ANNEX III

CONFORMITY ASSESSMENT PROCEDURES

12. MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the pressure equipment concerned.

The application shall include:

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

— the technical documentation for one model of each type of pressure equipment intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
  — a general description of the pressure equipment,
  — conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
  — descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment,
  — a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
  — results of design calculations made, examinations carried out, etc.,
  — test reports,

— the documentation concerning the quality system,

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

3.2. The quality system shall ensure compliance of the pressure equipment with the requirements of this Directive that apply to it.

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

It shall, in particular, contain an adequate description of:

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

— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment pertaining to the pressure

equipment type covered, particularly with regard to materials in accordance with point 4 of Annex I,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with point 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 and the non-destructive tests in accordance with points 3.1.2 and 3.1.3 of Annex I, etc.,

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

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

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant pressure equipment field and pressure equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

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

3.6. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.