 1: Fundamental requirements";

(l) EN 1251-2:2000, entitled "Cryogenic vessels—Transportable, vacuum insulated, of not more than 1000 litres volume—Part 2: Design, fabrication, inspection and testing"; and

(m) EN 1251-3:2000, entitled "Cryogenic vessels—Transportable, vacuum insulated, of not more than 1000 litres volume—Part 3: Operational requirements".

3. In respect of closures—

(a) EN 849:1996 (except Annex A), entitled "Transportable gas cylinders—Cylinder valves: Specification and type testing".

4. In respect of markings—

(a) EN 1089-1:1996, entitled "Transportable gas cylinders—Gas cylinder identification (excluding LPG)—Part 1: Stampmarking".

SCHEDULE 3

Regulations 4 and 5

CONFORMITY ASSESSMENT PROCEDURES
(This Schedule substantially reproduces the provisions of Part 1 of Annex IV to the Transportable Pressure Equipment Directive)

Module A—internal production control

1. This module describes the procedure whereby the manufacturer, or his authorised representative established within the Community who carries out the obligations laid down in paragraph 2, ensures and declares that certain transportable pressure vessels satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to all such transportable pressure vessels and draw up a written declaration of conformity.

2. The manufacturer must draw up the technical documentation described in paragraph 3 and either the manufacturer or his authorised representative established within the Community must keep it at the disposal of the Executive for inspection purposes for a period of 10 years after the last of the transportable pressure vessels have been manufactured. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure vessels on the market.

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

— a general description of the transportable pressure vessels,

— 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 vessels,

— a description of the solutions adopted to meet the requirements of these Regulations,

— results of the design calculations, examinations carried out, etc.,

— test reports.

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

5. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured transportable pressure vessels to comply with the technical documentation referred to in paragraph 2 and with the relevant requirements of these Regulations.

Module A1—internal manufacturing checks with monitoring of the final assessment

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

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

During such visits, the notified body must:

— ensure that the manufacturer actually performs final assessment,

— take samples of the transportable pressure vessels at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of vessels to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the samples of vessels.

Should one or more of the transportable pressure vessels not conform, the notified body must take appropriate measures.

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

Module B—EC type-examination

1. This module describes the part of the procedure by which a notified body ascertains and attests that a representative example of the production envisaged meets the relevant requirements of these Regulations.

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

The 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 the transportable pressure vessels 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 vessels with the relevant requirements of these Regulations. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure vessels 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 vessels,

— a description of the solutions adopted to meet the essential requirements of these Regulations,

— test reports,

— results of the design calculations made, examinations carried out, etc.,

— 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 requirements of these Regulations and in particular:

— examine the technical documentation with respect to the design and the manufacturing procedures,

— assess the materials used where these are not in conformity with the relevant provisions of these Regulations and check the certificate issued by the materials manufacturer,

— approve the procedures for the permanent joining of transportable pressure vessel parts or check that they have been previously approved,

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

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

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

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

5. Where the type satisfies the relevant provisions of these Regulations, the notified body must issue an EC type-examination certificate to the applicant. The certificate, which should be valid for 10 years and be renewable, must contain the name and address of the manufacturer, the conclusions of the examination and the necessary data for identification of the approved type.

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

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

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

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

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

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

9. The manufacturer, or his authorised representative established within the Community, must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of 10 years after the last of the transportable pressure vessels have been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module B1—EC design examination

1. This module describes the part of the procedure whereby a notified body ascertains and attests that the design of a certain transportable pressure vessel meets the relevant provisions of these Regulations.

2. The manufacturer, or his authorised representative established within the Community, must lodge an application for EC design examination with a single notified body which must include:

— the name, and address of the manufacturer and, if the application is lodged by the authorised representative established within the Community, his name and address as well,

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

— the technical documentation described in paragraph 3,

and may cover several versions of the transportable pressure vessel 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 vessel with the relevant requirements of these Regulations. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure vessel and contain:

— a general description of the vessel in question,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the vessel,

— a description of the solutions adopted to meet the relevant requirements of these Regulations,

— the necessary supporting evidence for the adequacy of the design solution; this supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,

— results of the design calculations made, examinations carried out, etc.,

— information regarding qualifications or approvals.

