DIRECTIVE 2014/68/EU (PED) – MODULE H1
CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. PURPOSE OF SERVICE

The PED Module H1 service proposed by Bureau Veritas is to assess the conformity of pressure equipment or assemblies to module H1 requirements, as defined in Annex III of Pressure Equipment Directive 2014/68/EU (PED), and national transposition.

The service shall be performed in compliance with the contract entered into between Bureau Veritas and the Applicant and/or the Bureau Veritas General Terms and Conditions of Service.

2. SCOPE OF APPLICATION

The service is performed by Bureau Veritas as a Notified Body, recognized by an European Member State, in compliance with statutory requirements and its own general procedures.

The conformity assessment procedure as per Module H1 applies to design, manufacture, final inspection and testing of pressure equipment and it is applicable to pressure equipment classified in category I, II, III or IV as defined in the Annex II of European Directive 2014/68/EU (PED) and to assemblies classified up to category IV as defined in art. 14.6.b of PED.

The applicant, applying for the assessment of the equipment or assembly, is the manufacturer who is responsible for design, manufacture and tests or its authorised representative. He must retain overall control and have the necessary competence to take the responsibility for the product.

3. APPLICABLE STANDARDS AND REGULATIONS

- European Directive 2014/68/EU (PED) and national transposition after July 19th, 2016
- The harmonized standards published in the Official Journal of the European Communities and national transpositions or equivalent standards ensuring the conformity with the essential safety requirements of the PED.
- European approvals for materials published in the Official Journal of the European Communities
- Official interpretation issued by European Commission (PED Guidelines) as published on the official website

4. PERFORMANCE OF SERVICE

The assessment procedure as per Module H1, as defined in PED Annex III and proposed by Bureau Veritas consists in:

Design examination

- Examination of design drawings and calculations.
- Verification of qualification of permanent joining procedures,
- Verification of qualification of staff engaged in permanent joining operations and non-destructive tests.
- Verification of conformity of materials to harmonized standards or EU materials approval.

If during the design assessment the materials used for equipment in category III or IV fail to conform to a harmonized standard or EU materials approval, Bureau Veritas will conduct a “particular material appraisal” in order to verify that the materials meet the applicable essential safety requirements of PED.

Examination to verify that relevant harmonized standards are applied or that the solutions adopted meet essential safety requirements. It includes results of tests carried out by an appropriate laboratory of the manufacturer or on his behalf).

- If relevant, witnesses to tests and checks as required in harmonised standards or technical referential of the manufacturer
- Keeps apprised of the acknowledged state of the art and may inform the manufacturer if any changes may put into question the conformity of the approved type with applicable PED requirements.

Initial Assessment

Assessment of the quality system introduced by the manufacturer (for design, manufacture, final assessment and testing), by means of a documentary review and visit of the manufacturer’s premises to determine if it satisfies the requirements referred to in 3.2 Annex III - Module H1 of PED.

The purpose of the initial assessment is to:

- Assess the application of the quality system described,
- Verify the manufacturer’s technical capacity to produce equipment in accordance with the quality system described and essential safety requirements of PED.

Periodic Audit

Surveillance of application of the quality system by means of periodic audits to make sure that the manufacturer maintains and applies the approved quality system and, where appropriate, assessment of points which had been the subject of comment during earlier audits or unexpected visits.

The frequency of periodic audits must be such that a full reassessment is carried out every three years.

The documentary review carried out during the audit includes:

- Company organization.
- Quality records provided for in the design part of the quality system, such as results of analyses, calculation and tests.
- Inspection reports, testing and quality assurance techniques at manufacturing level (e.g. qualification of permanent joining procedures).
- Inspections and tests before, during and after manufacture,
- Quality dossiers (e.g. inspection and calibration reports, staff qualifications for permanent joining and non-destructive tests)
- Survey methods used to check that the necessary quality is obtained and that the quality system functions properly.

Following the initial assessment, the periodic surveillance audits of the quality system are carried out by Bureau Veritas once per year. Where appropriate, depending on the requirements for module H1 (cf. PED annex III.3.4 and 4.3 – Module H), frequency of audits could be increased and extra charges being levied for such additional audit.

Unexpected visits

Where appropriate and depending on the effective production Bureau Veritas is to make unexpected visits, in addition to the periodic audit. For series production, minimum 2 unexpected visits will be performed per year.

During these unexpected visits Bureau Veritas conduct examination on pressure equipment and at least one complete technical file, on sample basis, should be checked to verify that the manufacturer satisfactorily operates the approved quality system.

Where appropriate, depending on the requirements for module H1 (cf. PED annex III. 4.4 Module H), additional unexpected visits may be made, extra charges being levied for such inspections.

Final assessment

For vessels (intended to contain fluid Group 1 or gas Group2) or heated pressure equipment, during unexpected visits, BV will take a sample of equipment in order to perform the final assessment as referred in annex I, point 3.2.

5. CONDITION OF PERFORMANCE

The applicant must:

- Lodge an application for examination of the design, which must include design specifications and supporting evidence for their adequacy.
- Lodge an official application for assessment of his quality system

as per Module H1, covering design, manufacture, final inspection and testing of pressure equipment.

The application must include:

- All relevant information in order to identify the pressure equipment concerned (type, range of design data, materials used, classification of risk category as per PED, etc.)
- Documentation concerning the quality system, assuring the compliance of the pressure equipment with the requirements of PED which apply to it.

