SCHEDULE 4

Regulation 13

(Annex III to the Pressure Equipment Directive)
CONFORMITY ASSESSMENT PROCEDURES

Commencement Information
I1 Sch. 4 in force at 29.11.1999, see **reg. 1(3)**

The obligations arising from the provisions on pressure equipment in this Annex also apply to assemblies.

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 section 2 ensures and declares that pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.

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

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

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

— a general description of the pressure equipment,

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

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

— a list of the standards referred to in Article 5, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,

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

— test reports.

2. 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 pressure equipment to comply with the technical documen tation referred to in section 2 and with the requirements of the Directive which apply to it.

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

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:

- establish that the manufacturer actually performs final assessment in accordance with section 3.2 of Annex I,
- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

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

On the responsibility of the notified body, the manufacturer must affix the former's identification number on each item of pressure equipment.

Module B (EC type-examination)

1. This module describes the part of the procedure by which a notified body ascertains and attests that a representative example of the production in question meets the provisions of the Directive which apply to it.

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

The application must include:

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

The applicant must place at the disposal of the notified body a representative example of the production envisaged, hereinafter called `type'. The notified body may request further examples should the test programme so require.

A type may cover several versions of pressure equipment provided that the differences between the versions do not affect the level of safety.

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

- a general description of the type,
- conceptual design and manufacturing drawings and diagrams of components, sub-assem blies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,

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

— test reports,

— information concerning the tests provided for in manufacture,

— information concerning the qualifications or approvals required under sections 3.1.2 and 3.1.3 of Annex I.

4. The notified body must:

(4.1) examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as those designed without applying the provisions of those standards.

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 harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section 4.3 of Annex I,

— approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with section 3.1.2 of Annex I,

— verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 or 3.1.3 of Annex I.

(4.2) perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied.

(4.3) perform or have performed the appropriate examinations and necessary tests to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

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

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

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

If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his 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 pressure equipment; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.

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

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

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

9. The manufacturer, or his 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 ten years after the last of the pressure equipment has been manufactured.

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

Module B1 (EC design-examination)

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

The experimental design method provided for in section 2.2.4 of Annex I may not be used in the context of this module.

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

The application must include:

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

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

— the technical documentation described in section 3.

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

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

— a general description of the pressure equipment,

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

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

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,

— the necessary supporting evidence for the adequacy of the design solution, in particular where the standards referred to in Article 5 have not been applied in full; this supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,

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

— information regarding the qualifications or approvals required under sections 3.1.2 and 3.1.3 of Annex 1.

4. The notified body must:

(4.1) examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as those which have been designed without applying the relevant provisions of those standards.

In particular, the notified body must:

— assess the materials where these are not in conformity with the relevant harmonised standards or with a European approval for pressure equipment materials,

— approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with section 3.1.2 of Annex I,

— verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 and 3.1.3 of Annex I.

(4.2) perform the necessary examinations to establish whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied.

(4.3) perform the necessary examinations to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

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

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

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

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

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

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

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

— the EC design-examination certificates and additions granted,

— the EC design-examination certificates and additions withdrawn.

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

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

Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative established within the Community, ensures and declares that pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured pressure equipment to comply with the type as described in the EC type-examination certificate and with the requirements of the Directive which apply to it.

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

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

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

During such visits, the notified body must:

— establish that the manufacturer actually performs final assessment in accordance with section 3.2 of Annex I,

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

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

On the responsibility of the notified body, the manufacturer must affix the former’s identification number on each item of pressure equipment.

Module D (production quality assurance)

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

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

3. Quality system

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

The application must include:

— all relevant information on the pressure equipment concerned,

— the documentation concerning the quality system,

— the technical documentation for the approved type and a copy of the EC type-examination certificate or EC design-examination certificate.

(3.2) The quality system must ensure compliance of the pressure equipment with the type described in the EC type-examination certificate or EC design-examination certificate and with the requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. 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 pressure equipment,

— the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I,

— 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, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with sections 3.1.2. and 3.1.3 of Annex I,

— the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(3.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 3.2.

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

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

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

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

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

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

4. Surveillance under the responsibility of the notified body

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

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

— the quality system documentation,

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

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

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

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action,

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

— significant changes in manufacturing organisation, policy or techniques.

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

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

— the documentation referred to in the second indent of 3.1;

— the adjustments referred to in the second paragraph of 3.4;

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

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

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

Module D1 (production quality assurance)

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

2. The manufacturer must draw up the technical documentation described below.

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

— a general description of the pressure equipment,

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

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

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,

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

— test reports.

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

4. Quality system

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

The application must include:

— all relevant information on the pressure equipment concerned,

— the documentation concerning the quality system.

(4.2) The quality system must ensure compliance of the pressure equipment with the requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the 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 pressure equipment,

— the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I,

— 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, particularly those of the personnel undertaking the permanent joining of parts in accordance with section 3.1.2 of Annex I,

— the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(4.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 4.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 4.2.

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

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

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

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

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

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

5. Surveillance under the responsibility of the notified body

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

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

— the quality system documentation,

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

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

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

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action,

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

— significant changes in manufacturing organisation, policy or techniques.

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

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

— the technical documentation referred to in section 2,

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

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

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

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

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

Module E (product quality assurance)

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

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

3. Quality system

(3.1) The manufacturer must lodge an application for assessment of his quality system for the pressure equipment with a notified body of his choice.

The application must include:

— all relevant information on the pressure equipment concerned,

— the documentation concerning the quality system,

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

(3.2) Under the quality system, each item of pressure equipment must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, particularly final assessment as referred to in section 3.2 of Annex I, must be carried out in order to ensure its conformity with the requirements of the Directive which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

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

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

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

— the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with sections 3.1.2 and 3.1.3 of Annex I.