4. The notified body must:

4.1 examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of these Regulations and in particular must:

— assess the materials used where these are not in conformity with the relevant provisions of these Regulations,

— approve the procedures for the permanent joining of transportable pressure vessel parts or check that they have been previously approved,

— verify that the staff undertaking the permanent joining of transportable pressure vessel 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 relevant requirements of these Regulations;

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

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

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

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

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

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

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

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

— the EC design-examination certificates and additions granted,

— the EC design-examination certificates and additions withdrawn.

9. The manufacturer, or his authorised representative established within the Community, must keep with the technical documentation referred to in paragraph 3, copies of EC design-examination certificates and their additions for a period of 10 years after the last of the transportable pressure vessels have been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module C1—conformity to type

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative established within the Community, ensures and declares that certain transportable pressure vessels are in conformity with the type as described in the EC type-examination certificate and satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to all such transportable pressure vessels 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 vessels to comply with the type as described in the EC type-examination certificate and with the relevant requirements of these Regulations.

3. The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity for a period of 10 years after the last of the transportable pressure vessels have been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the transportable pressure vessels on the market.

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

During such visits, the notified body must:

— ensure that the manufacturer actually performs the final assessment,

— take samples of transportable pressure vessels at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the samples.

Should one or more of the transportable pressure vessels not conform, the notified body must take appropriate measures.

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

Module D—production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the transportable pressure vessels concerned are in conformity with the type described in the EC type-examination certificate and satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to all such transportable pressure vessels and draw up a written declaration of conformity. The conformity marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 4.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in paragraph 3 and be subject to surveillance as specified in paragraph 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 and the application must include:

— all relevant information on the transportable pressure vessels 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 vessels with the type described in the EC type-examination certificate and with the relevant requirements of these Regulations.

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

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure vessels,

— 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 paragraph 3.2.

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

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

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

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 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 ensure 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 vessels,

— the results of previous surveillance visits,

— the need to follow up corrective action,

— where applicable, special conditions linked to the approval of the system,

— significant changes in manufacturing organisation, policy or techniques.

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

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure vessels have been manufactured, hold at the disposal of the Executive:

— the documentation referred to in the second indent of paragraph 3.1,

— the adjustments referred to in the second sub-paragraph of paragraph 3.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 3.3, in the last sub-paragraph of paragraph 3.4, and in paragraphs 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 paragraph 3 ensures and declares that the transportable pressure vessels concerned satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to all such transportable pressure vessels and draw up a written declaration of conformity. The conformity marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 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 vessels with the relevant requirements of these Regulations. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure vessels and contain:

— a general description of the vessels in question,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.

— descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the vessels,

— a description of the solutions adopted to meet the relevant requirements of these Regulations,

— results of the design calculations made, examinations carried out, etc.,

— test reports.

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

— the documentation concerning the quality system.

4.2 The quality system must ensure compliance of the transportable pressure vessels with relevant requirements of these Regulations.

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

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure vessels,

— 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 paragraph 4.2.

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

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

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

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 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 vessels,

— the results of previous surveillance visits,

— the need to follow up corrective action,

— where applicable, special conditions linked to the approval of the system,

— significant changes in manufacturing organisation, policy or techniques.

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

6. The manufacturer must, for a period of 10 years after the last of the transportable pressure vessels have been manufactured, hold at the disposal of the Executive:

— the documentation referred to in paragraph 2,

— the documentation referred to in the second indent of paragraph 4.1,

— the adjustments referred to in the second sub-paragraph of paragraph 4.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 4.3, in the last sub-paragraph of paragraph 4.4, and in paragraphs 5.3 and 5.4.

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

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

Module E—product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the transportable pressure vessel is in conformity with the type as described in the EC type-examination certificate and satisfies the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to each product and draw up a written declaration of conformity. The conformity marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 4.

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

— the documentation concerning the quality system,

— the technical documentation for the approval type and a copy of the EC type-examination certificate.

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

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure vessels,

— 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 paragraph 3.2.

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

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

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

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 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 ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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

— the quality system documentation,

— the technical documentation,

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

4.3 The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

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

— the category of the vessel,

— the results of previous surveillance visits,

— the need to follow up corrective action,

— where applicable, special conditions linked to the approval of the system,

— significant changes in manufacturing organisation, policy or techniques.

