SCHEDULE 4

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

Module D1 (production quality assurance)

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.