DIRECTIVE 2014/68/EU (PED) – MODULE E1
QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING

1. PURPOSE OF SERVICE

The PED Module E1 service proposed by Bureau Veritas is to assess the conformity of pressure equipment or assemblies to module E1 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 a European Member State, in compliance with statutory requirements and its own general procedures.

The conformity assessment procedure as per Module E1 applies to manufacture, final inspection and testing of products (specified pressure equipment)

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

The conformity assessment procedure as per Module E1 is applicable to pressure equipment classified up to category II as defined in the Annex II of Pressure Equipment Directive 2014/68/EU (PED)and to assemblies classified up to category II as defined in art. 14.6.b of PED.

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 E1, as defined in PED Annex III and proposed by Bureau Veritas, consists in:

Initial Assessment:

Assessment of the quality system introduced by the manufacturer (for final assessment and testing), by means of a documentary review and inspection of the manufacturer's premises to determine if it satisfies the requirements referred to in 4.2 Annex III - Module E1 - 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 type stipulated in the EU type examination-production type certificate or EU type examination-design type certificate, and in such a way as to meet essential safety requirements.

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

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The entire process spans over a three year period:

- Following the initial assessment, the periodic surveillance audits of the quality system are carried out by Bureau Veritas once per year.
- A full reassessment is carried out every three years

The document review carried out during the audit includes quality records such as:

- Company organization
- 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 E1 (eg PED annex III.5.5 and 6.3 – Module E1), frequency of audits could be increased and extra charges being levied for such additional audits.

Unexpected visits:

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

During these unexpected visits 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 E1 (cf PED annex III. 6.4 – Module E1), additional unexpected visits may be made, extra charges being levied for such inspections.

5. CONDITION OF PERFORMANCE

The applicant must lodge an official application for assessment of his quality system as per Module E1, covering manufacture, final inspection and testing of pressure equipment.

The application must include:

- All relevant data on pressure equipment concerned
- Documentation concerning the quality system, assuring the compliance of the pressure equipment with the requirements of PED.
- 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 pressure equipment,
- Procedure used for permanent joining of parts as approved in accordance with section 3.1.2 of Annex I of PED
- Examination 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 joining of parts in accordance with sections 3.1.2 of Annex I of PED
- 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 itself unable to provide in duplicate some relevant documents he must made them available on its premises for Bureau Veritas to consult.

The applicant must:

- Provide Bureau Veritas before the beginning of the inspection with:
  - Full technical documentation in duplicate concerning the equipment for assessment, as stipulated for module E1 (cf PED Annex III)
  - All descriptions and explanations needed to clarify the drawings, diagrams and functioning of the pressure equipment,
  - Results of design calculations, examination carried out and other relevant factors demonstrating that equipment meets the essential requirements of the Directive,
  - Test reports.
- 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, the Applicant must 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 5.2 Annex III of PED – Module E1 - or whether a reassessment is required.

- 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. BUREAU VERITAS DELIVERABLES

The deliverables that may be expected from Bureau Veritas are:

- When the conclusions of the initial assessment (document review and initial audit) of the quality system as well as the final inspection and testing are satisfying the requirements of the directive, 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 is issued describing:
  - Points in quality system that have been checked,
  - Details of supervision of the final assessment,
  - Inspection conclusions.
- After each unexpected visit, Bureau Veritas provides the applicant with a report containing:
  - Details of service provided,
  - Observations made.

7. LIMITS OF THE PRESENT SERVICE

The maximum validity of the quality system approval certificate issued by Bureau Veritas is **3 years** and it cannot exceed the duration of the contract with Bureau Veritas.

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 E1 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

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.

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