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

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure vessels have been manufactured, hold at the disposal of the Executive:

— the documentation referred to in the second indent of paragraph 3.1,

— the adjustments referred to in the second sub-paragraph of paragraph 3.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 3.3, in the last sub-paragraph of paragraph 3.4, and in paragraphs 4.3 and 4.4.

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

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

Module E1—production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 3 ensures and declares that the transportable pressure vessels satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to each transportable pressure vessel and draw up a written declaration of conformity. The conformity marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 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 vessels with the relevant requirements of these Regulations. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the transportable pressure vessels and contain:

— a general description of the vessels in question,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the vessels,

— a description of the solutions adopted to meet the requirements of these Regulations,

— results of the design calculations made, examinations carried out, etc.,

— test reports.

3. The manufacturer must operate an approved quality system for the final transportable pressure vessel inspection and testing as specified in paragraph 4 and be subject to surveillance as specified in paragraph 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 vessels concerned,

— the documentation concerning the quality system.

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

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure vessels,

— the procedures used for the joining of parts,

— the examinations and tests to be carried out after manufacture,

— the means of monitoring the effective operation of the quality system,

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the staff concerned.

4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 4.2.

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

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

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

The manufacturer, or his authorised representative established within the Community, must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 4.2 or whether a reassessment is required.

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

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

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

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

— the quality system documentation,

— the technical documentation,

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

5.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

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

— the category of the vessels,

— the results of previous surveillance visits,

— the need to follow up corrective action,

— where applicable, special conditions linked to the approval of the system,

— significant changes in manufacturing organisation, policy or techniques.

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

6. The manufacturer must, for a period of 10 years after the last of the transportable pressure vessels have been manufactured, hold at the disposal of the Executive:

— the documentation referred to in paragraph 2,

— the documentation referred to in the second indent of paragraph 4.1,

— the adjustments referred to in the second sub-paragraph of paragraph 4.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 4.3, in the last sub-paragraph of paragraph 4.4, and in paragraphs 5.3 and 5.4.

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

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

Module F—product verification

1. This module describes the procedure whereby a manufacturer, or his authorised representative established within the Community, ensures and declares that the transportable pressure vessels subject to the provisions of paragraph 3 are in conformity with the type described:

— in the EC type-examination certificate, or

— in the EC design-examination certificate,

and satisfy the relevant requirements of these Regulations.

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

— in the EC type-examination certificate, or

— in the EC design-examination certificate,

and with the relevant requirements of these Regulations.

The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to all transportable pressure vessels and draw up a declaration of conformity

3. The notified body must perform the appropriate examinations and tests in order to check the conformity of the transportable pressure vessels with the relevant requirements of these Regulations by examining and testing every product in accordance with paragraph 4.

The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity for a period of 10 years after the last of the transportable pressure vessels have been manufactured.

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

4.1. Each transportable pressure vessel must be individually examined and must undergo appropriate examinations and tests in order to verify that it conforms to the type and the relevant requirements of these Regulations.

In particular, the notified body must:

— verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved,

— check the certificate issued by the materials manufacturer,

— carry out the final inspection and proof test or have them carried out and, where appropriate, examine the safety devices.

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

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

Module G—EC unit verification

1. This module describes the procedure whereby the manufacturer ensures and declares that transportable pressure vessels which have been issued with the certificate referred to in paragraph 4.1 satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to the vessels and draw up a declaration of conformity.

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

— the name and address of the manufacturer and the location of the transportable pressure vessels,

— 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 vessels with the relevant requirements of these Regulations to be assessed and the design, manufacture and operation of the transportable pressure vessels to be understood.

The technical documentation must contain:

— a general description of the vessels in question,

— conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

— descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the vessels,

— results of design calculations made, examinations carried out, etc.,

— test reports,

— appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the staff concerned.

4. The notified body must examine the design and construction of each transportable pressure vessel and during manufacture perform appropriate tests to ensure its conformity with the relevant requirements of these Regulations.

4.1. The notified body must affix its identification number or have it affixed to each transportable pressure vessel and draw up a certificate of conformity for the tests carried out. This certificate must be kept for a period of 10 years.