(3.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 3.2.

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

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

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

The manufacturer, or his 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 3.2 or whether a reassessment is required.

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

4. Surveillance under the responsibility of the notified body

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

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

— the quality system documentation,

— the technical documentation,

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

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

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

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action,

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

— significant changes in manufacturing organisation, policy or techniques.

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

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

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

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

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

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

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

Module E1 (product quality assurance)

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

2. The manufacturer must draw up the technical documentation described below.

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

— a general description of the pressure equipment,

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

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

— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,

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

— test reports.

3. The manufacturer must operate an approved quality system for the final pressure equipment inspection and testing as specified in section 4 and be subject to surveillance as specified in section 5.

4. Quality system

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

The application must include:

— all relevant information on the pressure equipment concerned,

— the documentation concerning the quality system.

(4.2) Under the quality system, each item of pressure equipment must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, and particularly final assessment as referred to in section 3.2 of Annex I, must be carried out in order to ensure its conformity with the requirements of the Directive which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,
- the procedures used for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I,
- 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, particularly those of the personnel undertaking the permanent joining of parts in accordance with section 3.1.2 of Annex I.

(4.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 4.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 4.2.

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

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

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

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

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

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

5. Surveillance under the responsibility of the notified body

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

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

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

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

(5.4) In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control

system operated by the notified body. In particular, the following factors must be considered in the visit control system:

— the category of the equipment,

— the results of previous surveillance visits,

— the need to follow up corrective action,

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

— significant changes in manufacturing organisation, policy or techniques.

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

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

— the technical documentation referred to in section 2,

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

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

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

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

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

Module 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 pressure equipment subject to the provisions of section 3 is in conformity with the type described:

— in the EC type-examination certificate, or

— in the EC design-examination certificate

and satisfies the requirements of the Directive which apply to it.

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

— in the EC type-examination certificate, or

— in the EC design-examination certificate

and with the requirements of the Directive which apply to it.

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

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

The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity for a period of ten years after the last of the pressure equipment has been manufactured.

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

(4.1) Each item of pressure equipment must be individually examined and must undergo appropriate examinations and tests as set out in the relevant standard(s) referred to in Article 5 or equivalent examinations and tests in order to verify that it conforms to the type and the requirements of the Directive which apply to it.

In particular, the notified body must:

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 and 3.1.3 of Annex I,
- verify the certificate issued by the materials manufacturer in accordance with section 4.3 of Annex I,
- carry out or have carried out the final inspection and proof test referred to in section 3.2 of Annex I and examine the safety devices, if applicable.

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

(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 pressure equipment which has been issued with the certificate referred to in section 4.1 satisfies the requirements of the Directive which apply to it. The manufacturer must affix the CE marking to the pressure equipment and draw up a declaration of conformity.

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

The application must contain:

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

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

The technical documentation must contain:

- a general description of the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assem blies, circuits, etc.,
- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
- 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 personnel concerned in accordance with sections 3.1.2 and 3.1.3 of Annex I.

4. The notified body must examine the design and construction of each item of pressure equipment and during manufacture perform appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive, or equivalent examinations and tests, to ensure its conformity with the requirements of the Directive which apply to it.

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 harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section 4.3 of Annex I,

— approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with section 3.1.2 of Annex I,

— verify the qualifications or approvals required under sections 3.1.2 and 3.1.3 of Annex I,

— carry out the final inspection referred to in section 3.2.1 of Annex I, perform or have performed the proof test referred to in section 3.2.2 of Annex I, and examine the safety devices, if applicable.

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

(4.2) The manufacturer, or his 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.

Module H (full quality assurance)

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

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

3. Quality system

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

The application must include:

— all relevant information concerning the pressure equipment in question,

— the documentation concerning the quality system.

(3.2) The quality system must ensure compliance of the pressure equipment with the requirements of the Directive which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and

instructions. This quality system documentation must permit a consistent interpretation of the procedural and quality measures such as programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the 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 and, where the standards referred to in Article 5 are not applied in full, the means that will be used to ensure that the essential requirements of the Directive which apply to the pressure equipment will be met,
- the design control and design verification techniques, processes and systematic measures that will be used when designing the pressure equipment, particularly with regard to materials in accordance with section 4 of Annex I,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with section 3.1.2 of Annex I,
- 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, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with sections 3.1.2 and 3.1.3 of Annex I,
- the means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the quality system.

(3.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 3.2.

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

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

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

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

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

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

4. Surveillance under the responsibility of the notified body

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

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

- the quality system documentation,
- the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, report concerning the qualifications of the personnel concerned, etc.

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

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

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

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

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

- the documentation referred to in the second indent of the second subparagraph of 3.1;
- the adjustments referred to in the second subparagraph of 3.4;
- the decisions and reports from the notified body which are referred to in the last subparagraph of 3.3, the last subparagraph of 3.4, and in 4.3 and 4.4.

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

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

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

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 pressure equipment to be understood, and enable conformity with the relevant requirements of the Directive to be assessed.

It must include:

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

— the necessary supporting evidence for their adequacy, in particular where the standards referred to in Article 5 have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;

(c) the notified body must examine the application and where the design meets the provisions of the Directive which apply to it issue an EC design-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories;

(d) the applicant must inform the notified body that has issued the EC design-examination certificate of all modifications to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design-examination certificate where they may affect conformity with the essential requirements of the Directive or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC design-examination certificate;

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

2. Final assessment as referred to in section 3.2 of Annex I 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 pressure equipment.

Status:
Point in time view as at 01/04/2008.

Changes to legislation:
There are currently no known outstanding effects for the The Pressure Equipment Regulations 1999, SCHEDULE 4.