This includes the list of relevant quality documents, relating in particular to inspections and tests performed and surveillance of the quality system.

The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and include adequate description of:

- The quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality.
- The technical design specifications, including standards, that will be applied and, where needed, 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 of PED.
- 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 of PED.
- 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 of PED.
- The means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the quality system.
- Where appropriate, copy of document recording certification of the quality system and defining its scope.

Subject to agreement with Bureau Veritas, in case the applicant considers himself unable to provide in duplicate some relevant documents he must made them available on his premises for Bureau Veritas to consult.

- Undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

- In case of any intended adjustment to the quality system and manufacturing technology, inform Bureau Veritas in order to assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in 3.2 Annex III of PED – Module H - or whether a reassessment is required.
- Inform Bureau Veritas of all modification to the approved design. Modifications must receive additional approval where they may affect conformity with essential requirements of PED or the prescribed condition for use of the pressure equipment.
- Submit to Bureau Veritas:
  - Timetable for performance of final assessments to be monitored, enabling the inspector to carry out unexpected visits.
  - Whereas the applicant stops its production, he has to send relevant official statement to Bureau Veritas in order to suspend scheduling of unexpected visits.
  - A complete annual list of equipment manufactured within the framework of the application and bearing the notified body number assigned to Bureau Veritas.

The applicant must allow the Bureau Veritas access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information.

The Bureau Veritas inspector(s) must be accompanied by a competent person (appointed by the applicant) during the inspection.

The realization of the inspection on the premises is possible only where the technical conditions laid down by the directive can be achieved and the technical manufacturing documentation is made available to the inspector.

The applicant is responsible for ensuring a safe working environment to the Bureau Veritas inspector(s), wherever the performance of work takes place.

All appropriate measures must be taken, in accordance with applicable laws and regulation, international standards and state-of-the-art practices.

Evidences of satisfaction/performance of the above mentioned measures must be provided to the Bureau Veritas inspector(s) (if applicable) before the beginning of the inspection.

If Bureau Veritas inspector evaluates that his health or safety is exposed to a serious, uncontrolled and imminent risk, he or she may postpone the inspection.

When requested by Bureau Veritas, provides all measuring equipment used during the fabrication, inspection and testing. The equipment shall be calibrated accordingly, and the evidence of the current calibration shall be provided to the PED inspector for verification. In case the applicant issues NCR relating to calibration, he shall inform Bureau Veritas and propose appropriate corrective actions.

As requested by PED 2014/68/EU, the applicant shall:

- keep the technical documentation and the EU declaration of conformity for **10 years** after pressure equipment or assemblies have been placed on the market.
- further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority

6. UREAU VERITAS DELIVERABLES

The deliverables that may be expected from Bureau Veritas are:

- When the design is accepted as conforming to the relevant provisions of the Directive, an EC design examination certificate (H1D), detailing its validity conditions and the data needed to identify the approved design.
- Following delivering of the relevant EC design-examination certificate, when the conclusions of the initial assessment (documental review and initial audit visit) of the quality system for design, production, final inspection and testing are that the system satisfies the requirements of the directive which apply, a quality system approval certificate which authorizes the applicant to affix the Bureau Veritas notified body identification number on the equipment concerned and draw up the declaration of conformity.
- After each periodic audit, an audit report describing:
  - Points in quality system that have been checked,
  - Details of supervision of the final assessment,
  - Inspection conclusions.
- After each unexpected visit, a report containing:
  - Details of service provided,
  - Observations made.

7. LIMITS OF THE PRESENT SERVICE

This service does not comprise:

- Any service under the terms of another EC Directive applying to the relevant item,
- Design conformity assessment,
- Particular Material Appraisal
- Qualification of permanent joining procedures and operators where appropriate,

- Destructive and non destructive tests.
- Approval, as Notified Body, of operating procedures and personnel for permanent joining.
- Qualification of Non-destructive tests personnel
- Approval, as Notified Body, of personnel for non-destructive tests
- Material Manufacturer Quality System Assessment
- Material Certificates of specific product control (e.g. Certificate type 3.2 as per EN 10204)

8. OTHER SERVICES

Subject to an express agreement by the parties, the assessment as per Module H1 service may be supplemented, when appropriate and/or allowed by the Notification held by Bureau Veritas, by other services such as:

- Qualification of welding procedures and welding operator
- Approval as Notified Body, of operating procedures and personnel for permanent joining
- Approval as notified body, of personnel for non-destructive tests.

9. COMPLAINTS AND APPEALS

Should the Applicant wish to appeal against or dispute any decision of Bureau Veritas, it should do so in accordance with the Bureau Veritas appeals procedure, available upon request.

Should a complaint arise about Bureau Veritas, such complaint shall in the first instance be made to the local Bureau Veritas office. If the Applicant does not wish to complain directly to the local Bureau Veritas office, the complaint shall be sent in writing to Bureau Veritas Services, Le Triangle de l'Arche - 8 Cours du Triangle 92800 Puteaux FRANCE, attention to I&F TQR Direction.

10. CONFIDENTIALITY

The national competent authority may request from Bureau Veritas as a Notified Body information which Bureau Veritas and the Applicant may consider confidential.

The provision of such information to the national competent authority is a mandatory requirement for Bureau Veritas as a Notified Body and shall not be considered as a breach of confidentiality by Bureau Veritas.

End