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

In particular, the notified body must:

— examine the technical documentation with respect to the design and the manufacturing procedures,

— assess the materials used where these are not in conformity with the relevant provisions of these Regulations and check the certificate issued by the materials manufacturer,

— approve the procedures for the permanent joining of pressure vessel parts,

— verify the qualifications or approvals required,

— perform the final inspection, perform the proof test or have it performed and examine the safety devices if applicable.

Module H—full quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the transportable pressure vessels in question satisfy the relevant requirements of these Regulations. The manufacturer, or his authorised representative established within the Community, must affix the conformity marking to each transportable pressure vessel and draw up a written declaration of conformity. The conformity marking must be accompanied by the identification number of the notified body responsible for the surveillance referred to in paragraph 4.

2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in paragraph 3 and be subject to surveillance as specified in paragraph 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 vessels in question,

— the documentation concerning the quality system.

3.2. The quality system must ensure compliance of the transportable pressure vessel with the relevant requirements of these Regulations.

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

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality,

— the technical design specifications, including standards, that will be applied,

— the design control and design verification techniques, processes and systematic measures that will be used when designing the transportable pressure vessels,

— 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 vessel 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 paragraph 3.2.

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

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

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

The manufacturer, or his authorised representative established within the Community, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

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

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

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

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

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

— the quality system documentation,

— the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the staff concerned, etc.

4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

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

— the category of the vessel,

— the results of previous surveillance visits,

— the need to follow up corrective action,

— where applicable, special conditions linked to the approval of the system,

— significant changes in manufacturing organisation, policy or techniques.

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

5. The manufacturer must, for a period of 10 years after the last of the transportable pressure vessels have been manufactured, keep at the disposal of the Executive:

— the documentation referred to in the second indent of the second sub-paragraph of paragraph 3.1,

— the adjustments referred to in the second sub-paragraph of paragraph 3.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 3.3, in the last sub-paragraph of paragraph 3.4, and in paragraphs 4.3 and 4.4.

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

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

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

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

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

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

It must include:

— the technical design specifications, including standards, which have been applied,

— the necessary supporting evidence for their adequacy. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,

(c) the notified body must examine the application and where the design meets the relevant provisions of these Regulations 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 vessel,

(d) the applicant must inform the notified body that it 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 relevant requirements of these Regulations or the prescribed conditions for use of the transportable pressure vessel. 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 vessels.

SCHEDULE 4

Regulation 4

MODULES TO BE FOLLOWED FOR CONFORMITY ASSESSMENT

(This Schedule substantially reproduces the provisions of Annex V to the Transportable Pressure Equipment Directive)

The following table indicates which modules are to be followed when undertaking conformity assessment procedures.

Category of transportable pressure vessel	Modules
Vessels for which the product of the test pressure and the capacity is no more than 30 Mpa × litre (300 bar ×litre)	A1, D1, or E1
Vessels for which the product of the test pressure and the capacity is more than 30 and no more than 150 Mpa × litre (300 and 1500 bar × litre respectively)	H, B in combination with E, B in combination with C1, B1 in combination with F, or B1 in combination with D
Vessels for which the product of the test pressure and the capacity exceeds 150 Mpa × litre (1500 bar × litre)	G, H1, B in combination with D, or B in combination with F

1. Transportable pressure vessels must be subject, at the choice of the manufacturer, to one of the conformity assessment procedures laid down for the category in which it is classified. The manufacturer may also choose to apply one of the set procedures for the higher categories.
2. As part of the quality assurance procedures, the notified body must, when making unannounced visits, take a sample of the vessels at the manufacturing or storage premises for the purpose of carrying out a check, or having a check carried out, in conformity with the requirements of these Regulations. For this purpose the manufacturer must inform the notified body of the production programme planned. The notified body must make at least two visits during the first year of manufacture. The frequency of subsequent visits will be determined by the notified body on the basis of the criteria set out in paragraph 4.4 of the relevant modules in Schedule 3.

SCHEDULE 5

Regulation 6

CONFORMITY REASSESSMENT PROCEDURE

(This Schedule substantially reproduces the provisions of Part II of Annex IV to the Transportable Pressure Equipment Directive)

1. This procedure describes the method for ensuring that transportable pressure vessels placed on the market for reassessment of conformity comply with the relevant requirements of these Regulations.

2. The owner must make available to a notified body information regarding transportable pressure vessels placed on the market which enables that body to identify the vessel's precise origin, design rules and, for acetylene cylinders, also details of the porous mass. The owner must, where appropriate, notify any prescribed restrictions on use, and forward any notes on possible damage or repairs which have been carried out.

The notified body must also check that valves and other accessories having a direct safety function ensure a level of safety in accordance with the requirements of regulation 6(3) and (4).

3. The notified body must check whether transportable pressure vessels which have been placed on the market conform to the standards referred to in regulation 6. The check must be carried out on the basis of documents produced in accordance with paragraph 2 and, where appropriate, of further inspections.

4. If the results of the above checks are satisfactory, the transportable pressure vessels must be subject to the procedures for periodic inspection provided for in Schedule 6.

5. For vessels manufactured in series, including their valves and other accessories used for transport, the relevant conformity reassessment operations relating to individual inspections of vessels, as indicated in paragraphs 3 and 4, may be carried out by an approved body provided that a notified body has previously carried out the relevant conformity reassessment operations indicated in paragraph 3.

SCHEDULE 6

Regulation 7

PERIODIC INSPECTION PROCEDURES

(This Schedule substantially reproduces the provisions of Part III of Annex IV to the Transportable Pressure Equipment Directive)

Module 1—periodic inspection of products

1. This module describes the procedure whereby the owner or his authorised representative established within the Community ensures that transportable pressure vessels subject to paragraph 3 continue to meet the relevant requirements of these Regulations.

2. To meet the requirements referred to in paragraph 1, the owner or his authorised representative established in the Community must take all measures necessary to ensure that the conditions of use and of maintenance ensure the continued conformity of the transportable pressure vessels to the relevant requirements of these Regulations, in particular so that:

— the transportable pressure vessels are used as intended,

— the transportable pressure vessels are filled in appropriate filling centres,

— any maintenance work or repairs are carried out,

— the periodic inspections necessary are carried out.

The measures carried out must be recorded in documents and held at the disposal of the Executive by the owner or his authorised representative established in the Community.

3. The notified or approved body must perform the appropriate examinations and tests in order to check the conformity of the transportable pressure vessels with the relevant requirements of these Regulations by examining and testing every product.

3.1. All transportable pressure vessels must be examined individually and appropriate tests, as set out in Chapter 6.2 of ADR, must be carried out in order to check that it meets the requirements of these Regulations.

3.2. The notified or approved body must affix, or have affixed, its identification number to each vessel periodically inspected immediately after the periodic inspection has taken place and draw up a written periodic-inspection certificate. That certificate may cover a number of vessels.

3.3. The owner or his authorised representative established in the Community must keep the periodic-inspection certificate required under paragraph 3.2 and the documents required under paragraph 2 at least until the next periodic inspection.

Module 2—periodic inspection through quality assurance

1. This module describes the procedure whereby the owner or his authorised representative established in the Community, who satisfies the obligations of paragraph 2, ensures and declares that the transportable pressure vessels continue to meet the relevant requirements of these Regulations. The owner or his authorised representative established in the Community must affix the date of periodic inspection to all such transportable pressure vessels and draw up a written declaration of conformity. The date of periodic inspection must be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 4.

2. The owner or his authorised representative established in the Community must take all steps necessary to ensure that the conditions of use and of maintenance are such as to enable the transportable pressure vessels to comply permanently with the requirements of these Regulations and in particular that:

— the transportable pressure vessels are used as intended,

— the transportable pressure vessels are filled in appropriate filling centres,

— any maintenance work or repairs are carried out,

— the periodic inspections necessary are carried out.

The measures carried out must be recorded in documents and held by the owner or his authorised representative established in the Community at the disposal of the Executive.

The owner or his authorised representative established within the Community must ensure that the qualified staff and necessary facilities are available for the purpose of the periodic inspections.

The owner or his authorised representative established in the Community must operate an approved quality system for the periodic inspection and tests of the vessels as specified in paragraph 3, and be subject to surveillance as specified in paragraph 4.

3. *Quality system*

3.1. The owner or his authorised representative established in the Community must lodge an application for assessment of his quality system for the transportable pressure vessels with a notified body of his choice.

The application must include:

— all relevant information on the transportable pressure vessels being submitted for periodic inspection,

— the documentation regarding the quality system.

3.2. Under the quality system, each transportable pressure vessel must be examined and appropriate tests must be carried out in order to ensure its conformity with the relevant requirements of these Regulations. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the transportable pressure vessels,

— the examinations and tests to be carried out for the periodic inspection,

— the means of monitoring the effective operation of the quality system,

— the quality records such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the staff concerned.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2.

The auditing team must have at least one member with experience of assessing the transportable pressure vessels concerned. The assessment procedure must include an inspection visit to the premises of the owner or his authorised representative established in the Community.

The decision must be notified to the owner or his authorised representative established in the Community. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The owner or his authorised representative established in the Community must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The owner or his authorised representative established in the Community 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 paragraph 3.2 or whether a reassessment is required.

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

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

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

4.2. The owner or his authorised representative established in the Community must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation,

— the quality records, such as inspection reports and test data, reports concerning the qualifications of the personnel concerned, etc.

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

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

5. The owner or his authorised representative established in the Community must, for a period of 10 years from the date of the last periodic inspection of the transportable pressure vessels, hold at the disposal of the Executive:

— the documentation referred to in the second indent of the second sub-paragraph of paragraph 3.1,

— the adjustments referred to in the second sub-paragraph of paragraph 3.4,

— the decisions and reports from the notified body which are referred to in the last sub-paragraph of paragraph 3.3, in the last sub-paragraph of paragraph 3.4 and in paragraphs 4.3 and 4.4.

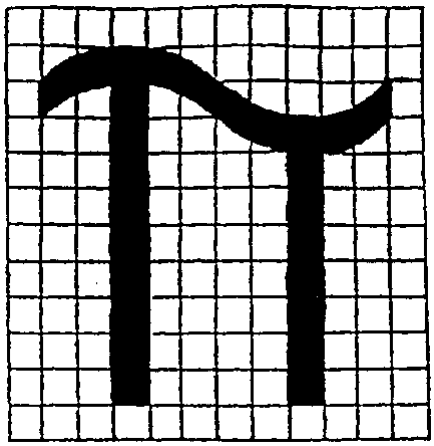
SCHEDULE 7

Regulations 2(1) and 11

CONFORMITY MARKING

(This Schedule substantially reproduces the provisions of Annex VII to the Transportable Pressure Equipment Directive)

The conformity marking shall take the following form—



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

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

This minimum dimension may be waived for small vessels.

SCHEDULE 8

Regulation 14(5)

AMENDMENTS TO THE CDGCPL REGULATIONS

1. The CDGCPL Regulations shall be amended in accordance with the following paragraphs of this Schedule.

2. In regulation 1, for the words "1st July 2001" there shall be substituted "1st July 2003".

3. In regulation 2(1)—

(a) for the definition of "competent person" there shall be substituted the following definition—

> ""competent person" means a competent individual (other than an employee) or a competent body of persons corporate or unincorporate, and any reference to a competent person performing a function includes a reference to his performing it through his employees;"; and

(b) the definitions of "approved person", "EEC-type cylinder", "Pressure Vessels Framework Directive" and "separate Directives" shall be deleted.

4. For paragraphs (4) and (5) of regulation 3, there shall be substituted the following paragraphs—

"(4) Subject to paragraphs (5) and (5A) and to the exceptions contained in Schedule 9, Schedules 4 and 8 shall apply to transportable pressure receptacles manufactured before 1 July 2003 which are used or intended to be used, or carried or intended to be carried, at work.

(5) Schedules 4 and 8 shall not apply—

(a) to any receptacle where the exceptions contained in paragraph (1)(a) to (g) apply;

(b) to any receptacle known as a two-part beer keg, one part of which is intended to contain a gas or a mixture of gases under pressure;

(c) to any receptacle used for the conveyance or storage of beer or carbonated drinks, the capacity of which does not exceed 0.252 cubic metres and the maximum working pressure of which is not greater than 12 bar above atmospheric pressure; or

(d) to any portable fire extinguisher with a working pressure below 25 bar at 60oC and having a total mass not exceeding 23 kilograms.

(5A) Schedule 4 and paragraphs 1(1) and (2), 2, 3, 4(1)(a)(i) and 8(1) of Schedule 8 shall not apply to any pressure equipment to which the Pressure Equipment Regulations 1999(**6**) apply or to any transportable pressure vessel to which the Transportable Pressure Vessels Regulations 2001 apply.".

5. Regulations 12 to 17 shall be deleted.

6. In regulation 19, for paragraph (5) there shall be substituted the following paragraph—

"(5) For the purposes of paragraph (4) the specified provisions are paragraphs 2(2), 3(1) and (3), 4 and 8(2) of Schedule 8.".

7. Paragraph (10) of regulation 21 shall be deleted.

8. In Schedule 4—

(a) in paragraph 1, for the words "an approved person" there shall be substituted "a person in accordance with paragraph 2(4)(a) of Schedule 8"; and

(b) in paragraph 6, for the words "under regulation 15(3)" there shall be substituted "in accordance with paragraph 2(7) of Schedule 8".

9. Schedule 7 shall be deleted.

10. For Schedule 8 there shall be substituted the following Schedule—

"SCHEDULE 8 Regulation 3(4)

REQUIREMENTS FOR TRANSPORTABLE PRESSURE RECEPTACLES MANUFACTURED BEFORE 1ST JULY 2003

1.—(1) Any person who designs, manufactures, imports or supplies any transportable pressure receptacle or any article which is intended to be a component part thereof shall ensure that sub-paragraph (2) is complied with.

(2) The transportable pressure receptacle, or article, as the case may be, shall be—

(a) properly designed and properly constructed from suitable material, so as to prevent danger;

(b) so designed and constructed that all necessary examinations for preventing danger can be carried out; and

(**6**) S.I. 1999/2001.

(c) provided with such protective devices as may be necessary for preventing danger and any such device which is designed to release contents shall do so safely, so far as is practicable.

(3) The employer of a person who modifies or repairs a transportable pressure receptacle at work shall ensure that nothing about the way in which it is modified or repaired gives rise to danger or otherwise impairs the operation of any protective device or inspection facility.

2.—(1) No person shall supply or import a transportable pressure receptacle unless the condition specified in sub-paragraph (3) has been met.

(2) Before a person fills a transportable pressure receptacle he shall ensure, so far as is reasonably practicable, that the condition specified in sub-paragraph (3) has been met.

(3) The condition referred to in sub-paragraphs (1) and (2) is that the receptacle has been verified in accordance with sub-paragraph (4) (either by a certificate in writing or by means of stamping on the receptacle) as conforming to a design standard or design specification approved by the Executive.

(4) For the purposes of sub-paragraph (3) a receptacle shall be verified—

(a) by a person approved by the Executive under this sub-paragraph (and for this purpose, any approval given under regulation 16(2)(a)(i) of the Pressure Systems and Transportable Gas Containers Regulations 1989, as in force immediately before the coming into force of these Regulations, shall be deemed, subject to sub-paragraph (5), to be an approval under this sub-paragraph but shall remain subject to any conditions attached to it, and to the expiry date specified therein); or

(b) in accordance with a quality assurance scheme approved by the Executive.

(5) An approval under the Regulations referred to in sub-paragraph (4) which has not expired on 30th June 2003 shall cease to have effect on that date.

(6) An approval under sub-paragraph (4)(a) shall be by a certificate in writing, may be made subject to conditions and may be revoked by a certificate in writing at any time.

(7) Following an approval under sub-paragraph (4)(a), the Executive shall carry out, upon reasonable notice, a surveillance inspection of the person approved at such intervals as the Executive considers appropriate and for that purpose the person approved shall, at his own cost, afford any facilities and assistance and make available any information which may reasonably be required by the Executive.

(8) No person approved by the Executive shall be charged for more than one surveillance inspection in any 12 month period.

(9) In this paragraph, a "surveillance inspection" means an inspection of such premises, equipment and documents and the making of such enquiries as the Executive considers appropriate for the purpose of verifying compliance by a person approved with any condition specified in the certificate of approval by the Executive.

3.—(1) The owner of a transportable pressure receptacle shall ensure, for the purpose of determining whether it is safe, that the receptacle is examined at appropriate intervals by a competent person.

(2) Where a competent person undertakes an examination for the purposes of this paragraph, he shall carry out that examination properly, and if, on completing that examination, he is satisfied that the receptacle is safe, he shall ensure that there is affixed to the receptacle a mark showing the date of the examination.

(3) No person, other than a competent person or a person authorised by any such person, shall affix to a transportable pressure receptacle the mark referred to in sub-paragraph (3) or a mark liable to be confused with it.

4.—(1) The employer of a person who is to fill with a gas a transportable pressure receptacle at work, shall ensure that before the receptacle is filled that person—

(a) checks from the marks on the receptacle—

(i) that it appears to have been examined at appropriate intervals by a competent person, and

(ii) that it is suitable for containing that gas; and

(b) makes all other appropriate safety checks.

(2) The employer of a person who fills a transportable pressure receptacle at work shall ensure that that person—

(a) checks that, after filling, the receptacle is within its safe operating limits;

(b) checks that the receptacle is not overfilled; and

(c) in the event of overfilling, removes any excess gas in a safe manner.

(3) Every employer shall ensure that no person employed by him refills at work a non-refillable receptacle with a gas.

5.—(1) Subject to sub-paragraph (2)—

(a) every employer shall ensure that no person employed by him modifies at work the body of a transportable pressure receptacle—

(i) of seamless construction, or

(ii) which has contained acetylene;

(b) every employer shall ensure that no person employed by him modifies at work the body of any other type of transportable pressure receptacle if that modification would put the receptacle outside the scope of the design standard or design specification to which it was originally constructed; and

(c) no person shall supply any modified transportable pressure receptacle for use unless following such modification a person approved under paragraph 2(4)(a) has marked or certified the receptacle as being fit for use.

(2) Sub-paragraph (1) shall not apply in relation to any modification constituting the remaking of a thread if such modification is carried out in accordance with a standard approved by the Executive.

6.—(1) Every employer shall ensure that no person employed by him carries out at work any major repair on the body of a transportable pressure receptacle—

(a) of seamless construction; or

(b) which has contained acetylene.

(2) Every employer shall ensure that no person employed by him carries out at work any major repair on the body of any other type of transportable pressure receptacle unless he is competent to do so.

(3) No person shall supply a transportable pressure receptacle which has undergone a major repair unless following such work a person approved under paragraph 2(4)(a) has marked or certified it as being fit for use.

(4) In this paragraph "major repair" means any repair involving hot work or welding on the body of a transportable pressure receptacle but (except in relation to sub-paragraph (1)(b)) it does not mean any repair involving heat treatment applied for the purpose of restoring the metallurgical properties of the receptacle.

7.—(1) Every employer shall ensure that no person employed by him re-rates a transportable pressure receptacle at work unless he is competent to do so and does so in accordance with suitable written procedures drawn up by the owner of the receptacle.

(2) No person shall supply a transportable pressure receptacle which has been re-rated unless, following the re-rating, a person approved under paragraph 2(4)(a) has certified it as being safe for use.

(3) In this paragraph—

(a) "re-rating" means reassessing the capability of a transportable pressure receptacle to contain compressed gas safely with a view to improving its capacity by means of an increase in the charging pressure (or, in the case of liquefied gas, the filling ratio) from that originally assessed and marked on the receptacle at the time of manufacture, and "re-rates" and "re-rated" shall be interpreted accordingly; and

(b) "filling ratio" means the ratio of the volume of the liquid gas in the receptacle to the total volume of the receptacle.

8.—(1) The manufacturer or, if he does not have a place of business in Great Britain, his agent in Great Britain or, if he has no such agent, the importer of a transportable pressure receptacle—

(a) which is made to an approved design specification, shall keep a copy of the design specification to which the said receptacle was manufactured together with any certificate of conformity issued under paragraph 2(3);

(b) which is made to an approved design standard, shall keep a copy of any certificate of conformity issued under paragraph 2(3);

(c) which—

(i) is a refillable receptacle,

(ii) is used solely for containing liquefied petroleum gas, and

(iii) has a water capacity up to and including 6.5 litres,

shall keep a copy of the design specification to which the said receptacle was manufactured.

(2) The owner of a transportable pressure receptacle for acetylene shall keep records of the tare weight of the receptacle, including the porous substance and acetone or other solvent, the nature of the solvent and the maximum pressure allowed in the receptacle.".

11. In Schedule 9—

(a) in paragraph 2, for the words "paragraph 5(4)" there shall be substituted "paragraph 4(3)"; and

(b) in paragraph 3, for the words "Paragraphs 3, 4, 5(1)(a), 2(a) and 10(1) of Schedule 8" there shall be substituted "Paragraphs 2, 3 and 4(1)(a) of Schedule 8".